



Australian Government

Department of Health



Schedule of Pharmaceutical Benefits

Summary of Changes

Effective 1 November 2021



Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 November 2021 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	\$7.78
	Dangerous drug fee	\$4.82
	Extemporaneously-prepared	\$9.82
	Allowable additional patient charge*	\$4.42
Additional Fees (for safety net prices):	Ready-prepared	\$1.30
	Extemporaneously-prepared	\$1.67
Patient Co-payments:	General	\$41.30
	Concessional	\$6.60
Safety Net Thresholds:	General	\$1497.20
	Concessional	\$316.80
Safety Net Card Issue Fee:		\$10.34

* 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 November 2021. The Schedule is updated on the first day of each month and is available on the internet at www.pbs.gov.au.

Prescriber Bag

Advance Notices

1 December 2021

Deletion – Brand

3495Y Ventolin CFC-free, GK – **SALBUTAMOL**, salbutamol 100 microgram/actuation inhalation, 200 actuations

General Pharmaceutical Benefits

Additions

Addition – Item

- 12680J **ABATACEPT**, abatacept 125 mg/mL injection, 4 x 1 mL pen devices (*Orencia ClickJect*)
- 12758L **ABATACEPT**, abatacept 125 mg/mL injection, 4 x 1 mL syringes (*Orencia*)
- 12678G **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes (*Humira*)
- 12700K **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices (*Humira*)
- 12701L **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices (*Humira*)
- 12752E **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes (*Humira*)
- 12690X **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (*Amgevita, Hadlima, Hyrimoz, Idacio*)
- 12719K **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (*Amgevita, Hadlima, Hyrimoz, Idacio*)
- 12729Y **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (*Amgevita, Hadlima, Hyrimoz, Idacio*)
- 12741N **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (*Amgevita, Hadlima, Hyrimoz, Idacio*)
- 12708W **BARICITINIB**, baricitinib 2 mg tablet, 28 (*Olumiant*)
- 12730B **BARICITINIB**, baricitinib 4 mg tablet, 28 (*Olumiant*)
- 12672Y **BUDESONIDE + GLYCOPYRRONIUM + FORMOTEROL (EFORMOTEROL)**, budesonide 160 microgram/actuation + glycopyrronium 7.2 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 5 microgram/actuation inhalation, 120 actuations (*Breztri Aerosphere*)
- 12712C **CERTOLIZUMAB PEGOL**, certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes (*Cimzia*)
- 12724Q **CERTOLIZUMAB PEGOL**, certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes (*Cimzia*)
- 12743Q **CERTOLIZUMAB PEGOL**, certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes (*Cimzia*)
- 12691Y **CERTOLIZUMAB PEGOL**, certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices (*Cimzia*)
- 12702M **CERTOLIZUMAB PEGOL**, certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices (*Cimzia*)
- 12742P **CERTOLIZUMAB PEGOL**, certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices (*Cimzia*)
- 12683M **DARATUMUMAB**, daratumumab 1.8 g/15 mL injection, 15 mL vial (*Darzalex*)
- 12704P **DARATUMUMAB**, daratumumab 1.8 g/15 mL injection, 15 mL vial (*Darzalex*)
- 12725R **DARATUMUMAB**, daratumumab 1.8 g/15 mL injection, 15 mL vial (*Darzalex*)
- 12755H **DARATUMUMAB**, daratumumab 1.8 g/15 mL injection, 15 mL vial (*Darzalex*)

12684N	DAROLUTAMIDE , darolutamide 300 mg tablet, 112 (<i>Nubeqa</i>)
12718J	ETANERCEPT , etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack (<i>Enbrel</i>)
12750C	ETANERCEPT , etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack (<i>Enbrel</i>)
12679H	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL pen devices (<i>Brenzys, Enbrel</i>)
12716G	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL pen devices (<i>Enbrel</i>)
12676E	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Enbrel</i>)
12737J	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Brenzys, Enbrel</i>)
12703N	GOLIMUMAB , golimumab 50 mg/0.5 mL injection, 0.5 mL syringe (<i>Simponi</i>)
12744R	GOLIMUMAB , golimumab 50 mg/0.5 mL injection, 0.5 mL pen device (<i>Simponi</i>)
12709X	IMATINIB , imatinib 100 mg capsule, 60 (<i>IMATINIB-DRLA</i>)
12710Y	IMATINIB , imatinib 100 mg capsule, 60 (<i>IMATINIB-DRLA, Imatinib-APOTEX</i>)
12722N	IMATINIB , imatinib 100 mg capsule, 60 (<i>IMATINIB-DRLA</i>)
12759M	IMATINIB , imatinib 100 mg capsule, 60 (<i>IMATINIB-DRLA, Imatinib-APOTEX</i>)
12681K	IMATINIB , imatinib 400 mg capsule, 30 (<i>IMATINIB-DRLA, Imatinib-APOTEX</i>)
12711B	IMATINIB , imatinib 400 mg capsule, 30 (<i>IMATINIB-DRLA, Imatinib-APOTEX</i>)
12723P	IMATINIB , imatinib 400 mg capsule, 30 (<i>IMATINIB-DRLA</i>)
12754G	IMATINIB , imatinib 400 mg capsule, 30 (<i>IMATINIB-DRLA</i>)
12677F	INFLIXIMAB , infliximab 120 mg/mL injection, 1 mL syringe (<i>Remsima SC</i>)
12687R	INFLIXIMAB , infliximab 120 mg/mL injection, 1 mL pen device (<i>Remsima SC</i>)
12688T	INFLIXIMAB , infliximab 120 mg/mL injection, 1 mL syringe (<i>Remsima SC</i>)
12689W	INFLIXIMAB , infliximab 120 mg/mL injection, 1 mL pen device (<i>Remsima SC</i>)
12748Y	INFLIXIMAB , infliximab 120 mg/mL injection, 1 mL pen device (<i>Remsima SC</i>)
12753F	INFLIXIMAB , infliximab 120 mg/mL injection, 1 mL syringe (<i>Remsima SC</i>)
12720L	TOFACITINIB , tofacitinib 5 mg tablet, 56 (<i>Xeljanz</i>)
12685P	UPADACITINIB , upadacitinib 15 mg modified release tablet, 28 (<i>Rinvoq</i>)

Addition – Brand

2518M	<i>APREPITANT SCP, XC</i> – APREPITANT , aprepitant 165 mg capsule, 1
9483D	<i>EZESIM 10/10, RZ</i> – EZETIMIBE + SIMVASTATIN , ezetimibe 10 mg + simvastatin 10 mg tablet, 30
9484E	<i>EZESIM 10/20, RZ</i> – EZETIMIBE + SIMVASTATIN , ezetimibe 10 mg + simvastatin 20 mg tablet, 30
8881K	<i>EZESIM 10/40, RZ</i> – EZETIMIBE + SIMVASTATIN , ezetimibe 10 mg + simvastatin 40 mg tablet, 30
8882L	<i>EZESIM 10/80, RZ</i> – EZETIMIBE + SIMVASTATIN , ezetimibe 10 mg + simvastatin 80 mg tablet, 30
11762C	<i>Imatinib-Teva, SZ</i> – IMATINIB , imatinib 100 mg tablet, 60
11784F	<i>Gilmat, CR</i> – IMATINIB , imatinib 100 mg tablet, 60
11784F	<i>Imatinib-Teva, SZ</i> – IMATINIB , imatinib 100 mg tablet, 60
11787J	<i>Gilmat, CR</i> – IMATINIB , imatinib 100 mg tablet, 60
11787J	<i>Imatinib-Teva, SZ</i> – IMATINIB , imatinib 100 mg tablet, 60
5443L	<i>Gilmat, CR</i> – IMATINIB , imatinib 100 mg tablet, 60
5443L	<i>Imatinib-Teva, SZ</i> – IMATINIB , imatinib 100 mg tablet, 60
9111M	<i>Gilmat, CR</i> – IMATINIB , imatinib 100 mg tablet, 60
9111M	<i>Imatinib-Teva, SZ</i> – IMATINIB , imatinib 100 mg tablet, 60
9178C	<i>Imatinib-Teva, SZ</i> – IMATINIB , imatinib 100 mg tablet, 60
11778X	<i>Gilmat, CR</i> – IMATINIB , imatinib 400 mg tablet, 30
11778X	<i>Imatinib-Teva, SZ</i> – IMATINIB , imatinib 400 mg tablet, 30
11785G	<i>Imatinib-Teva, SZ</i> – IMATINIB , imatinib 400 mg tablet, 30

11788K *Gilmat, CR* – **IMATINIB**, imatinib 400 mg tablet, 30
11788K *Imatinib-Teva, SZ* – **IMATINIB**, imatinib 400 mg tablet, 30
5444M *Gilmat, CR* – **IMATINIB**, imatinib 400 mg tablet, 30
5444M *Imatinib-Teva, SZ* – **IMATINIB**, imatinib 400 mg tablet, 30
9112N *Gilmat, CR* – **IMATINIB**, imatinib 400 mg tablet, 30
9112N *Imatinib-Teva, SZ* – **IMATINIB**, imatinib 400 mg tablet, 30
9179D *Imatinib-Teva, SZ* – **IMATINIB**, imatinib 400 mg tablet, 30
2723H *Alodorm, AF* – **NITRAZEPAM**, nitrazepam 5 mg tablet, 25
2732T *Alodorm, AF* – **NITRAZEPAM**, nitrazepam 5 mg tablet, 25
5189D *Alodorm, AF* – **NITRAZEPAM**, nitrazepam 5 mg tablet, 25
8449Q *APO-Perindopril/Indapamide, TX* – **PERINDOPRIL + INDAPAMIDE**, perindopril erbumine 4 mg + indapamide hemihydrate 1.25 mg tablet, 30

Addition – Equivalence Indicator

2518M *Aprepitant APOTEX, TX* – **APREPITANT**, aprepitant 165 mg capsule, 1
11784F *Glivec, AF* – **IMATINIB**, imatinib 100 mg tablet, 60
11787J *Glivec, AF* – **IMATINIB**, imatinib 100 mg tablet, 60
5443L *Glivec, AF* – **IMATINIB**, imatinib 100 mg tablet, 60
9111M *Glivec, AF* – **IMATINIB**, imatinib 100 mg tablet, 60
11778X *Glivec, AF* – **IMATINIB**, imatinib 400 mg tablet, 30
11788K *Glivec, AF* – **IMATINIB**, imatinib 400 mg tablet, 30
5444M *Glivec, AF* – **IMATINIB**, imatinib 400 mg tablet, 30
9112N *Glivec, AF* – **IMATINIB**, imatinib 400 mg tablet, 30
2723H *Mogadon, IL* – **NITRAZEPAM**, nitrazepam 5 mg tablet, 25
2732T *Mogadon, IL* – **NITRAZEPAM**, nitrazepam 5 mg tablet, 25
5189D *Mogadon, IL* – **NITRAZEPAM**, nitrazepam 5 mg tablet, 25

Addition – Note

11876C **ABEMACICLIB**, abemaciclib 50 mg tablet, 56 (*Verzenio*)
11871T **ABEMACICLIB**, abemaciclib 100 mg tablet, 56 (*Verzenio*)
11868P **ABEMACICLIB**, abemaciclib 150 mg tablet, 56 (*Verzenio*)
11784F **IMATINIB**, imatinib 100 mg tablet, 60 (*Gilmat, Glivec, Imatinib-Teva*)
11787J **IMATINIB**, imatinib 100 mg tablet, 60 (*Gilmat, Glivec, Imatinib-Teva*)
5443L **IMATINIB**, imatinib 100 mg tablet, 60 (*Gilmat, Glivec, Imatinib-Teva*)
9111M **IMATINIB**, imatinib 100 mg tablet, 60 (*Gilmat, Glivec, Imatinib-Teva*)
11778X **IMATINIB**, imatinib 400 mg tablet, 30 (*Gilmat, Glivec, Imatinib-Teva*)
11788K **IMATINIB**, imatinib 400 mg tablet, 30 (*Gilmat, Glivec, Imatinib-Teva*)
5444M **IMATINIB**, imatinib 400 mg tablet, 30 (*Gilmat, Glivec, Imatinib-Teva*)
9112N **IMATINIB**, imatinib 400 mg tablet, 30 (*Gilmat, Glivec, Imatinib-Teva*)
5297T **TRIPTORELIN**, triptorelin 22.5 mg injection [1 vial] (&) inert substance diluent [2 mL ampoule], 1 pack (*Diphereline*)

Addition – Restriction

8165R **TOPIRAMATE**, topiramate 100 mg tablet, 60 (*APO-Topiramate, Epiramax 100, RBX Topiramate, Tamate, Topamax, Topiramate AN, Topiramate Sandoz*)
5297T **TRIPTORELIN**, triptorelin 22.5 mg injection [1 vial] (&) inert substance diluent [2 mL ampoule], 1 pack (*Diphereline*)

Deletions

Deletion – Item

12224J **PINDOLOL**, pindolol 5 mg tablet, 100 (*APO-PINDOL*)

Deletion – Brand

- 8844L *Angiomax, XM* – **BIVALIRUDIN**, bivalirudin 250 mg injection, 1 vial
- 8019C *Cyprostat-100, SY* – **CYPROTERONE**, cyproterone acetate 100 mg tablet, 50
- 3196F *restore O.R.S., EA* – **SODIUM CHLORIDE + POTASSIUM CHLORIDE + GLUCOSE MONOHYDRATE + CITRIC ACID**, sodium chloride 470 mg + potassium chloride 300 mg (potassium 4 mmol) + glucose monohydrate 3.56 g + sodium acid citrate 530 mg powder for oral liquid, 10 x 4.9 g sachets

Deletion – Equivalence Indicator

- 8844L *Bivalirudin APOTEX, TX* – **BIVALIRUDIN**, bivalirudin 250 mg injection, 1 vial
- 3062E *Barbloc 5, AF* – **PINDOLOL**, pindolol 5 mg tablet, 100
- 3196F *O.R.S., AF* – **SODIUM CHLORIDE + POTASSIUM CHLORIDE + GLUCOSE MONOHYDRATE + CITRIC ACID**, sodium chloride 470 mg + potassium chloride 300 mg (potassium 4 mmol) + glucose monohydrate 3.56 g + sodium acid citrate 530 mg powder for oral liquid, 10 x 4.9 g sachets

Deletion – Note

- 12117R **ACALABRUTINIB**, acalabrutinib 100 mg capsule, 56 (*Calquence*)
- 12468F **BECLOMETASONE + FORMOTEROL (EFORMOTEROL) + GLYCOPYRRONIUM**, beclometasone dipropionate 100 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation + glycopyrronium 10 microgram/actuation inhalation, 120 actuations (*Trimbow*)
- 12092K **ENTRECTINIB**, entrectinib 200 mg capsule, 90 (*Rozlytrek*)
- 11379X **FLUTICASONE FUROATE + UMECLIDINIUM + VILANTEROL**, fluticasone furoate 100 microgram/actuation + umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations (*Trelegy Ellipta 100/62.5/25*)

Deletion – Restriction

- 12117R **ACALABRUTINIB**, acalabrutinib 100 mg capsule, 56 (*Calquence*)
- 12092K **ENTRECTINIB**, entrectinib 200 mg capsule, 90 (*Rozlytrek*)
- 10958R **EVOLOCUMAB**, evolocumab 140 mg/mL injection, 1 mL pen device (*Repatha*)
- 11484K **EVOLOCUMAB**, evolocumab 140 mg/mL injection, 1 mL pen device (*Repatha*)
- 11193D **EVOLOCUMAB**, evolocumab 420 mg/3.5 mL injection, 3.5 mL cartridge (*Repatha*)
- 11485L **EVOLOCUMAB**, evolocumab 420 mg/3.5 mL injection, 3.5 mL cartridge (*Repatha*)
- 11960L **LEUPRORELIN**, leuporelin acetate 30 mg modified release injection [1 chamber] (& inert substance diluent [1.5 mL chamber], 1 dual chamber syringe (*Lucrin Depot Paediatric 30 mg PDS*)
- 12096P **LORLATINIB**, lorlatinib 25 mg tablet, 90 (*Lorviqua*)
- 12091J **LORLATINIB**, lorlatinib 100 mg tablet, 30 (*Lorviqua*)

Alterations

Alteration – Item Description

From

- 1928L **METHYLPREDNISOLONE**, methylprednisolone acetate 40 mg/mL injection, 5 x 1 mL vials (*Depo-Medrol, Depo-Nisolone*)

To

- 1928L **METHYLPREDNISOLONE**, methylprednisolone acetate 40 mg/mL modified release injection, 5 x 1 mL vials (*Depo-Medrol, Depo-Nisolone*)

From

- 5148Y **METHYLPREDNISOLONE**, methylprednisolone acetate 40 mg/mL injection, 5 x 1 mL vials (*Depo-Medrol, Depo-Nisolone*)

To

- 5148Y **METHYLPREDNISOLONE**, methylprednisolone acetate 40 mg/mL modified release injection, 5 x 1 mL vials (*Depo-Medrol, Depo-Nisolone*)

Alteration – Note

- 12005W **CERTOLIZUMAB PEGOL**, certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes (*Cimzia*)
- 12040Q **CERTOLIZUMAB PEGOL**, certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes (*Cimzia*)
- 12063X **CERTOLIZUMAB PEGOL**, certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes (*Cimzia*)
- 12013G **CERTOLIZUMAB PEGOL**, certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices (*Cimzia*)

12027B	CERTOLIZUMAB PEGOL , certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices (<i>Cimzia</i>)
12028C	CERTOLIZUMAB PEGOL , certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices (<i>Cimzia</i>)
11516D	GOLIMUMAB , golimumab 50 mg/0.5 mL injection, 0.5 mL syringe (<i>Simponi</i>)
11521J	GOLIMUMAB , golimumab 50 mg/0.5 mL injection, 0.5 mL pen device (<i>Simponi</i>)
11538G	GOLIMUMAB , golimumab 50 mg/0.5 mL injection, 0.5 mL pen device (<i>Simponi</i>)
11560K	GOLIMUMAB , golimumab 50 mg/0.5 mL injection, 0.5 mL syringe (<i>Simponi</i>)
12297F	SECUKINUMAB , secukinumab 150 mg/mL injection, 1 mL pen device (<i>Cosentyx</i>)
12307R	SECUKINUMAB , secukinumab 150 mg/mL injection, 1 mL pen device (<i>Cosentyx</i>)
12321L	SECUKINUMAB , secukinumab 150 mg/mL injection, 1 mL pen device (<i>Cosentyx</i>)

Alteration – Restriction

11876C	ABEMACICLIB , abemaciclib 50 mg tablet, 56 (<i>Verzenio</i>)
11871T	ABEMACICLIB , abemaciclib 100 mg tablet, 56 (<i>Verzenio</i>)
11868P	ABEMACICLIB , abemaciclib 150 mg tablet, 56 (<i>Verzenio</i>)
2698B	ABIRATERONE , abiraterone acetate 250 mg tablet, 120 (<i>Zytiga</i>)
11206T	ABIRATERONE , abiraterone acetate 500 mg tablet, 60 (<i>Zytiga</i>)
12468F	BECLOMETASONE + FORMOTEROL (EFORMOTEROL) + GLYCOPYRRONIUM , beclometasone dipropionate 100 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation + glycopyrronium 10 microgram/actuation inhalation, 120 actuations (<i>Trimbrow</i>)
12040Q	CERTOLIZUMAB PEGOL , certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes (<i>Cimzia</i>)
12013G	CERTOLIZUMAB PEGOL , certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices (<i>Cimzia</i>)
10174L	ENZALUTAMIDE , enzalutamide 40 mg capsule, 112 (<i>Xtandi</i>)
11379X	FLUTICASONE FUROATE + UMECLIDINIUM + VILANTEROL , fluticasone furoate 100 microgram/actuation + umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations (<i>Trelegy Ellipta 100/62.5/25</i>)
11944P	LEUPRORELIN , leuprorelin acetate 30 mg modified release injection [1 chamber] (& inert substance diluent [1.5 mL chamber], 1 dual chamber syringe (<i>Lucrin Depot Paediatric 30 mg PDS</i>)

Alteration – Manufacturer Code

		<i>From</i>	<i>To</i>
2687K	<i>Imazan</i> – AZATHIOPRINE , azathioprine 50 mg tablet, 100	ER	ZS
8094B	<i>Bicalox</i> – BICALUTAMIDE , bicalutamide 50 mg tablet, 28	ER	ZS
2502Q	<i>Calciprox</i> – CALCITRIOL , calcitriol 0.25 microgram capsule, 100	ER	ZS
8255L	<i>Volirop 3.125</i> – CARVEDILOL , carvedilol 3.125 mg tablet, 30	DO	ZS
8256M	<i>Volirop 6.25</i> – CARVEDILOL , carvedilol 6.25 mg tablet, 60	DO	ZS
8257N	<i>Volirop 12.5</i> – CARVEDILOL , carvedilol 12.5 mg tablet, 60	DO	ZS
8258P	<i>Volirop 25</i> – CARVEDILOL , carvedilol 25 mg tablet, 60	DO	ZS
8700X	<i>Cilopam-S</i> – ESCITALOPRAM , escitalopram 10 mg tablet, 28	ER	ZS
8701Y	<i>Cilopam-S</i> – ESCITALOPRAM , escitalopram 20 mg tablet, 28	ER	ZS
2412Y	<i>Frusax</i> – FUROSEMIDE (FRUSEMIDE) , furosemide (frusemide) 40 mg tablet, 100	ER	ZS
2591J	<i>Dermatane</i> – ISOTRETINOIN , isotretinoin 10 mg capsule, 60	ER	ZS
2592K	<i>Dermatane</i> – ISOTRETINOIN , isotretinoin 20 mg capsule, 60	ER	ZS
2549E	<i>Dermatane</i> – ISOTRETINOIN , isotretinoin 40 mg capsule, 30	ER	ZS
2848X	<i>Reedos 25</i> – LAMOTRIGINE , lamotrigine 25 mg tablet, 56	DO	ZS
2849Y	<i>Reedos 50</i> – LAMOTRIGINE , lamotrigine 50 mg tablet, 56	DO	ZS
2850B	<i>Reedos 100</i> – LAMOTRIGINE , lamotrigine 100 mg tablet, 56	DO	ZS
2851C	<i>Reedos 200</i> – LAMOTRIGINE , lamotrigine 200 mg tablet, 56	DO	ZS
8245Y	<i>Gynotril</i> – LETROZOLE , letrozole 2.5 mg tablet, 30	ER	ZS

9169N	<i>Kerron</i> – LEVETIRACETAM , levetiracetam 100 mg/mL oral liquid, 300 mL	DO	ZS
8654L	<i>Levactam</i> – LEVETIRACETAM , levetiracetam 250 mg tablet, 60	ER	ZS
8655M	<i>Levactam</i> – LEVETIRACETAM , levetiracetam 500 mg tablet, 60	ER	ZS
8656N	<i>Levactam</i> – LEVETIRACETAM , levetiracetam 1 g tablet, 60	ER	ZS
2430X	<i>Glucobete 500</i> – METFORMIN , metformin hydrochloride 500 mg tablet, 100	DO	ZS
1801T	<i>Glucobete 850</i> – METFORMIN , metformin hydrochloride 850 mg tablet, 60	DO	ZS
8607B	<i>Glucobete 1000</i> – METFORMIN , metformin hydrochloride 1 g tablet, 90	DO	ZS
1324Q	<i>Mistrom</i> – METOPROLOL TARTRATE , METOPROLOL TARTRATE Tablet 50 mg, 100	ER	ZS
1325R	<i>Mistrom</i> – METOPROLOL TARTRATE , METOPROLOL TARTRATE Tablet 100 mg, 60	ER	ZS
8170B	<i>Ozin 2.5</i> – OLANZAPINE , olanzapine 2.5 mg tablet, 28	DO	ZS
8185T	<i>Ozin 5</i> – OLANZAPINE , olanzapine 5 mg tablet, 28	DO	ZS
8186W	<i>Ozin 7.5</i> – OLANZAPINE , olanzapine 7.5 mg tablet, 28	DO	ZS
8187X	<i>Ozin 10</i> – OLANZAPINE , olanzapine 10 mg tablet, 28	DO	ZS
8399C	<i>Panthron</i> – PANTOPRAZOLE , pantoprazole 20 mg enteric tablet, 30	ER	ZS
11681T	<i>Panthron</i> – PANTOPRAZOLE , pantoprazole 40 mg enteric tablet, 30	ER	ZS
12277E	<i>Panthron</i> – PANTOPRAZOLE , pantoprazole 40 mg enteric tablet, 30	ER	ZS
8007K	<i>Panthron</i> – PANTOPRAZOLE , pantoprazole 40 mg enteric tablet, 30	ER	ZS
8008L	<i>Panthron</i> – PANTOPRAZOLE , pantoprazole 40 mg enteric tablet, 30	ER	ZS
9006B	<i>PREXUM 2.5</i> – PERINDOPRIL , perindopril arginine 2.5 mg tablet, 30	RW	RX
9007C	<i>PREXUM 5</i> – PERINDOPRIL , perindopril arginine 5 mg tablet, 30	RW	RX
9008D	<i>PREXUM 10</i> – PERINDOPRIL , perindopril arginine 10 mg tablet, 30	RW	RX
9346X	<i>Reaptan 5/5</i> – PERINDOPRIL + AMLODIPINE , perindopril arginine 5 mg + amlodipine 5 mg tablet, 30	RW	RX
9347Y	<i>Reaptan 5/10</i> – PERINDOPRIL + AMLODIPINE , perindopril arginine 5 mg + amlodipine 10 mg tablet, 30	RW	RX
9348B	<i>Reaptan 10/5</i> – PERINDOPRIL + AMLODIPINE , perindopril arginine 10 mg + amlodipine 5 mg tablet, 30	RW	RX
9349C	<i>Reaptan 10/10</i> – PERINDOPRIL + AMLODIPINE , perindopril arginine 10 mg + amlodipine 10 mg tablet, 30	RW	RX
2190G	<i>PREXUM Combi LD 2.5/0.625</i> – PERINDOPRIL + INDAPAMIDE , perindopril arginine 2.5 mg + indapamide hemihydrate 625 microgram tablet, 30	RW	RX
2845R	<i>Prexum Combi 5/1.25</i> – PERINDOPRIL + INDAPAMIDE , perindopril arginine 5 mg + indapamide hemihydrate 1.25 mg tablet, 30	RW	RX
8694N	<i>Actos</i> – PIOGLITAZONE , pioglitazone 15 mg tablet, 28	TK	EW
8695P	<i>Actos</i> – PIOGLITAZONE , pioglitazone 30 mg tablet, 28	TK	EW
8696Q	<i>Actos</i> – PIOGLITAZONE , pioglitazone 45 mg tablet, 28	TK	EW
8456C	<i>Kaptan</i> – QUETIAPINE , quetiapine 25 mg tablet, 60	ER	ZS
8457D	<i>Kaptan</i> – QUETIAPINE , quetiapine 100 mg tablet, 90	ER	ZS
8458E	<i>Kaptan</i> – QUETIAPINE , quetiapine 200 mg tablet, 60	ER	ZS
8580N	<i>Kaptan</i> – QUETIAPINE , quetiapine 300 mg tablet, 60	ER	ZS
8363E	<i>Fixta 60</i> – RALOXIFENE , raloxifene hydrochloride 60 mg tablet, 28	DO	ZS
11869Q	<i>Rispermia</i> – RISPERIDONE , risperidone 500 microgram tablet, 60	ER	ZS
11881H	<i>Rispermia</i> – RISPERIDONE , risperidone 500 microgram tablet, 60	ER	ZS
8787L	<i>Rispermia</i> – RISPERIDONE , risperidone 500 microgram tablet, 60	ER	ZS
8869T	<i>Rispermia</i> – RISPERIDONE , risperidone 500 microgram tablet, 60	ER	ZS
11877D	<i>Rispermia</i> – RISPERIDONE , risperidone 1 mg tablet, 60	ER	ZS

11879F	<i>Rispermia</i> – RISPERIDONE , risperidone 1 mg tablet, 60	ER	ZS
3169T	<i>Rispermia</i> – RISPERIDONE , risperidone 1 mg tablet, 60	ER	ZS
8789N	<i>Rispermia</i> – RISPERIDONE , risperidone 1 mg tablet, 60	ER	ZS
3170W	<i>Rispermia</i> – RISPERIDONE , risperidone 2 mg tablet, 60	ER	ZS
9079W	<i>Rispermia</i> – RISPERIDONE , risperidone 2 mg tablet, 60	ER	ZS
3171X	<i>Rispermia</i> – RISPERIDONE , risperidone 3 mg tablet, 60	ER	ZS
3172Y	<i>Rispermia</i> – RISPERIDONE , risperidone 4 mg tablet, 60	ER	ZS
5480K	<i>Shilova 500</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 30	DO	ZS
8134D	<i>Shilova 500</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 30	DO	ZS

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

10075G **CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE**, calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% gel, 60 g (*Daivobet 50/500 gel*)

Advance Notices

1 December 2021

Deletion – Brand

2019G	<i>Novatin, TX</i> – ACITRETIN , acitretin 10 mg capsule, 100
2020H	<i>Novatin, TX</i> – ACITRETIN , acitretin 25 mg capsule, 100
5551E	<i>APO-Bimatoprost, TX</i> – BIMATOPROST , bimatoprost 0.03% eye drops, 3 mL
8620Q	<i>APO-Bimatoprost, TX</i> – BIMATOPROST , bimatoprost 0.03% eye drops, 3 mL
2129C	<i>Minirin, FP</i> – DESMOPRESSIN , desmopressin acetate 100 microgram/mL nasal drops, 2.5 mL
2715X	<i>Doryx, YN</i> – DOXYCYCLINE , doxycycline 100 mg modified release capsule, 21
2487X	<i>GenRx Famotidine, GX</i> – FAMOTIDINE , famotidine 20 mg tablet, 60
2488Y	<i>GenRx Famotidine, GX</i> – FAMOTIDINE , famotidine 40 mg tablet, 30
8288F	<i>Ventolin CFC-free, GK</i> – SALBUTAMOL , salbutamol 100 microgram/actuation inhalation, 200 actuations
2115H	<i>Andriol Testocaps, MK</i> – TESTOSTERONE UNDECANOATE , testosterone undecanoate 40 mg capsule, 60

1 April 2022

Deletion – Brand

8748K *Edecrin, FK* – **ETACRYNIC ACID**, etacrynic acid 25 mg tablet, 100

Palliative Care

Additions

Addition – Brand

5359C *Alodorm, AF* – **NITRAZEPAM**, nitrazepam 5 mg tablet, 25

Addition – Equivalence Indicator

12502B *Morphine Juno, JU* – **MORPHINE**, morphine hydrochloride trihydrate 10 mg/mL injection, 5 x 1 mL ampoules

5359C *Mogadon, IL* – **NITRAZEPAM**, nitrazepam 5 mg tablet, 25

Highly Specialised Drugs Program (Private Hospital)

Additions

Addition – Item

12738K **ABATACEPT**, abatacept 250 mg injection, 1 vial (*Orencia*)

12686Q **ADALIMUMAB**, adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes (*Humira*)

12674C **ADALIMUMAB**, adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe (*Amgevita*)

12732D	ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices (<i>Humira</i>)
12749B	ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes (<i>Humira</i>)
12715F	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Amgevita, Hadlima, Hyrimoz, Idacio</i>)
12731C	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (<i>Amgevita, Hadlima, Hyrimoz, Idacio</i>)
12734F	ETANERCEPT , etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack (<i>Enbrel</i>)
12736H	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL pen devices (<i>Enbrel</i>)
12757K	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Enbrel</i>)
12751D	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflixtra, Remicade, Renflexis</i>)
12721M	RITUXIMAB , rituximab 500 mg/50 mL injection, 50 mL vial (<i>Riximyo, Truxima</i>)
12693C	TOCILIZUMAB , tocilizumab 80 mg/4 mL injection, 4 mL vial (<i>RoActemra</i>)
12727W	TOCILIZUMAB , tocilizumab 80 mg/4 mL injection, 4 x 4 mL vials (<i>RoActemra</i>)
12726T	TOCILIZUMAB , tocilizumab 200 mg/10 mL injection, 10 mL vial (<i>RoActemra</i>)
12747X	TOCILIZUMAB , tocilizumab 200 mg/10 mL injection, 4 x 10 mL vials (<i>RoActemra</i>)
12705Q	TOCILIZUMAB , tocilizumab 400 mg/20 mL injection, 4 x 20 mL vials (<i>RoActemra</i>)
12728X	TOCILIZUMAB , tocilizumab 400 mg/20 mL injection, 20 mL vial (<i>RoActemra</i>)

Addition – Equivalence Indicator

1419Q	<i>Actemra, RO</i> – TOCILIZUMAB , tocilizumab 80 mg/4 mL injection, 4 mL vial
1423X	<i>Actemra, RO</i> – TOCILIZUMAB , tocilizumab 200 mg/10 mL injection, 10 mL vial
1464C	<i>Actemra, RO</i> – TOCILIZUMAB , tocilizumab 400 mg/20 mL injection, 20 mL vial

Addition – Note

1419Q	TOCILIZUMAB , tocilizumab 80 mg/4 mL injection, 4 mL vial (<i>Actemra</i>)
1423X	TOCILIZUMAB , tocilizumab 200 mg/10 mL injection, 10 mL vial (<i>Actemra</i>)
1464C	TOCILIZUMAB , tocilizumab 400 mg/20 mL injection, 20 mL vial (<i>Actemra</i>)

Deletions

Deletion – Brand

6100C	<i>Vidaza, CJ</i> – AZACITIDINE , azacitidine 100 mg injection, 1 vial
6138C	<i>Vidaza, CJ</i> – AZACITIDINE , azacitidine 100 mg injection, 1 vial

Alterations

Alteration – Item Description

<i>From</i>	
10880P	PASIREOTIDE , pasireotide 20 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack (<i>Signifor LAR</i>)
<i>To</i>	
10880P	PASIREOTIDE EMBONATE , pasireotide (as embonate) 20 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack (<i>Signifor LAR</i>)
<i>From</i>	
10884W	PASIREOTIDE , pasireotide 40 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack (<i>Signifor LAR</i>)
<i>To</i>	
10884W	PASIREOTIDE EMBONATE , pasireotide (as embonate) 40 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack (<i>Signifor LAR</i>)
<i>From</i>	
10887B	PASIREOTIDE , pasireotide 60 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack (<i>Signifor LAR</i>)
<i>To</i>	
10887B	PASIREOTIDE EMBONATE , pasireotide (as embonate) 60 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack (<i>Signifor LAR</i>)

Alteration – Manufacturer Code

		From	To
6100C	<i>Celazadine</i> – AZACITIDINE , azacitidine 100 mg injection, 1 vial	JU	CJ
6138C	<i>Celazadine</i> – AZACITIDINE , azacitidine 100 mg injection, 1 vial	JU	CJ
6148N	<i>Imukin</i> – INTERFERON GAMMA-1B , interferon gamma-1b 2 million units (100 microgram)/0.5 mL injection, 6 x 0.5 mL vials	EU	LM

Advance Notices

1 December 2021

Deletion – Brand

11504L	<i>Fasenra, AP</i> – BENRALIZUMAB , benralizumab 30 mg/mL injection, 1 mL syringe
11523L	<i>Fasenra, AP</i> – BENRALIZUMAB , benralizumab 30 mg/mL injection, 1 mL syringe
11847M	<i>Fasenra, AP</i> – BENRALIZUMAB , benralizumab 30 mg/mL injection, 1 mL syringe

Highly Specialised Drugs Program (Public Hospital)

Additions

Addition – Item

12756J	ABATACEPT , abatacept 250 mg injection, 1 vial (<i>Orencia</i>)
12699J	ADALIMUMAB , adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes (<i>Humira</i>)
12695E	ADALIMUMAB , adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe (<i>Amgevita</i>)
12696F	ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices (<i>Humira</i>)
12697G	ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes (<i>Humira</i>)
12698H	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Amgevita, Hadlima, Hyrimoz, Idacio</i>)
12733E	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (<i>Amgevita, Hadlima, Hyrimoz, Idacio</i>)
12740M	ETANERCEPT , etanercept 25 mg injection [4 vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack (<i>Enbrel</i>)
12735G	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL pen devices (<i>Enbrel</i>)
12675D	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Enbrel</i>)
12717H	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflixtra, Remicade, Renflexis</i>)
12739L	RITUXIMAB , rituximab 500 mg/50 mL injection, 50 mL vial (<i>Riximyo, Truxima</i>)
12713D	TOCILIZUMAB , tocilizumab 80 mg/4 mL injection, 4 mL vial (<i>RoActemra</i>)
12714E	TOCILIZUMAB , tocilizumab 80 mg/4 mL injection, 4 x 4 mL vials (<i>RoActemra</i>)
12692B	TOCILIZUMAB , tocilizumab 200 mg/10 mL injection, 4 x 10 mL vials (<i>RoActemra</i>)
12706R	TOCILIZUMAB , tocilizumab 200 mg/10 mL injection, 10 mL vial (<i>RoActemra</i>)
12694D	TOCILIZUMAB , tocilizumab 400 mg/20 mL injection, 20 mL vial (<i>RoActemra</i>)
12707T	TOCILIZUMAB , tocilizumab 400 mg/20 mL injection, 4 x 20 mL vials (<i>RoActemra</i>)

Addition – Equivalence Indicator

1476Q	<i>Actemra, RO</i> – TOCILIZUMAB , tocilizumab 80 mg/4 mL injection, 4 mL vial
1481Y	<i>Actemra, RO</i> – TOCILIZUMAB , tocilizumab 200 mg/10 mL injection, 10 mL vial
1482B	<i>Actemra, RO</i> – TOCILIZUMAB , tocilizumab 400 mg/20 mL injection, 20 mL vial

Addition – Note

1476Q	TOCILIZUMAB , tocilizumab 80 mg/4 mL injection, 4 mL vial (<i>Actemra</i>)
1481Y	TOCILIZUMAB , tocilizumab 200 mg/10 mL injection, 10 mL vial (<i>Actemra</i>)
1482B	TOCILIZUMAB , tocilizumab 400 mg/20 mL injection, 20 mL vial (<i>Actemra</i>)

Deletions

Deletion – Brand

9597D	<i>Vidaza, CJ</i> – AZACITIDINE , azacitidine 100 mg injection, 1 vial
9598E	<i>Vidaza, CJ</i> – AZACITIDINE , azacitidine 100 mg injection, 1 vial

Alterations

Alteration – Item Description

From

10886Y **PASIREOTIDE**, pasireotide 20 mg modified release injection [1 vial] (& inert substance diluent [2 mL syringe], 1 pack (*Signifor LAR*))

To

10886Y **PASIREOTIDE EMBONATE**, pasireotide (as embonate) 20 mg modified release injection [1 vial] (& inert substance diluent [2 mL syringe], 1 pack (*Signifor LAR*))

From

10883T **PASIREOTIDE**, pasireotide 40 mg modified release injection [1 vial] (& inert substance diluent [2 mL syringe], 1 pack (*Signifor LAR*))

To

10883T **PASIREOTIDE EMBONATE**, pasireotide (as embonate) 40 mg modified release injection [1 vial] (& inert substance diluent [2 mL syringe], 1 pack (*Signifor LAR*))

From

10882R **PASIREOTIDE**, pasireotide 60 mg modified release injection [1 vial] (& inert substance diluent [2 mL syringe], 1 pack (*Signifor LAR*))

To

10882R **PASIREOTIDE EMBONATE**, pasireotide (as embonate) 60 mg modified release injection [1 vial] (& inert substance diluent [2 mL syringe], 1 pack (*Signifor LAR*))

Alteration – Manufacturer Code

		From	To
9597D	<i>Celazadine</i> – AZACITIDINE , azacitidine 100 mg injection, 1 vial	JU	CJ
9598E	<i>Celazadine</i> – AZACITIDINE , azacitidine 100 mg injection, 1 vial	JU	CJ
5769P	<i>Imukin</i> – INTERFERON GAMMA-1B , interferon gamma-1b 2 million units (100 microgram)/0.5 mL injection, 6 x 0.5 mL vials	EU	LM

Advance Notices

1 December 2021

Deletion – Brand

11529T *Fasenra, AP* – **BENRALIZUMAB**, benralizumab 30 mg/mL injection, 1 mL syringe

11549W *Fasenra, AP* – **BENRALIZUMAB**, benralizumab 30 mg/mL injection, 1 mL syringe

11830P *Fasenra, AP* – **BENRALIZUMAB**, benralizumab 30 mg/mL injection, 1 mL syringe

Highly Specialised Drugs Program (Community Access)

Advance Notices

1 January 2022

Deletion – Brand

10344K *Aptivus, BY* – **TIPRANAVIR**, tipranavir 250 mg capsule, 120

Botulinum Toxin Program

Deletions

Deletion – Restriction

12017L **BOTULINUM TOXIN TYPE A**, botulinum toxin type A 100 units injection, 1 vial (*Botox*)

12087E **INCOBOTULINUMTOXINA**, incobotulinumtoxinA 100 units injection, 1 vial (*Xeomin*)

Repatriation Pharmaceutical Benefits

Additions

Addition – Brand

4342M *Elocon Alcohol Free, AL* – **MOMETASONE**, mometasone furoate 0.1% cream, 50 g

Deletions

Deletion – Item

10574M **SODIUM CHLORIDE + POTASSIUM CHLORIDE + GLUCOSE MONOHYDRATE + CITRIC ACID**, sodium chloride 470 mg + potassium chloride 300 mg (potassium 4 mmol) + glucose monohydrate 3.56 g + sodium acid citrate 530 mg powder for oral liquid, 10 x 4.9 g sachets (*restore O.R.S.*)

Deletion – Brand

4342M	<i>Elocon, AL</i> – MOMETASONE , mometasone furoate 0.1% cream, 50 g
4572P	<i>Nicabate CQ 14, GC</i> – NICOTINE , nicotine 14 mg/24 hours patch, 7
4573Q	<i>Nicabate CQ 21, GC</i> – NICOTINE , nicotine 21 mg/24 hours patch, 7

Alterations**Alteration – Item Description***From*

4560B **SALICYLIC ACID + BENZALKONIUM CHLORIDE + ALCOHOL + COAL TAR SOLUTION + POLYOXYETHYLENE ETHERS**, SALICYLIC ACID with COAL TAR SOLUTION Scalp cleanser 20 mg-50 mg per mL (2%-5%), 200 mL, 1 (*lonil-T*)

To

4560B **COAL TAR SOLUTION + SALICYLIC ACID**, coal tar solution 5% + salicylic acid 2% shampoo, 200 mL (*lonil-T*)

Alteration – Manufacturer Code

		<i>From</i>	<i>To</i>
2471C	<i>Sorbact Absorption Dressing S98222</i> – DRESSING HYDROGEL , dressing hydrogel 10 cm x 10 cm dressing, 20	YB	BV
11395R	<i>Sorbact Gel Dressing S98137</i> – DRESSING HYDROGEL , dressing hydrogel 7.5 cm x 15 cm dressing, 10	YB	BV
2533H	<i>Sorbact Foam Dressing S98310</i> – DRESSING HYDROGEL FOAM , dressing hydrogel foam 10 cm x 10 cm dressing, 10	YB	BV
2512F	<i>Sorbact Ribbon Gauze S98118</i> – DRESSING HYDROGEL RIBBON , dressing hydrogel ribbon 1 cm x 50 cm dressing, 20	YB	BV
2529D	<i>Sorbact Ribbon Gauze S98120</i> – DRESSING HYDROGEL RIBBON , dressing hydrogel ribbon 5 cm x 200 cm dressing, 10	YB	BV
11392N	<i>Sorbact Foam Gentle Border 98532</i> – DRESSING HYDROPHOBIC , dressing hydrophobic 10 cm x 10 cm dressing, 10	YB	BV
11402D	<i>Sorbact Superabsorbent 98501</i> – DRESSING HYDROPHOBIC , dressing hydrophobic 10 cm x 10 cm dressing, 10	YB	BV
11394Q	<i>Sorbact Foam Gentle Border 98533</i> – DRESSING HYDROPHOBIC , dressing hydrophobic 15 cm x 15 cm dressing, 10	YB	BV
11404F	<i>Sorbact Foam Dressing S98315</i> – DRESSING HYDROPHOBIC , dressing hydrophobic 15 cm x 15 cm foam dressing, 10	YB	BV
11403E	<i>Sorbact Superabsorbent 98503</i> – DRESSING HYDROPHOBIC , dressing hydrophobic 20 cm x 20 cm dressing, 10	YB	BV
4463X	<i>Lamisil DermGel</i> – TERBINAFINE , terbinafine 1% gel, 15 g	GK	GJ

Advance Notices**1 December 2021****Deletion – Brand**

4029C	<i>Logicin Sinus, AS</i> – PSEUDOEPHEDRINE , pseudoephedrine hydrochloride 60 mg tablet, 12
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General Pharmaceutical Benefits

▪ ABATACEPT

Note No 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: Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab)

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 been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **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 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 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 has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided.

If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

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.

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.

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 5 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 5 repeats.

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 The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage.

The term biological medicine refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - critical shortage of tocilizumab' PBS listing.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - Critical shortage of tocilizumab - Temporary listing

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 Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab),

AND

- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly, **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.

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 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.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis.

This PBS listings is a temporary listing and may only be used when an application for initial supply of this medicine has been made under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab).

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

12758L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	958.82	41.30	Orencia [BQ]

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

12680J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	958.82	41.30	Orencia ClickJect [BQ]

■ ABEMACICLIB

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 Cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitors for the purposes of this restriction are abemaciclib, palbociclib and ribociclib.

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

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

Note Special Pricing Arrangements apply.

Authority required

Locally advanced or metastatic breast cancer

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; OR
- Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with one of: (i) anastrozole, (ii) letrozole, (iii) fulvestrant; OR
- The treatment must be in combination, where the patient has recurrence/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.

Population criteria:

- Patient must not be premenopausal.

Authority required

Locally advanced or metastatic breast cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- The treatment must be in combination with one of: (i) anastrozole, (ii) letrozole, (iii) fulvestrant, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.

Population criteria:

- Patient must not be premenopausal.

Authority required

Locally advanced or metastatic breast cancer

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

Clinical criteria:

- Patient must have received treatment with this drug for this PBS indication prior to 1 November 2021, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- Patient must have been untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy at the time non-PBS supply was initiated; OR
- Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable, **AND**
- Patient must have had a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 2 at the time of non-PBS supply was initiated, **AND**
- The treatment must be in combination with one of: (i) anastrozole, (ii) letrozole, (iii) fulvestrant, where the patient had never been treated with endocrine therapy for advanced/metastatic disease at the time non-PBS supply was initiated; OR
- The treatment must be in combination with fulvestrant only, where at the time non-PBS supply was initiated, the patient had recurrent/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.

Population criteria:

- Patient must not be premenopausal.

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.

abemaciclib 50 mg tablet, 56

11876C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4249.07	41.30	Verzenio [LY]

abemaciclib 150 mg tablet, 56

11868P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4249.07	41.30	Verzenio [LY]

abemaciclib 100 mg tablet, 56

11871T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	4249.07	41.30	Verzenio [LY]

■ ABIRATERONE

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

Castration resistant metastatic carcinoma of the prostate

Clinical criteria:

- The treatment must be used in combination with a corticosteroid, **AND**
- The treatment must not be used in combination with chemotherapy, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, **AND**
- Patient must not be undergoing treatment with this drug following treatment with any of: (i) darolutamide, (ii) enzalutamide; OR
- Patient must have developed an intolerance to enzalutamide of a severity necessitating permanent treatment withdrawal.

abiraterone acetate 250 mg tablet, 120

2698B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3442.08	41.30	Zytiga [JC]

abiraterone acetate 500 mg tablet, 60

11206T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3442.08	41.30	Zytiga [JC]

■ ADALIMUMAB

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

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 juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab)

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 been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**

- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

Population criteria:

- Patient must be aged 18 years or older.

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

- (1) a completed authority prescription form; and
- (2) a completed 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 has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided.

If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab.

An adequate response to treatment is defined as:

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

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

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 The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, and etanercept for patients over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS-subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage.

Alternative biological medicine refers to adalimumab and etanercept.

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - Temporary listing' PBS listing.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: First continuing treatment - Critical shortage of tocilizumab - Temporary listing

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 Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab),

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) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

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

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

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

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.

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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

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

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

This PBS listings is a temporary listing and may only be used when an application for initial supply of this medicine has been made under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab).

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

12701L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	885.50	41.30	Humira [VE]

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

12690X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	885.50	41.30	^a Amgevita [AN]	^a Hadlima [RF]
						^a Hyrimoz [SZ]	^a Idacio [PK]

ADALIMUMAB

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

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 juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab)

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 been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

Population criteria:

- Patient must be aged 18 years or older.

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

- (1) a completed authority prescription form; and
- (2) a completed 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 has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided.

If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab.

An adequate response to treatment is defined as:

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

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

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 The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, and etanercept for patients over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS-subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage.

Alternative biological medicine refers to adalimumab and etanercept.

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - Temporary listing' PBS listing.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: First continuing treatment - Critical shortage of tocilizumab - Temporary listing

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 Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab),

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) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

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

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

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

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.

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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

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

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

This PBS listings is a temporary listing and may only be used when an application for initial supply of this medicine has been made under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab).

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

12752E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	885.50	41.30	Humira [VE]

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

12741N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	885.50	41.30	^a Amgevita [AN] ^a Hyrimoz [SZ]	^a Hadlima [RF] ^a Idacio [PK]

▪ ADALIMUMAB

Note No 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 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

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 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab)

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 been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **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.

Population criteria:

- Patient must be aged 18 years or older.

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

(1) a completed authority prescription form; and

(2) a completed 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 has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided.

If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

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.

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

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. This listing is a temporary listing and is only to be used to

transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage.

The term biological medicine refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - critical shortage of tocilizumab' PBS listing.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - Critical shortage of tocilizumab - Temporary listing

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 Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab),

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).

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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.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis.

This PBS listings is a temporary listing and may only be used when an application for initial supply of this medicine has been made under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab).

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

12678G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	885.50	41.30	Humira [VE]

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

12719K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	885.50	41.30	^a Amgevita [AN]	^a Hadlima [RF]
						^a Hyrimoz [SZ]	^a Idacio [PK]

▪ ADALIMUMAB

Note No 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 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

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 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab)

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 been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **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.

Population criteria:

- Patient must be aged 18 years or older.

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

(1) a completed authority prescription form; and

(2) a completed 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 has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided.

If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

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.

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

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. This listing is a temporary listing and is only to be used to

transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage.

The term biological medicine refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - critical shortage of tocilizumab' PBS listing.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - Critical shortage of tocilizumab - Temporary listing

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 Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab),

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:

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(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

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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.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

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This PBS listings is a temporary listing and may only be used when an application for initial supply of this medicine has been made under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab).

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

12700K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	885.50	41.30	Humira [VE]

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

12729Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	885.50	41.30	^a Amgevita [AN]	^a Hadlima [RF]
						^a Hyrimoz [SZ]	^a Idacio [PK]

▪ BARICITINIB

Note No 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: Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab)

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 been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **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.

Population criteria:

- Patient must be aged 18 years or older.

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

(1) a completed authority prescription form; and

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If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

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.

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.

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Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - critical shortage of tocilizumab' PBS listing.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - Critical shortage of tocilizumab - Temporary listing

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 Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab),

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:

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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).

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- (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.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis.

This PBS listings is a temporary listing and may only be used when an application for initial supply of this medicine has been made under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab).

baricitinib 4 mg tablet, 28

12730B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1271.40	41.30	Olumiant [LY]

baricitinib 2 mg tablet, 28

12708W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1271.40	41.30	Olumiant [LY]

▪ BECLOMETASONE + FORMOTEROL (EFORMOTEROL) + GLYCOPYRRONIUM

Note Formal assessment and correction of inhaler technique should be performed in accordance with the COPD-X Plan (available at <http://copdx.org.au/>); the assessment and adherence to correct technique should be documented in the patient's medical records.

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

Note A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

Note Continuing Therapy Only:

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

Authority required (STREAMLINED)

12349

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months, with significant symptoms despite regular bronchodilator therapy with a long acting muscarinic antagonist (LAMA) and a long acting beta-2 agonist (LABA) or an inhaled corticosteroid (ICS) and a LABA; OR
- Patient must have been stabilised on a combination of a LAMA, LABA and an ICS for this condition.

Treatment criteria:

- Patient must not be undergoing treatment with this product in each of the following circumstances: (i) treatment of asthma in the absence of a COPD diagnosis, (ii) initiation of bronchodilator therapy in COPD, (iii) use as reliever therapy for asthma, (iv) dosed at an interval/frequency that differs to that recommended in the approved Product Information.

beclometasone dipropionate 100 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation + glycopyrronium 10 microgram/actuation inhalation, 120 actuations

12468F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	88.10	41.30	Trimbow [EU]

▪ BUDESONIDE + GLYCOPYRRONIUM + FORMOTEROL (EFORMOTEROL)

Note Formal assessment and correction of inhaler technique should be performed in accordance with the COPD-X Plan (available at <http://copdx.org.au/>); the assessment and adherence to correct technique should be documented in the patient's medical records.

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

Note A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

Note Continuing Therapy Only:

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

Authority required (STREAMLINED)

12349

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months, with significant symptoms despite regular bronchodilator therapy with a long acting muscarinic antagonist (LAMA) and a long acting beta-2 agonist (LABA) or an inhaled corticosteroid (ICS) and a LABA; OR
- Patient must have been stabilised on a combination of a LAMA, LABA and an ICS for this condition.

Treatment criteria:

- Patient must not be undergoing treatment with this product in each of the following circumstances: (i) treatment of asthma in the absence of a COPD diagnosis, (ii) initiation of bronchodilator therapy in COPD, (iii) use as reliever therapy for asthma, (iv) dosed at an interval/frequency that differs to that recommended in the approved Product Information.

budesonide 160 microgram/actuation + glycopyrronium 7.2 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 5 microgram/actuation inhalation, 120 actuations

12672Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	88.10	41.30	Breztri Aerosphere [AP]

▪ CERTOLIZUMAB PEGOL

Note No 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 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: Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) - 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 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) restriction to complete 24 weeks treatment, depending on the dosage regimen, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

12724Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	4	..	1025.77	41.30	Cimzia [UC]

▪ **CERTOLIZUMAB PEGOL**

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

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

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting 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: Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) - 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 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) restriction to complete 24 weeks treatment, depending on the dosage regimen, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

12742P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	4	..	1025.77	41.30	Cimzia [UC]

▪ **CERTOLIZUMAB PEGOL**

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

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage.

The term biological medicine refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - critical shortage of tocilizumab' PBS listing.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab)

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 been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **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.

Population criteria:

- Patient must be aged 18 years or older.

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

- (1) a completed authority prescription form; and
- (2) a completed 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 has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided.

If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

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.

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.

certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

12702M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	*3017.62	41.30	Cimzia [UC]

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

12712C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	*3017.62	41.30	Cimzia [UC]

■ CERTOLIZUMAB PEGOL

Note No 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

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis.
This PBS listing is a temporary listing and may only be used when an application for initial supply of this medicine has been made under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab).

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - Critical shortage of tocilizumab - Temporary listing

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 Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab),

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.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

12691Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1025.77	41.30	Cimzia [UC]

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

12743Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1025.77	41.30	Cimzia [UC]

■ CERTOLIZUMAB PEGOL

Note TREATMENT OF ADULT PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of secukinumab, certolizumab pegol and golimumab for adult patients with non-radiographic axial spondyloarthritis.

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

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

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

A serious adverse reaction requiring 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.

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 (once with any biological medicine) within the same treatment cycle, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

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

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

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

How to prescribe PBS-subsidised biological medicine treatment with secukinumab, certolizumab pegol and golimumab

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient)

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(2) Continuing treatment.

For continuing courses of PBS-subsidised biological medicine it is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

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 biological medicine provided they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment in courses of up to 24 weeks provided they continue to sustain an adequate response.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. 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 requiring permanent treatment withdrawal.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements.

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 will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

(4) Baseline measurements to determine response.

A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records. For a new patient, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.

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.

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

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must qualify under the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

Note No 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 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

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment

Clinical criteria:

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

Treatment criteria:

- Must be treated by a rheumatologist; OR
 - Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.
- An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:
- (a) a CRP measurement no greater than 10 mg per L; or
 - (b) a CRP measurement reduced by at least 20% from baseline.

If the requirement to demonstrate an elevated CRP level could not be met under an initial treatment restriction, a reduction in the BASDAI score from baseline will suffice for the purposes of administering this continuing treatment restriction.

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 in the month prior to completing their current course of treatment.

certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

12028C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1025.77	41.30	Cimzia [UC]

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

12005W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1025.77	41.30	Cimzia [UC]

■ **CERTOLIZUMAB PEGOL**

Note TREATMENT OF ADULT PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of secukinumab, certolizumab pegol and golimumab for adult patients with non-radiographic axial spondyloarthritis.

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

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

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

A serious adverse reaction requiring 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.

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 (once with any biological medicine) within the same treatment cycle, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

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

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

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

How to prescribe PBS-subsidised biological medicine treatment with secukinumab, certolizumab pegol and golimumab

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient)
- (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years); or
- (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(2) Continuing treatment.

For continuing courses of PBS-subsidised biological medicine it is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

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 biological medicine provided they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment in courses of up to 24 weeks provided they continue to sustain an adequate response.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later

than 4 weeks from the cessation of that treatment course. 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 requiring permanent treatment withdrawal.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements.

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 will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

(4) Baseline measurements to determine response.

A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records. For a new patient, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.

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.

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

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must qualify under the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

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. EST Monday to Friday).

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial 1 (New patient), Initial 2 (Change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 18 to 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 18 to 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 18 to 20 weeks treatment,

AND

- The treatment must provide no more than the balance of up to 20 weeks treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

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

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

12013G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1025.77	41.30	Cimzia [UC]

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

12040Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1025.77	41.30	Cimzia [UC]

▪ **CERTOLIZUMAB PEGOL**

Note TREATMENT OF ADULT PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS

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

certolizumab pegol and golimumab for adult patients with non-radiographic axial spondyloarthritis.

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

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

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

A serious adverse reaction requiring 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.

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 (once with any biological medicine) within the same treatment cycle, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

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

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

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

How to prescribe PBS-subsidised biological medicine treatment with secukinumab, certolizumab pegol and golimumab

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient)

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(2) Continuing treatment.

For continuing courses of PBS-subsidised biological medicine it is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

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 biological medicine provided they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment in courses of up to 24 weeks provided they continue to sustain an adequate response.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. 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 requiring permanent treatment withdrawal.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements.

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 will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

(4) Baseline measurements to determine response.

A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records. For a new patient, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.

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.

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

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must qualify under the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

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

Authority required

Non-radiographic axial spondyloarthritis

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

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

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

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and
- (b) C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. 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.

The assessment of the patient's response to the 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 in this treatment cycle.

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

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

The baseline BASDAI score and CRP level must also be documented 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. 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

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 2 (Change or re-commencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with biological medicines more than three times for this PBS-indication during the current treatment cycle, **AND**

- Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS indication more than once in the current treatment cycle, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
 - Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.
- An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment.

A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application.

An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:

- a CRP measurement no greater than 10 mg per L; or
- a CRP measurement reduced by at least 20% from baseline.

The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment.

BASDAI scores and CRP levels must be documented in the patient's medical records.

The assessment of the patient's response to the 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 in this treatment cycle.

The following must be provided at the time of application and documented in the patient's medical records:

- the BASDAI score; and
- the C-reactive protein (CRP) level.

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

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

The following must be provided at the time of application and documented in the patient's medical records:

- a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and
- C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI score and CRP level must be no more than 4 weeks old at the time of this application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application.

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.

The assessment of the patient's response to the 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 in this treatment cycle.

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).

certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

12027B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	*3017.62	41.30	Cimzia [UC]

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

12063X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	*3017.62	41.30	Cimzia [UC]

■ DARATUMUMAB

Note This drug is not PBS-subsidised for use in patients with multiple myeloma who have received two or more prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent, or, who are refractory to both a PI and an immunomodulatory agent, as monotherapy.

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

Note Special Pricing Arrangements apply.

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Initial treatment as second-line drug therapy for weeks 1 to 9 (administered once weekly)

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must be in combination with bortezomib and dexamethasone, **AND**
- Patient must have progressive disease after only one prior therapy (i.e. use must be as second-line drug therapy; use as third-line drug therapy or beyond is not PBS-subsidised), **AND**
- Patient must not be receiving concomitant PBS-subsidised carfilzomib, thalidomide or its analogues.

Treatment criteria:

- Patient must be undergoing treatment with this drug in one of the following situations: (i) for the first time, (ii) changing the drug's form (intravenous/subcutaneous) within the first 9 weeks of treatment.

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.

Details of: the histological diagnosis of multiple myeloma; prior treatments including name(s) of drug(s) and date of most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and which disease activity parameters will be used to assess response, must be documented in the patient's medical records.

Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records:

- (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; 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 must be used to determine response, results for either (a) or (b) or (c) should be documented 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) must be documented in the patient's medical records. 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 documented in the patient's medical records.

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.

daratumumab 1.8 g/15 mL injection, 15 mL vial

12683M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	8	..	7171.50	41.30	Darzalex [JC]

▪ DARATUMUMAB

Note This drug is not PBS-subsidised for use in patients with multiple myeloma who have received two or more prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent, or, who are refractory to both a PI and an immunomodulatory agent, as monotherapy.

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

Note Special Pricing Arrangements apply.

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment of second-line drug therapy from week 25 until disease progression (administered every 4 weeks)

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 treatment with this drug for this condition, **AND**
 - Patient must not be receiving concomitant PBS-subsidised bortezomib, carfilzomib or thalidomide or its analogues. 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.

daratumumab 1.8 g/15 mL injection, 15 mL vial

12725R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	7171.50	41.30	Darzalex [JC]

▪ DARATUMUMAB

Note This drug is not PBS-subsidised for use in patients with multiple myeloma who have received two or more prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent, or, who are refractory to both a PI and an immunomodulatory agent, as monotherapy.

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

Note Special Pricing Arrangements apply.

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment of second-line drug therapy for weeks 10 to 24 (administered every 3 weeks)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with bortezomib and 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 carfilzomib, thalidomide or its analogues. 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.

daratumumab 1.8 g/15 mL injection, 15 mL vial

12755H	Max. Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	4	..	7171.50	41.30	Darzalex [JC]

▪ DARATUMUMAB

- Note** This drug is not PBS-subsidised for use in patients with multiple myeloma who have received two or more prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent, or, who are refractory to both a PI and an immunomodulatory agent, as monotherapy.
- 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** No increase in the maximum number of repeats may be authorised.
- Note** Special Pricing Arrangements apply.
- 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 3 months after the date specified in the clinical criteria.

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

Clinical criteria:

- Patient must have been on treatment with this drug in the subcutaneous form for this condition prior to 1 November 2021, **AND**
- Patient must have met all initial treatment PBS-eligibility criteria applying to a non-grandfathered patient prior to having commenced treatment with this drug, which are: (i) the condition was confirmed by histological diagnosis, (ii) the treatment is/was being used as part of triple combination therapy with bortezomib and dexamethasone, (iii) the condition progressed (see definition of progressive disease below) after one prior therapy, but not after more than two prior lines of therapies (i.e. this drug was commenced as second-line treatment), (iv) the treatment was/is not to be used in combination with PBS-subsidised carfilzomib, thalidomide or its analogues, and (v) the patient had never been treated with this drug, **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 carfilzomib, thalidomide or its analogues.

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.

Details of: the histological diagnosis of multiple myeloma; prior treatments including name(s) of drug(s) and date of most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and which disease activity parameters will be used to assess response, must be documented in the patient's medical records.

Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records:

- (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; 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 must be used to determine response, results for either (a) or (b) or (c) should be documented 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) must be documented in the patient's medical records. 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 documented in the patient's medical records.

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.

daratumumab 1.8 g/15 mL injection, 15 mL vial

12704P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	7	..	7171.50	41.30	Darzalex [JC]

▪ DAROLUTAMIDE

Note Special Pricing Arrangements apply.

Authority required

Castration resistant non-metastatic carcinoma of the prostate

Clinical criteria:

- The condition must have evidence of an absence of distant metastases on the most recently performed conventional medical imaging used to evaluate the condition, **AND**
- The condition must be associated with a prostate-specific antigen level that was observed to have at least doubled in value in a time period of within 10 months anytime prior to first commencing treatment with this drug, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

Treatment criteria:

- Patient must be undergoing concurrent treatment with androgen deprivation therapy.

Prescribing instructions:

Retain the results of all investigative imaging and prostate-specific antigen (PSA) level measurements on the patient's medical records - do not submit copies of these with this authority application.

The PSA level doubling time must be based on at least three PSA levels obtained within a time period of 10 months anytime prior to first commencing treatment with this drug. The third reading is to demonstrate that the doubling was durable and must be at least 1 week apart from the second reading.

darolutamide 300 mg tablet, 112

12684N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3536.86	41.30	Nubeqa [BN]

▪ ENZALUTAMIDE

Note No 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

Castration resistant metastatic carcinoma of the prostate

Clinical criteria:

- The treatment must not be used in combination with chemotherapy, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, **AND**
- Patient must not be undergoing treatment with this drug following treatment with any of: (i) darolutamide, (ii) abiraterone; **OR**
- Patient must have developed an intolerance to abiraterone of a severity necessitating permanent treatment withdrawal.

enzalutamide 40 mg capsule, 112

10174L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3536.86	41.30	Xtandi [LL]

▪ ETANERCEPT

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

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

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 juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab)

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 been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

Population criteria:

- Patient must be aged 18 years or older.

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

(1) a completed authority prescription form; and

(2) a completed 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 has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided.

If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab.

An adequate response to treatment is defined as:

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

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

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 The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, and etanercept for patients over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS-subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage.

Alternative biological medicine refers to adalimumab and etanercept.

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - Temporary listing' PBS listing.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: First continuing treatment - Critical shortage of tocilizumab - Temporary listing

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 Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab),

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) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

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

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

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

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.

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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

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

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

This PBS listings is a temporary listing and may only be used when an application for initial supply of this medicine has been made under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab).

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

12716G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1050.14	41.30	Enbrel [PF]

etanercept 25 mg injection [4 vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack

12750C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1050.16	41.30	Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

12676E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1050.14	41.30	Enbrel [PF]

■ ETANERCEPT

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

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

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 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab)

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 been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**

- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **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.

Population criteria:

- Patient must be aged 18 years or older.

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

(1) a completed authority prescription form; and

(2) a completed 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 has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided.

If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

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.

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

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage.

The term biological medicine refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor

(tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - critical shortage of tocilizumab' PBS listing.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - Critical shortage of tocilizumab - Temporary listing

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 Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab),

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.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis.

This PBS listings is a temporary listing and may only be used when an application for initial supply of this medicine has been made under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab).

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

12679H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1050.14	41.30	^a Brenzys [RF]	^a Enbrel [PF]

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

12718J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1050.16	41.30	Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

12737J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1050.14	41.30	^a Brenzys [RF]	^a Enbrel [PF]

■ FLUTICASONE FUROATE + UMECLIDINIUM + VILANTEROL

Note Formal assessment and correction of inhaler technique should be performed in accordance with the COPD-X Plan (available at <http://copdx.org.au/>); the assessment and adherence to correct technique should be documented in the patient's medical records.

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

Note A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

Note Continuing Therapy Only:

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

Authority required (STREAMLINED)

12349

Chronic obstructive pulmonary disease (COPD)


Clinical criteria:

- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months, with significant symptoms despite regular bronchodilator therapy with a long acting muscarinic antagonist (LAMA) and a long acting beta-2 agonist (LABA) or an inhaled corticosteroid (ICS) and a LABA; OR
- Patient must have been stabilised on a combination of a LAMA, LABA and an ICS for this condition.

Treatment criteria:

- Patient must not be undergoing treatment with this product in each of the following circumstances: (i) treatment of asthma in the absence of a COPD diagnosis, (ii) initiation of bronchodilator therapy in COPD, (iii) use as reliever therapy for asthma, (iv) dosed at an interval/frequency that differs to that recommended in the approved Product Information.

fluticasone furoate 100 microgram/actuation + umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations

11379X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	94.63	41.30	Trelegy Ellipta 100/62.5/25 [GK]

■ GOLIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of secukinumab, certolizumab pegol and golimumab for adult patients with non-radiographic axial spondyloarthritis.

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

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

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

A serious adverse reaction requiring 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.

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 (once with any biological medicine) within the same treatment cycle, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

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

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

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

How to prescribe PBS-subsidised biological medicine treatment with secukinumab, certolizumab pegol and golimumab

(1) 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)
- a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy 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 of less than 5 years with the same 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).

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of

therapy.

(2) Continuing treatment.

For continuing courses of PBS-subsidised biological medicine it is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

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 biological medicine provided they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment in courses of up to 24 weeks provided they continue to sustain an adequate response.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. 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 requiring permanent treatment withdrawal.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements.

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 will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

(4) Baseline measurements to determine response.

A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records. For a new patient, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.

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.

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

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must qualify under the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

Note No 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. EST Monday to Friday).

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment

Clinical criteria:

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

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:
 - (a) a CRP measurement no greater than 10 mg per L; or
 - (b) a CRP measurement reduced by at least 20% from baseline.

If the requirement to demonstrate an elevated CRP level could not be met under an initial treatment restriction, a reduction in the BASDAI score from baseline will suffice for the purposes of administering this continuing treatment restriction.

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 in the month prior to completing their current course of treatment.

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

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

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

golimumab 50 mg/0.5 mL injection, 0.5 mL pen device

11521J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1160.58	41.30	Simponi [JC]

golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

11516D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1160.58	41.30	Simponi [JC]

■ GOLIMUMAB

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

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

Note Any queries concerning the arrangements to prescribe may be directed to 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 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab)

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 been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**

- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**

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

Population criteria:

- Patient must be aged 18 years or older.

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

(1) a completed authority prescription form; and

(2) a completed 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 has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided.

If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

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.

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

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage.

The term biological medicine refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - critical shortage of tocilizumab' PBS listing.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - Critical shortage of tocilizumab - Temporary listing

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 Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab),

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.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis.

This PBS listing is a temporary listing and may only be used when an application for initial supply of this medicine has been made under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab).

golimumab 50 mg/0.5 mL injection, 0.5 mL pen device

12744R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1160.58	41.30	Simponi [JC]

golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

12703N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1160.58	41.30	Simponi [JC]

▪ **GOLIMUMAB**

Note TREATMENT OF ADULT PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of secukinumab, certolizumab pegol and golimumab for adult patients with non-radiographic axial spondyloarthritis.

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

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

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

A serious adverse reaction requiring 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.

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 (once with any biological medicine) within the same treatment cycle, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

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

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

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

How to prescribe PBS-subsidised biological medicine treatment with secukinumab, certolizumab pegol and golimumab

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient)

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(2) Continuing treatment.

For continuing courses of PBS-subsidised biological medicine it is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

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 biological medicine provided they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment in courses of up to 24 weeks provided they continue to sustain an adequate response.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. 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 requiring permanent treatment withdrawal.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements.

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 will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

(4) Baseline measurements to determine response.

A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records.

For a new patient, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.

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.

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

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must qualify under the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

Note No 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

Non-radiographic axial spondyloarthritis

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

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- The treatment must not exceed a maximum of 16 weeks with this drug under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

The application must include details of the NSAIDs trialed, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

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

- a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and
- C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. 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.

The assessment of the patient's response to the 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 in this treatment cycle.

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

- a completed authority prescription form(s); 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 baseline BASDAI score and CRP level must also be documented 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. 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

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 2 (Change or re-commencement of treatment after a break of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with biological medicines more than three times for this PBS-indication during the current treatment cycle, **AND**
- The treatment must not exceed a maximum of 16 weeks with this drug under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

Clinical criteria:

- Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS indication more than once in the current treatment cycle.

An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment.

A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application.

An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:

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

The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment.

BASDAI scores and CRP levels must be documented in the patient's medical records.

The assessment of the patient's response to the 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 in this treatment cycle.

The following must be provided at the time of application and documented in the patient's medical records:

- (a) the BASDAI score; and
- (b) the C-reactive protein (CRP) level.

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

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- The treatment must not exceed a maximum of 16 weeks duration under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
 - Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.
- The following must be provided at the time of application and documented in the patient's medical records:
- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and
 - (b) C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI score and CRP level must be no more than 4 weeks old at the time of this application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application.

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.

The assessment of the patient's response to the 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 in this treatment cycle.

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

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial 1 (New patient), Initial 2 (Change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

Note 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).

golimumab 50 mg/0.5 mL injection, 0.5 mL pen device

11538G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1160.58	41.30	Simponi [JC]

golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

11560K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1160.58	41.30	Simponi [JC]

■ IMATINIB

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

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

Authority required

Gastrointestinal stromal tumour

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST), **AND**
- Patient must be at high risk of recurrence following complete surgical resection of primary GIST, **AND**
- The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining, **AND**
- The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy).

High risk of recurrence is defined as:

Primary GIST greater than 5 cm with a mitotic count of greater than 5/50 high power fields (HPF); or

Primary GIST greater than 10 cm with any mitotic rate; or

Primary GIST with a mitotic count of greater than 10/50 HPF.

A pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining must be documented in the patient's medical records.

The pathology report must include the size and mitotic rate of the tumour, and the date of tumour resection, which must not be more than 3 months prior to treatment initiation must be recorded in the patient's medical records.

imatinib 400 mg capsule, 30

12681K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	662.61	41.30	^a Imatinib-APOTEX [TX]	^a IMATINIB-DRLA [RZ]

imatinib 400 mg tablet, 30

5444M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	662.61	41.30	^a Gilmat [CR] ^a Imatinib-Teva [SZ]	^a Glivec [AF]

■ IMATINIB

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

Note 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)**9278**

Gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST), **AND**
- Patient must be at high risk of recurrence following complete surgical resection of primary GIST, **AND**
- The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy), **AND**
- Patient must have previously been issued with an authority prescription for imatinib for adjuvant treatment following complete resection of primary GIST.

imatinib 100 mg capsule, 60

12710Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	334.85	41.30	^a Imatinib-APOTEX [TX]	^a IMATINIB-DRLA [RZ]

imatinib 100 mg tablet, 60

11784F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	334.85	41.30	^a Gilmat [CR] ^a Imatinib-Teva [SZ]	^a Glivec [AF]

■ IMATINIB

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

Note 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)**9278**

Gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST), **AND**
- Patient must be at high risk of recurrence following complete surgical resection of primary GIST, **AND**
- The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy), **AND**
- Patient must have previously been issued with an authority prescription for imatinib for adjuvant treatment following complete resection of primary GIST.

imatinib 400 mg capsule, 30

12711B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	662.61	41.30	^a Imatinib-APOTEX [TX]	^a IMATINIB-DRLA [RZ]

imatinib 400 mg tablet, 30

11788K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	662.61	41.30	^a Gilmat [CR] ^a Imatinib-Teva [SZ]	^a Glivec [AF]

■ IMATINIB

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

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

Gastrointestinal stromal tumour

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST), **AND**
- Patient must be at high risk of recurrence following complete surgical resection of primary GIST, **AND**
- The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining, **AND**
- The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy).

High risk of recurrence is defined as:

Primary GIST greater than 5 cm with a mitotic count of greater than 5/50 high power fields (HPF); or

Primary GIST greater than 10 cm with any mitotic rate; or

Primary GIST with a mitotic count of greater than 10/50 HPF.

A pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining must be documented in the patient's medical records.

The pathology report must include the size and mitotic rate of the tumour, and the date of tumour resection, which must not be more than 3 months prior to treatment initiation must be recorded in the patient's medical records.

imatinib 100 mg capsule, 60

12759M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	334.85	41.30	^a Imatinib-APOTEX [TX]	^a IMATINIB-DRLA [RZ]

imatinib 100 mg tablet, 60

5443L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	334.85	41.30	^a Gilmat [CR] ^a Imatinib-Teva [SZ]	^a Glivec [AF]

▪ **IMATINIB**

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

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
	1	2	..	334.85	41.30	^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	..	334.85	41.30	^a Gilmat [CR] ^a Imatinib-Teva [SZ]	^a Glivec [AF]

▪ **IMATINIB**

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

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

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)

9208

Malignant gastrointestinal stromal tumour
Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be metastatic; OR
- The condition must be unresectable, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given at a dose not exceeding 600 mg per day.

Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib
Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

imatinib 100 mg capsule, 60

12722N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	334.85	41.30	^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	..	334.85	41.30	^a Gilmat [CR]	^a Glivec [AF]
						^a Imatinib-Teva [SZ]	

▪ **IMATINIB**

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

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

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)

9208

Malignant gastrointestinal stromal tumour
Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be metastatic; OR
- The condition must be unresectable, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given at a dose not exceeding 600 mg per day.

Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib
Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

imatinib 400 mg capsule, 30

12723P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	662.61	41.30	^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	..	662.61	41.30	^a Gilmat [CR]	^a Glivec [AF]
						^a Imatinib-Teva [SZ]	

▪ **IMATINIB**

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

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

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
	1	2	..	662.61	41.30	^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	..	662.61	41.30	^a Gilmat [CR]	^a Glivec [AF]
						^a Imatinib-Teva [SZ]	

▪ **INFLIXIMAB**

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: Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) - 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 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) restriction, with subcutaneous form restriction to complete 22 weeks initial treatment (intravenous and subcutaneous inclusive), **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) - subcutaneous form.

Population criteria:

- Patient must be aged 18 years or older.

infliximab 120 mg/mL injection, 1 mL pen device

12689W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	382.80	41.30	Remsima SC [EW]

infliximab 120 mg/mL injection, 1 mL syringe

12688T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	382.80	41.30	Remsima SC [EW]

▪ **INFLIXIMAB**

Note No 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

Note The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis.
 This PBS listings is a temporary listing and may only be used when an application for initial supply of this medicine has been made under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab).

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - Critical shortage of tocilizumab - Temporary listing

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 Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab),

AND

- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly, **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.

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 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.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

infliximab 120 mg/mL injection, 1 mL pen device

12748Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*758.52	41.30	Remsima SC [EW]

infliximab 120 mg/mL injection, 1 mL syringe

12753F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*758.52	41.30	Remsima SC [EW]

■ INFLIXIMAB

Note No 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

Note The application should indicate which formulation eg. pre-filled pen or pre-filled syringe to ensure appropriate item is approved.

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 The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage.

The term biological medicine refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - critical shortage of tocilizumab' PBS listing.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - Change of treatment due to critical shortage of tocilizumab) - subcutaneous form at weeks 6, 8, 10, 12, 14 and 16

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 been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must have received 2 intravenous infusions with this drug for this condition at weeks 0 and 2 under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab), **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 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 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 has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided.

If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

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.

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.

infliximab 120 mg/mL injection, 1 mL pen device

12687R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*758.52	41.30	Remsima SC [EW]

infliximab 120 mg/mL injection, 1 mL syringe

12677F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*758.52	41.30	Remsima SC [EW]

▪ LEUPRORELIN

Restricted benefit

Central precocious puberty

Treatment Phase: Continuing treatment with this drug, or, switching gonadotropin releasing hormone analogue therapy

Treatment criteria:

- Must be treated by a medical practitioner identifying as one of: (i) a paediatric endocrinologist, (ii) an endocrinologist specialising in paediatrics; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing continuing treatment with a gonadotropin releasing hormone analogue initiated through the PBS for this PBS indication.

leuprorelin acetate 30 mg modified release injection [1 chamber] (& inert substance diluent [1.5 mL chamber], 1 dual chamber syringe

11944P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1189.19	41.30	Lucrin Depot Paediatric 30 mg PDS [VE]

▪ SECUKINUMAB

Note TREATMENT OF ADULT PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of secukinumab, certolizumab pegol and golimumab for adult patients with non-radiographic axial spondyloarthritis.

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

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

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

A serious adverse reaction requiring 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.

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 (once with any biological medicine) within the same treatment cycle, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

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

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

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

How to prescribe PBS-subsidised biological medicine treatment with secukinumab, certolizumab pegol and golimumab

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient)
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).
A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(2) Continuing treatment.

For continuing courses of PBS-subsidised biological medicine it is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

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 biological medicine provided they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment in courses of up to 24 weeks provided they continue to sustain an adequate response.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. 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 requiring permanent treatment withdrawal.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements.

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 will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

(4) Baseline measurements to determine response.

A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records. For a new patient, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.

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.

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

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must qualify under the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

Note No increase in the maximum quantity or number of units 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. EST Monday to Friday).

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial 1 (New patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patients) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 20 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 20 weeks treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment or Grandfather patient - balance of supply

Clinical criteria:

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

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

secukinumab 150 mg/mL injection, 1 mL pen device

12297F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	709.65	41.30	Cosentyx [NV]

■ SECUKINUMAB**Note TREATMENT OF ADULT PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of secukinumab, certolizumab pegol and golimumab for adult patients with non-radiographic axial spondyloarthritis.

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

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

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

A serious adverse reaction requiring 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.

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 (once with any biological medicine) within the same treatment cycle, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

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

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

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

How to prescribe PBS-subsidised biological medicine treatment with secukinumab, certolizumab pegol and golimumab

(1) 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)
 - a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy 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 of less than 5 years with the same 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).
- A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(2) Continuing treatment.

For continuing courses of PBS-subsidised biological medicine it is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

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 biological medicine provided they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment in courses of up to 24 weeks provided they continue to sustain an adequate response.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. 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 requiring permanent treatment withdrawal.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements.

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 will be deemed to have failed

treatment with that biological medicine unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

(4) Baseline measurements to determine response.

A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records. For a new patient, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.

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.

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

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must qualify under the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

Note No 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

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment

Clinical criteria:

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

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:

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

If the requirement to demonstrate an elevated CRP level could not be met under an initial treatment restriction, a reduction in the BASDAI score from baseline will suffice for the purposes of administering this continuing treatment restriction.

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 in the month prior to completing their current course of treatment.

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

Non-radiographic axial spondyloarthritis

Treatment Phase: Grandfather treatment

Clinical criteria:

- Patient must have previously received non-PBS-subsidised treatment with this drug for this indication prior to 1 April 2021, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that was relieved by exercise but not rest, prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27); prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis prior to commencing non-PBS-subsidised treatment with this biological medicine, **AND**
- The condition must have been diagnosed as non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, prior to having commenced non-PBS-subsidised treatment with this biological medicine, **AND**
- The condition must have been sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI) prior to commencing non-PBS-subsidised treatment with this biological medicine, **AND**
- The condition must have had presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent) prior to commencing non-PBS-subsidised treatment with this biological medicine, **AND**
- The condition must have had BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium) prior to commencing non-PBS-subsidised treatment with this biological medicine, **AND**
- The treatment must not exceed a maximum of 24 weeks with this drug under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. The application must include details of the NSAIDs trialed, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response to NSAIDs and must have been demonstrated prior to initiation of non-PBS subsidised treatment with this biological medicine for this condition:

- a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and
- C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI score and CRP level must have been determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must have been no more than 1 month old at the time of initiating non-PBS subsidised treatment with this biological medicine for this condition.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. 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.

The assessment of the patient's response to the 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 in this treatment cycle.

A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria.

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

- a completed authority prescription form(s); 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 baseline BASDAI score and CRP level must also be documented 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. 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

secukinumab 150 mg/mL injection, 1 mL pen device

12307R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	709.65	41.30	Cosentyx [NV]

▪ SECUKINUMAB

Note TREATMENT OF ADULT PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of secukinumab, certolizumab pegol and golimumab for adult patients with non-radiographic axial spondyloarthritis.

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

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

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

A serious adverse reaction requiring 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.

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 (once with any biological medicine) within the same treatment cycle, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

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

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

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

How to prescribe PBS-subsidised biological medicine treatment with secukinumab, certolizumab pegol and golimumab
(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient)
 - (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
 - (iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years); or
 - (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).
- A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(2) Continuing treatment.

For continuing courses of PBS-subsidised biological medicine it is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

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 biological medicine provided they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment in courses of up to 24 weeks provided they continue to sustain an adequate response.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. 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 requiring permanent treatment withdrawal.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements.

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 will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

(4) Baseline measurements to determine response.

A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records. For a new patient, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.

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.

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

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must qualify under the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

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

Note Special Pricing Arrangements apply.

Authority required

Non-radiographic axial spondyloarthritis

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

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**

- Patient must not receive more than 20 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

The stated maximum quantity of 5 with zero repeats is intended for a patient undergoing the loading dose regimen of 150 mg administered at weeks 0, 1, 2, 3, and 4 (a total of 5 doses) followed by monthly administration thereafter.

State in the application whether a loading dose regimen is intended or not.

Where a loading dose regimen is intended, request a maximum quantity of 5 and zero repeats to cover doses at weeks 0, 1, 2, 3 and 4. Doses at week 8, 12, and 16 can be sought under the relevant 'Balance of supply' listing.

Where no loading dose regimen is intended, request a maximum quantity of 1 and seek an increase in the number of repeats from zero to 4 repeats to cover dosing at weeks 4, 8, 12 and 16. Where increased repeats are sought, the maximum quantity sought must not be greater than 1.

The application must include details of the NSAIDs trialed, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

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

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and
- (b) C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application.

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.

The assessment of the patient's response to the 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 in this treatment cycle.

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

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

The baseline BASDAI score and CRP level must also be documented 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. 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

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with biological medicines more than three times for this PBS-indication during the current treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS indication more than once in the current treatment cycle, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment.

A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application.

An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:

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

The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment.

BASDAI scores and CRP levels must be documented in the patient's medical records.

The assessment of the patient's response to the 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 in this treatment cycle.

The following must be provided at the time of application and documented in the patient's medical records:

- (a) the BASDAI score; and
- (b) the C-reactive protein (CRP) level.

The stated maximum quantity of 5 with zero repeats is intended for a patient undergoing the loading dose regimen of 150 mg administered at weeks 0, 1, 2, 3, and 4 (a total of 5 doses) followed by monthly administration thereafter.

State in the application whether a loading dose regimen is intended or not.

Where a loading dose regimen is intended, request a maximum quantity of 5 and zero repeats to cover doses at weeks 0, 1, 2, 3 and 4. Doses at week 8, 12, and 16 can be sought under the relevant 'Balance of supply' listing.

Where no loading dose regimen is intended, request a maximum quantity of 1 and seek an increase in the number of repeats from zero to 4 repeats to cover dosing at weeks 4, 8, 12 and 16. Where increased repeats are sought, the maximum quantity sought must not be greater than 1.

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

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, **AND**
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, **AND**
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), **AND**
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

The following must be provided at the time of application and documented in the patient's medical records:

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and
- (b) C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI score and CRP level must be no more than 4 weeks old at the time of this application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application.

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.

The assessment of the patient's response to the 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 in this treatment cycle.

The stated maximum quantity of 5 with zero repeats is intended for a patient undergoing the loading dose regimen of 150 mg administered at weeks 0, 1, 2, 3, and 4 (a total of 5 doses) followed by monthly administration thereafter.

State in the application whether a loading dose regimen is intended or not.

Where a loading dose regimen is intended, request a maximum quantity of 5 and zero repeats to cover doses at weeks 0, 1, 2, 3 and 4. Doses at week 8, 12, and 16 can be sought under the relevant 'Balance of supply' listing.

Where no loading dose regimen is intended, request a maximum quantity of 1 and seek an increase in the number of repeats from zero to 4 repeats to cover dosing at weeks 4, 8, 12 and 16. Where increased repeats are sought, the maximum quantity sought must not be greater than 1.

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).

secukinumab 150 mg/mL injection, 1 mL pen device

12321L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	*3452.63	41.30	Cosentyx [NV]

▪ TOFACITINIB

Note No 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: Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab)

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 been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **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.

Population criteria:

- Patient must be aged 18 years or older.

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

(1) a completed authority prescription form; and

(2) a completed 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 has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided.

If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

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.

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

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage.

The term biological medicine refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - critical shortage of tocilizumab' PBS listing.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - Critical shortage of tocilizumab - Temporary listing

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 Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab),

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.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis.

This PBS listings is a temporary listing and may only be used when an application for initial supply of this medicine has been made under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab).

tofacinib 5 mg tablet, 56

12720L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1211.02	41.30	Xeljanz [PF]

▪ TOPIRAMATE**Note Continuing Therapy Only:**

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

Authority required (STREAMLINED)**5516**

Seizures

Clinical criteria:

- Patient must have partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures; OR
- Patient must have seizures of the Lennox-Gastaut syndrome, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

Authority required (STREAMLINED)**5325**


Migraine

Clinical criteria:

- The treatment must be for prophylaxis, **AND**
- Patient must have experienced an average of 3 or more migraines per month over a period of at least 6 months, **AND**
- Patient must have a contraindication to beta-blockers, as described in the relevant TGA-approved Product Information; OR
- Patient must have experienced intolerance of a severity necessitating permanent withdrawal during treatment with a beta-blocker, **AND**
- Patient must have a contraindication to pizotifen because the weight gain associated with this drug poses an unacceptable risk; OR
- Patient must have experienced intolerance of a severity necessitating permanent withdrawal during treatment with pizotifen.

Details of the contraindication and/or intolerance(s) must be documented in the patient's medical records when treatment is initiated.

topiramate 100 mg tablet, 60

8165R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	29.57	30.87	^a APO-Topiramate [TX] ^a RBX Topiramate [RA] ^a Topamax [JC] ^a Topiramate Sandoz [SZ]	^a Epiramax 100 [RW] ^a Tamate [AF] ^a Topiramate AN [EA]

▪ TRIPTORELIN**Restricted benefit**

Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate

Restricted benefit

Central precocious puberty

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a paediatric endocrinologist; OR
- Must be treated by an endocrinologist specialising in paediatrics.

Population criteria:

- Patient must be of an age that is prior to their 12th birthday if female; OR
- Patient must be of an age that is prior to their 13th birthday if male, **AND**
- Patient must have had onset of signs/symptoms of central precocious puberty prior to their 9th birthday if female; OR
- Patient must have had onset of signs/symptoms of central precocious puberty prior to their 10th birthday if male.

Restricted benefit

Central precocious puberty

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements

Treatment criteria:

- Must be treated by a paediatric endocrinologist; OR
- Must be treated by an endocrinologist specialising in paediatrics; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Clinical criteria:

- Patient must be each of: (i) currently receiving this drug for the PBS-indication, (ii) commenced on non-PBS-subsidised supply prior to 1 November 2021.

Population criteria:

- Patient must have met each of: (i) experienced signs/symptoms of central precocious puberty prior to their 9th birthday, (ii) initiated treatment with this drug prior to their 12th birthday, if female; OR
- Patient must have met each of: (i) experienced signs/symptoms of central precocious puberty prior to their 10th birthday, (ii) initiated treatment with this drug prior to their 13th birthday, if male.

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.

Restricted benefit

Central precocious puberty

Treatment Phase: Continuing treatment with this drug, or, switching gonadotropin releasing hormone analogue therapy

Treatment criteria:

- Must be treated by a medical practitioner identifying as one of: (i) a paediatric endocrinologist, (ii) an endocrinologist specialising in paediatrics; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing continuing treatment with a gonadotropin releasing hormone analogue initiated through the PBS for this PBS indication.

triptorelin 22.5 mg injection [1 vial] (&) inert substance diluent [2 mL ampoule], 1 pack

5297T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1839.34	41.30	Diphereline [IS]

▪ UPADACITINIB

Note No 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: Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab)

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 been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **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.

Population criteria:

- Patient must be aged 18 years or older.

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

- (1) a completed authority prescription form; and
- (2) a completed 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 has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided.

If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

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.

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

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage.

The term biological medicine refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - critical shortage of tocilizumab' PBS listing.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - Critical shortage of tocilizumab - Temporary listing

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 Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab),

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.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis.

This PBS listing is a temporary listing and may only be used when an application for initial supply of this medicine has been made under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab).

upadacitinib 15 mg modified release tablet, 28

12685P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1271.40	41.30	Rinvoq [VE]

Highly Specialised Drugs Program (Private Hospital)

▪ ABATACEPT

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab)

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 been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **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 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 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 has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided.

If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

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.

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.

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 5 repeats will be authorised.

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 The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage.

The term biological medicine refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - critical shortage of tocilizumab' PBS listing.

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: First continuing treatment - Critical shortage of tocilizumab - Temporary listing

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 Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab),

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, **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.

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.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis.

This PBS listing is a temporary listing and may only be used when an application for initial supply of this medicine has been made under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab).

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 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) - 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 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) restriction to complete 24 weeks treatment, depending on the dosage regimen, **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 Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

abatacept 250 mg injection, 1 vial

12738K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	284.77	Orencia [BQ]

■ ADALIMUMAB

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

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 juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**

- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

Population criteria:

- Patient must be under 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).

If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided.

If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab.

An adequate response to treatment is defined as:

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

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

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

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

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 5 repeats will be authorised.

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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

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 The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, and etanercept for patients who have severe active juvenile idiopathic arthritis.

This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage. Alternative biological medicine refers to adalimumab and etanercept.

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - Temporary listing' PBS listing.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: First continuing treatment - Critical shortage of tocilizumab - Temporary listing

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab),

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 under 18 years of age.

An adequate response to treatment is defined as:

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

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

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

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

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

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 5 repeats will be authorised.

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.

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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient who has severe active juvenile idiopathic arthritis.

This PBS listings is a temporary listing and may only be used when an application for initial supply of this medicine has been made under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab).

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

12732D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	859.06	Humira [VE]

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

12715F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	859.06	^a Amgevita [AN]	^a Hadlima [RF]
					^a Hyrimoz [SZ]	^a Idacio [PK]

■ ADALIMUMAB

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

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 juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**

-
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

Population criteria:

- Patient must be under 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).

If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided.

If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab.

An adequate response to treatment is defined as:

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

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

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

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

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 5 repeats will be authorised.

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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

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 The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, and etanercept for patients who have severe active juvenile idiopathic arthritis.

This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage. Alternative biological medicine refers to adalimumab and etanercept.

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - Temporary listing' PBS listing.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: First continuing treatment - Critical shortage of tocilizumab - Temporary listing

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab),

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 under 18 years of age.

An adequate response to treatment is defined as:

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

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

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

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

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

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

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 5 repeats will be authorised.

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.

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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient who has severe active juvenile idiopathic arthritis.

This PBS listing is a temporary listing and may only be used when an application for initial supply of this medicine has been made under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab).

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

12749B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	859.06	Humira [VE]

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

12731C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	859.06	^a Amgevita [AN]	^a Hadlima [RF]
					^a Hyrimoz [SZ]	^a Idacio [PK]

■ ADALIMUMAB

Note Pharmaceutical benefits that have the form adalimumab 20 mg/0.2 mL syringes and pharmaceutical benefits that have the form adalimumab 20 mg/0.4 mL syringes are equivalent for the purposes of substitution

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

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 juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021,

AND

- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**

- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

Population criteria:

- Patient must be under 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).

If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided.

If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab.

An adequate response to treatment is defined as:

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

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

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

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

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 5 repeats will be authorised.

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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

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 The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, and etanercept for patients who have severe active juvenile idiopathic arthritis.

This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage. Alternative biological medicine refers to adalimumab and etanercept.

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - Temporary listing' PBS listing.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: First continuing treatment - Critical shortage of tocilizumab - Temporary listing

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab),

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 under 18 years of age.

An adequate response to treatment is defined as:

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

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

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

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

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

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 5 repeats will be authorised.

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.

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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient who has severe active juvenile idiopathic arthritis.

This PBS listings is a temporary listing and may only be used when an application for initial supply of this medicine has been made under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab).

adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes

12686Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	859.06	Humira [VE]

adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe

12674C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	*859.06	Amgevita [AN]

■ ETANERCEPT

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 juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

Population criteria:

- Patient must be under 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).

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised.

If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided.

If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab.

An adequate response to treatment is defined as:

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

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

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

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

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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

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 The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, and etanercept for patients who have severe active juvenile idiopathic arthritis.

This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage. Alternative biological medicine refers to adalimumab and etanercept.

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - Temporary listing' PBS listing.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: First continuing treatment - Critical shortage of tocilizumab - Temporary listing

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab),

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 under 18 years of age.

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).
Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

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

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

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised.

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.

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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient who has severe active juvenile idiopathic arthritis.

This PBS listings is a temporary listing and may only be used when an application for initial supply of this medicine has been made under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab).

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

12736H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	984.60	Enbrel [PF]

etanercept 25 mg injection [4 vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack

12734F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	496.20	Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

12757K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	984.60	Enbrel [PF]

■ INFLIXIMAB

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 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab)

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 been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **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 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 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 has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided.

If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

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.

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.

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.

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 The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage.

The term biological medicine refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - critical shortage of tocilizumab' PBS listing.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - Critical shortage of tocilizumab - Temporary listing

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 Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab),

AND

- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly, **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.

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 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.

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.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis.

This PBS listing is a temporary listing and may only be used when an application for initial supply of this medicine has been made under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab).

infliximab 100 mg injection, 1 vial

12751D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	341.32	^a Inflectra [PF] ^a Renflexis [OQ]	^a Remicade [JC]

▪ RITUXIMAB

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

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage.

The term biological medicine refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - critical shortage of tocilizumab' PBS listing.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab)

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 been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist 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 treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly, **AND**
- Patient must not receive more than 2 infusions of this drug 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 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 has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided.

If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab. An adequate response to treatment is defined as:

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

AND either of the following:

(a) 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.

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.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this drug provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with this drug. The demonstration of response must be submitted within 4 weeks of assessment.

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.

A patient whose most recent course of PBS-subsidised therapy was with this drug and whose response to this treatment is demonstrated at 12 weeks, may apply for a further course of this drug under the First continuing treatment restriction.

If a patient fails to demonstrate a response to 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 fails to demonstrate a response to this drug and who qualifies to trial an alternate biological medicine according to the interchangeability arrangements for biological medicines for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

rituximab 500 mg/50 mL injection, 50 mL vial

12721M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	569.83	^a Riximyo [SZ]	^a Truxima [EW]

▪ TOCILIZUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tocilizumab for a patient who has severe active systemic juvenile idiopathic arthritis (sJIA).

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy, and
- (ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

Once a patient has either failed or ceased to sustain an adequate response to 2 courses of treatment, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised tocilizumab therapy before they are eligible to commence another cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was approved to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

A 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, will not be considered as a treatment failure.

How to prescribe PBS-subsidised tocilizumab treatment therapy after 1 May 2012.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised tocilizumab treatment and wishes to commence such therapy (Initial 1 - New patient); or
- (ii) a patient has received the first course of PBS-subsidised (initial or continuing) tocilizumab therapy in a treatment cycle and is deemed to have failed to respond or sustain an adequate response and the treating physician wishes to trial a second course, provided any break in therapy is less than 12 months (Initial 2 - retreat or recommencement of treatment after a break of less than 12 months); or
- (iii) a patient wishes to recommence treatment with tocilizumab following a break in PBS-subsidised therapy of less than 12 months (Initial 2 - retreat or recommencement of treatment after a break of less than 12 months).
- (iv) a patient wishes to recommence treatment following a break in PBS-subsidised tocilizumab therapy of more than 12 months (Initial 3 - recommencement of a new treatment cycle after a break of more than 12 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with tocilizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with this drug provided they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks provided 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 tocilizumab supply.

Assessments of response to a course of PBS-subsidised therapy must be conducted after a minimum of 12 weeks of treatment and no later than 4 weeks from the completion of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

For the second and subsequent courses of PBS-subsidised tocilizumab, it is recommended that a patient be assessed for response in the 4 weeks prior to completing their current course of treatment and that an application is posted to Services Australia no later than 2 weeks prior to the patient completing their current treatment course.

(3) Treatment cycle.

Once initial treatment with PBS-subsidised tocilizumab is approved, a patient deemed to have failed to respond to the first course of treatment may have a second course without having to requalify with respect to the indices of disease severity (joint count, fever and/or CRP level and platelet count), except if the patient has had a break in therapy of more than 12 months.

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 approved, within the timeframes specified in the relevant restriction.

(4) Baseline measurements to determine response.

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count submitted with the first authority application for tocilizumab.

Where a patient is deemed to have failed to respond or to sustain an adequate response to the first course of therapy in a treatment cycle, prescribers may provide new baseline measurements for the second course of treatment within that cycle. Assessment of response according to these revised baseline measurements may then occur. If new baseline measurements are not submitted with the initial application for the second course of treatment, then those submitted with the first course will be used to assess response to the second course.

(5) Recommencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised tocilizumab therapy of at least 12 months, must requalify for treatment under the Initial 3 treatment restriction.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with tocilizumab should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to Services Australia at the time treatment is ceased.

Note Pharmaceutical benefits that have the brand Actemra 400 mg injection in a pack size of 1 and pharmaceutical benefits that have the brand RoActemra 400 mg injection in a pack size of 1 or a pack size of 4 are equivalent for the purposes of substitution in the case of a shortage.

Authority required

Systemic juvenile idiopathic arthritis

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

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; OR
- Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient at the time of the initial application:

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

The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application:

- (a) an active joint count of at least 2 active joints; and
- (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or
- (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

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

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

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

- (1) completed authority prescription form(s); and
- (2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the date of assessment of severe active systemic juvenile idiopathic arthritis;
 - (ii) details of prior treatment including dose and duration of treatment;
 - (iii) pathology reports detailing CRP and platelet count where appropriate.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

The assessment of the patient's response to the 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 in this treatment cycle.

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

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (retrial or recommencement of treatment after a break of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with this drug for this condition in the previous 12 months, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

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

(b) in a patient with refractory systemic symptoms:

- (i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or
- (ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or
- (iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). 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) completed authority prescription form(s); and
- (2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate.

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

The assessment of the patient's response to the most recent course of biological medicine 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 that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to 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

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break of more than 12 months)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from this drug for this condition, **AND**
- Patient must have polyarticular course disease and the condition must have (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or ii) shoulder, cervical spine and/or hip (assessed as pain in passive

movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); OR

- Patient must have refractory systemic symptoms and the condition must have (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Population criteria:

- Patient must be under 18 years of age.

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

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

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes the following:

(i) the date of assessment of severe active systemic juvenile idiopathic arthritis;

(ii) pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

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

The assessment of the patient's response to the most recent course of biological medicine 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 that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

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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HOBART TAS 7001

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Balance of supply for Initial treatment - Initial 1 (new patient) or Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) or Initial 3 (recommencement of treatment after a break of more than 12 months)

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 (retrial or recommencement of treatment after a break of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under Initial 3 (recommencement of treatment after a break of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

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

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

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

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

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) 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

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

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

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

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity submitted with the initial treatment application.

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

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

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes baseline and current pathology reports detailing CRP and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

The assessment of the patient's response to the most recent course of biological medicine 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 that most recent course of treatment in this treatment cycle.

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 in the month prior to completing their current course of treatment.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to 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

Systemic juvenile idiopathic arthritis

Treatment Phase: Balance of supply - Continuing treatment

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 therapy available under Continuing treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

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).

tocilizumab 400 mg/20 mL injection, 20 mL vial

12728X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2306.86	^a RoActemra [DZ]

tocilizumab 400 mg/20 mL injection, 20 mL vial

1464C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	429.39	^a Actemra [RO]

tocilizumab 400 mg/20 mL injection, 4 x 20 mL vials

12705Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	0.2	*2308.06	^a RoActemra [DZ]

■ TOCILIZUMAB**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tocilizumab for a patient who has severe active systemic juvenile idiopathic arthritis (sJIA).

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy, and

(ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

Once a patient has either failed or ceased to sustain an adequate response to 2 courses of treatment, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised tocilizumab therapy before they are eligible to commence another cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was approved to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

A 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, will not be considered as a treatment failure.

How to prescribe PBS-subsidised tocilizumab treatment therapy after 1 May 2012.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised tocilizumab treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received the first course of PBS-subsidised (initial or continuing) tocilizumab therapy in a treatment cycle and is deemed to have failed to respond or sustain an adequate response and the treating physician wishes to trial a second course, provided any break in therapy is less than 12 months (Initial 2 - re-trial or recommencement of treatment after a break of less than 12 months); or

(iii) a patient wishes to recommence treatment with tocilizumab following a break in PBS-subsidised therapy of less than 12 months (Initial 2 - re-trial or recommencement of treatment after a break of less than 12 months).

(iv) a patient wishes to recommence treatment following a break in PBS-subsidised tocilizumab therapy of more than 12 months (Initial 3 - recommencement of a new treatment cycle after a break of more than 12 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with tocilizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with this drug provided they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks provided 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 tocilizumab supply.

Assessments of response to a course of PBS-subsidised therapy must be conducted after a minimum of 12 weeks of treatment and no later than 4 weeks from the completion of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

For the second and subsequent courses of PBS-subsidised tocilizumab, it is recommended that a patient be assessed for response in the 4 weeks prior to completing their current course of treatment and that an application is posted to Services Australia no later than 2 weeks prior to the patient completing their current treatment course.

(3) Treatment cycle.

Once initial treatment with PBS-subsidised tocilizumab is approved, a patient deemed to have failed to respond to the first course of treatment may have a second course without having to requalify with respect to the indices of disease severity (joint count, fever and/or CRP level and platelet count), except if the patient has had a break in therapy of more than 12 months.

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 approved, within the timeframes specified in the relevant restriction.

(4) Baseline measurements to determine response.

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count submitted with the first authority application for tocilizumab.

Where a patient is deemed to have failed to respond or to sustain an adequate response to the first course of therapy in a treatment cycle, prescribers may provide new baseline measurements for the second course of treatment within that cycle. Assessment of response according to these revised baseline measurements may then occur. If new baseline measurements are not submitted with the initial application for the second course of treatment, then those submitted with the first course will be used to assess response to the second course.

(5) Recommencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised tocilizumab therapy of at least 12 months, must requalify for treatment under the Initial 3 treatment restriction.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with tocilizumab should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to Services Australia at the time treatment is ceased.

Note Pharmaceutical benefits that have the brand Actemra 80 mg injection in a pack size of 1 and pharmaceutical benefits that have the brand RoActemra 80 mg injection in a pack size of 1 or a pack size of 4 are equivalent for the purposes of substitution in the case of a shortage.

Authority required

Systemic juvenile idiopathic arthritis

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

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; OR
- Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient at the time of the initial application:

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

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

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

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

The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application:

(a) an active joint count of at least 2 active joints; and

(b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or

(c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

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

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

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

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

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes the following:

(i) the date of assessment of severe active systemic juvenile idiopathic arthritis;

(ii) details of prior treatment including dose and duration of treatment;

(iii) pathology reports detailing CRP and platelet count where appropriate.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

The assessment of the patient's response to the 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 in this treatment cycle.

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

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (retrial or recommencement of treatment after a break of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with this drug for this condition in the previous 12 months, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) 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

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

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

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

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). 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) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate.

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

The assessment of the patient's response to the most recent course of biological medicine 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 that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to 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

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break of more than 12 months)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from this drug for this condition, **AND**
- Patient must have polyarticular course disease and the condition must have (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); OR
- Patient must have refractory systemic symptoms and the condition must have (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Population criteria:

- Patient must be under 18 years of age.

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

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

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes the following:

(i) the date of assessment of severe active systemic juvenile idiopathic arthritis;

(ii) pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

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

The assessment of the patient's response to the most recent course of biological medicine 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 that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

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

Systemic juvenile idiopathic arthritis

Treatment Phase: Balance of supply for Initial treatment - Initial 1 (new patient) or Initial 2 (retiral or recommencement of treatment after a break of less than 12 months) or Initial 3 (recommencement of treatment after a break of more than 12 months)

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 (retiral or recommencement of treatment after a break of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under Initial 3 (recommencement of treatment after a break of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

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

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

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

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) 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

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

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

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

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity submitted with the initial treatment application.

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

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

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes baseline and current pathology reports detailing CRP and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

The assessment of the patient's response to the most recent course of biological medicine 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 that most recent course of treatment in this treatment cycle.

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 in the month prior to completing their current course of treatment.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to 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

Systemic juvenile idiopathic arthritis

Treatment Phase: Balance of supply - Continuing treatment

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 therapy available under Continuing treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

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).

tocilizumab 80 mg/4 mL injection, 4 x 4 mL vials

12727W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	0.2	*530.31	^a RoActemra [DZ]

tocilizumab 80 mg/4 mL injection, 4 mL vial

12693C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	529.11	^a RoActemra [DZ]

tocilizumab 80 mg/4 mL injection, 4 mL vial

1419Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	93.97	^a Actemra [RO]

■ TOCILIZUMAB**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tocilizumab for a patient who has severe active systemic juvenile idiopathic arthritis (sJIA).

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

- continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy, and
- fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

Once a patient has either failed or ceased to sustain an adequate response to 2 courses of treatment, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised tocilizumab therapy before they are eligible to commence another cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was approved to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

A 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, will not be considered as a treatment failure.

How to prescribe PBS-subsidised tocilizumab treatment therapy after 1 May 2012.

(1) Initial treatment.

Applications for initial treatment should be made where:

- a patient has not received prior PBS-subsidised tocilizumab treatment and wishes to commence such therapy (Initial 1 - New patient); or
- a patient has received the first course of PBS-subsidised (initial or continuing) tocilizumab therapy in a treatment cycle and is deemed to have failed to respond or sustain an adequate response and the treating physician wishes to trial a second course, provided any break in therapy is less than 12 months (Initial 2 - retrial or recommencement of treatment after a break of less than 12 months); or
- a patient wishes to recommence treatment with tocilizumab following a break in PBS-subsidised therapy of less than 12 months (Initial 2 - retrial or recommencement of treatment after a break of less than 12 months).
- a patient wishes to recommence treatment following a break in PBS-subsidised tocilizumab therapy of more than 12 months (Initial 3 - recommencement of a new treatment cycle after a break of more than 12 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with tocilizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with this drug provided they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks provided 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 tocilizumab supply.

Assessments of response to a course of PBS-subsidised therapy must be conducted after a minimum of 12 weeks of treatment and no later than 4 weeks from the completion of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

For the second and subsequent courses of PBS-subsidised tocilizumab, it is recommended that a patient be assessed for response in the 4 weeks prior to completing their current course of treatment and that an application is posted to Services Australia no later than 2 weeks prior to the patient completing their current treatment course.

(3) Treatment cycle.

Once initial treatment with PBS-subsidised tocilizumab is approved, a patient deemed to have failed to respond to the first course of treatment may have a second course without having to requalify with respect to the indices of disease severity (joint count, fever and/or CRP level and platelet count), except if the patient has had a break in therapy of more than 12 months.

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 approved, within the timeframes specified in the relevant restriction.

(4) Baseline measurements to determine response.

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count submitted with the first authority application for tocilizumab.

Where a patient is deemed to have failed to respond or to sustain an adequate response to the first course of therapy in a treatment cycle, prescribers may provide new baseline measurements for the second course of treatment within that cycle. Assessment of response according to these revised baseline measurements may then occur. If new baseline measurements are not submitted with the initial application for the second course of treatment, then those submitted with the first course will be used to assess response to the second course.

(5) Recommencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised tocilizumab therapy of at least 12 months, must requalify for treatment under the Initial 3 treatment restriction.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with tocilizumab should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to Services Australia at the time treatment is ceased.

Note Pharmaceutical benefits that have the brand Actemra 200 mg injection in a pack size of 1 and pharmaceutical benefits that have the brand RoActemra 200 mg injection in a pack size of 1 or a pack size of 4 are equivalent for the purposes of substitution in the case of a shortage.

Authority required

Systemic juvenile idiopathic arthritis

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

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; OR
- Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient at the time of the initial application:

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

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

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

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

The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application:

(a) an active joint count of at least 2 active joints; and

(b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or

(c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

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

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

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

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

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes the following:

-
- (i) the date of assessment of severe active systemic juvenile idiopathic arthritis;
 - (ii) details of prior treatment including dose and duration of treatment;
 - (iii) pathology reports detailing CRP and platelet count where appropriate.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised. The assessment of the patient's response to the 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 in this treatment cycle.

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

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (retrial or recommencement of treatment after a break of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with this drug for this condition in the previous 12 months, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) 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

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

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

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

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). 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) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate.

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

The assessment of the patient's response to the most recent course of biological medicine 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 that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to 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

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break of more than 12 months)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from this drug for this condition, **AND**
- Patient must have polyarticular course disease and the condition must have (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); OR
- Patient must have refractory systemic symptoms and the condition must have (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Population criteria:

- Patient must be under 18 years of age.

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

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

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes the following:

(i) the date of assessment of severe active systemic juvenile idiopathic arthritis;

(ii) pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

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

The assessment of the patient's response to the most recent course of biological medicine 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 that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

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:
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HOBART TAS 7001

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Balance of supply for Initial treatment - Initial 1 (new patient) or Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) or Initial 3 (recommencement of treatment after a break of more than 12 months)

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 (retrial or recommencement of treatment after a break of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under Initial 3 (recommencement of treatment after a break of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

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

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

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

Treatment criteria:

- Must be treated by a rheumatologist; OR
 - Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.
- An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) 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

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

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

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

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity submitted with the initial treatment application.

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

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

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes baseline and current pathology reports detailing CRP and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

The assessment of the patient's response to the most recent course of biological medicine 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 that most recent course of treatment in this treatment cycle.

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 in the month prior to completing their current course of treatment.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to 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

Systemic juvenile idiopathic arthritis

Treatment Phase: Balance of supply - Continuing treatment

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 therapy available under Continuing treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

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).

tocilizumab 200 mg/10 mL injection, 10 mL vial

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
12726T	1	1209.39	^a RoActemra [DZ]

tocilizumab 200 mg/10 mL injection, 10 mL vial

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
1423X	1	219.66	^a Actemra [RO]

tocilizumab 200 mg/10 mL injection, 4 x 10 mL vials

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
12747X	0.2	*1210.59	^a RoActemra [DZ]

Highly Specialised Drugs Program (Public Hospital)

▪ ABATACEPT

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab)

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 been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **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 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 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 has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided.

If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

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.

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.

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 5 repeats will be authorised.

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 The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage.

The term biological medicine refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - critical shortage of tocilizumab' PBS listing.

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: First continuing treatment - Critical shortage of tocilizumab - Temporary listing

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 Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab),

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, **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.

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.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis.

This PBS listing is a temporary listing and may only be used when an application for initial supply of this medicine has been made under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab).

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 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) - 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 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) restriction to complete 24 weeks treatment, depending on the dosage regimen, **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 Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

abatacept 250 mg injection, 1 vial

12756J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	266.34	Orencia [BQ]

■ ADALIMUMAB

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

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 juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**

- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

Population criteria:

- Patient must be under 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).

If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided.

If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab.

An adequate response to treatment is defined as:

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

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

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

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

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 5 repeats will be authorised.

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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

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 The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, and etanercept for patients who have severe active juvenile idiopathic arthritis.

This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage. Alternative biological medicine refers to adalimumab and etanercept.

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - Temporary listing' PBS listing.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: First continuing treatment - Critical shortage of tocilizumab - Temporary listing

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab),

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 under 18 years of age.

An adequate response to treatment is defined as:

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

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

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

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

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

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 5 repeats will be authorised.

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.

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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient who has severe active juvenile idiopathic arthritis.

This PBS listing is a temporary listing and may only be used when an application for initial supply of this medicine has been made under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab).

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

12696F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	818.54	Humira [VE]

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

12698H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	818.54	^a Amgevita [AN]	^a Hadlima [RF]
					^a Hyrimoz [SZ]	^a Idacio [PK]

ADALIMUMAB

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

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 juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**

- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

Population criteria:

- Patient must be under 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).

If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided.

If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab.

An adequate response to treatment is defined as:

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

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 5 repeats will be authorised.

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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

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 The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, and etanercept for patients who have severe active juvenile idiopathic arthritis. This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage. Alternative biological medicine refers to adalimumab and etanercept. Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - Temporary listing' PBS listing.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: First continuing treatment - Critical shortage of tocilizumab - Temporary listing

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab),

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 under 18 years of age.

An adequate response to treatment is defined as:

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

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

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

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

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

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 5 repeats will be authorised.

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.

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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient who has severe active juvenile idiopathic arthritis.

This PBS listing is a temporary listing and may only be used when an application for initial supply of this medicine has been made under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab).

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

12697G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	818.54	Humira [VE]

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

12733E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	818.54	^a Amgevita [AN]	^a Hadlima [RF]
					^a Hyrimoz [SZ]	^a Idacio [PK]

ADALIMUMAB

Note Pharmaceutical benefits that have the form adalimumab 20 mg/0.2 mL syringes and pharmaceutical benefits that have the form adalimumab 20 mg/0.4 mL syringes are equivalent for the purposes of substitution

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

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 juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021,

AND

- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**

- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

Population criteria:

- Patient must be under 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).

If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided.

If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab.

An adequate response to treatment is defined as:

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

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

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

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

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 5 repeats will be authorised.

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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

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 The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, and etanercept for patients who have severe active juvenile idiopathic arthritis.

This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage. Alternative biological medicine refers to adalimumab and etanercept.

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - Temporary listing' PBS listing.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: First continuing treatment - Critical shortage of tocilizumab - Temporary listing

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab),

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 under 18 years of age.

An adequate response to treatment is defined as:

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

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

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

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

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

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 5 repeats will be authorised.

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.

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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient who has severe active juvenile idiopathic arthritis.

This PBS listings is a temporary listing and may only be used when an application for initial supply of this medicine has been made under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab).

adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes

12699J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	818.54	Humira [VE]

adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe

12695E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	*818.54	Amgevita [AN]

▪ ETANERCEPT

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 juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

Population criteria:

- Patient must be under 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).

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised.

If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided.

If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab.

An adequate response to treatment is defined as:

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

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

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

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

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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

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 The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, and etanercept for patients who have severe active juvenile idiopathic arthritis.

This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage. Alternative biological medicine refers to adalimumab and etanercept.

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - Temporary listing' PBS listing.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: First continuing treatment - Critical shortage of tocilizumab - Temporary listing

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab),

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 under 18 years of age.

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).
Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

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

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

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised.

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.

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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient who has severe active juvenile idiopathic arthritis.

This PBS listings is a temporary listing and may only be used when an application for initial supply of this medicine has been made under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab).

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

12735G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	939.25	Enbrel [PF]

etanercept 25 mg injection [4 vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack

12740M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	469.63	Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

12675D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	939.25	Enbrel [PF]

■ INFLIXIMAB

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 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab)

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 been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **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 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 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 has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided.

If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

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.

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.

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.

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 The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage.

The term biological medicine refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - critical shortage of tocilizumab' PBS listing.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - Critical shortage of tocilizumab - Temporary listing

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 Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab),

AND

- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly, **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.

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 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.

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.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis.

This PBS listing is a temporary listing and may only be used when an application for initial supply of this medicine has been made under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab).

infliximab 100 mg injection, 1 vial

12717H	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]

▪ RITUXIMAB

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

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage.

The term biological medicine refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - critical shortage of tocilizumab' PBS listing.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab)

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 been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist 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 treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly, **AND**
- Patient must not receive more than 2 infusions of this drug 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 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 has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided.

If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab. An adequate response to treatment is defined as:

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

AND either of the following:

- (a) 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.

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.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this drug provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with this drug. The demonstration of response must be submitted within 4 weeks of assessment.

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.

A patient whose most recent course of PBS-subsidised therapy was with this drug and whose response to this treatment is demonstrated at 12 weeks, may apply for a further course of this drug under the First continuing treatment restriction.

If a patient fails to demonstrate a response to 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 fails to demonstrate a response to this drug and who qualifies to trial an alternate biological medicine according to the interchangeability arrangements for biological medicines for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

rituximab 500 mg/50 mL injection, 50 mL vial

12739L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	540.43	^a Riximyo [SZ]	^a Truxima [EW]

▪ TOCILIZUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tocilizumab for a patient who has severe active systemic juvenile idiopathic arthritis (sJIA).

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy, and
- (ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

Once a patient has either failed or ceased to sustain an adequate response to 2 courses of treatment, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised tocilizumab therapy before they are eligible to commence another cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was approved to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

A 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, will not be considered as a treatment failure.

How to prescribe PBS-subsidised tocilizumab treatment therapy after 1 May 2012.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised tocilizumab treatment and wishes to commence such therapy (Initial 1 - New patient); or
- (ii) a patient has received the first course of PBS-subsidised (initial or continuing) tocilizumab therapy in a treatment cycle and is deemed to have failed to respond or sustain an adequate response and the treating physician wishes to trial a second course, provided any break in therapy is less than 12 months (Initial 2 - retreat or recommencement of treatment after a break of less than 12 months); or
- (iii) a patient wishes to recommence treatment with tocilizumab following a break in PBS-subsidised therapy of less than 12 months (Initial 2 - retreat or recommencement of treatment after a break of less than 12 months).
- (iv) a patient wishes to recommence treatment following a break in PBS-subsidised tocilizumab therapy of more than 12 months (Initial 3 - recommencement of a new treatment cycle after a break of more than 12 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with tocilizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with this drug provided they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks provided 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 tocilizumab supply.

Assessments of response to a course of PBS-subsidised therapy must be conducted after a minimum of 12 weeks of treatment and no later than 4 weeks from the completion of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

For the second and subsequent courses of PBS-subsidised tocilizumab, it is recommended that a patient be assessed for response in the 4 weeks prior to completing their current course of treatment and that an application is posted to Services Australia no later than 2 weeks prior to the patient completing their current treatment course.

(3) Treatment cycle.

Once initial treatment with PBS-subsidised tocilizumab is approved, a patient deemed to have failed to respond to the first course of treatment may have a second course without having to requalify with respect to the indices of disease severity (joint count, fever and/or CRP level and platelet count), except if the patient has had a break in therapy of more than 12 months.

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 approved, within the timeframes specified in the relevant restriction.

(4) Baseline measurements to determine response.

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count submitted with the first authority application for tocilizumab.

Where a patient is deemed to have failed to respond or to sustain an adequate response to the first course of therapy in a treatment cycle, prescribers may provide new baseline measurements for the second course of treatment within that cycle. Assessment of response according to these revised baseline measurements may then occur. If new baseline measurements are not submitted with the initial application for the second course of treatment, then those submitted with the first course will be used to assess response to the second course.

(5) Recommencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised tocilizumab therapy of at least 12 months, must requalify for treatment under the Initial 3 treatment restriction.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with tocilizumab should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to Services Australia at the time treatment is ceased.

Note Pharmaceutical benefits that have the brand Actemra 200 mg injection in a pack size of 1 and pharmaceutical benefits that have the brand RoActemra 200 mg injection in a pack size of 1 or a pack size of 4 are equivalent for the purposes of substitution in the case of a shortage.

Authority required

Systemic juvenile idiopathic arthritis

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

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; OR
- Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient at the time of the initial application:

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

The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application:

- (a) an active joint count of at least 2 active joints; and
- (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or
- (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

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

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

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

- (1) completed authority prescription form(s); and
- (2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the date of assessment of severe active systemic juvenile idiopathic arthritis;
 - (ii) details of prior treatment including dose and duration of treatment;
 - (iii) pathology reports detailing CRP and platelet count where appropriate.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

The assessment of the patient's response to the 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 in this treatment cycle.

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

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (retial or recommencement of treatment after a break of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with this drug for this condition in the previous 12 months, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

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

(b) in a patient with refractory systemic symptoms:

- (i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or
- (ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or
- (iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). 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) completed authority prescription form(s); and
- (2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate.

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

The assessment of the patient's response to the most recent course of biological medicine 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 that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to 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

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break of more than 12 months)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from this drug for this condition, **AND**
- Patient must have polyarticular course disease and the condition must have (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or ii) shoulder, cervical spine and/or hip (assessed as pain in passive

movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); OR

- Patient must have refractory systemic symptoms and the condition must have (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Population criteria:

- Patient must be under 18 years of age.

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

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

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes the following:

(i) the date of assessment of severe active systemic juvenile idiopathic arthritis;

(ii) pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

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

The assessment of the patient's response to the most recent course of biological medicine 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 that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

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

Systemic juvenile idiopathic arthritis

Treatment Phase: Balance of supply for Initial treatment - Initial 1 (new patient) or Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) or Initial 3 (recommencement of treatment after a break of more than 12 months)

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 (retrial or recommencement of treatment after a break of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under Initial 3 (recommencement of treatment after a break of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

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

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

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

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

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) 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

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

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

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

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity submitted with the initial treatment application.

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

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

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes baseline and current pathology reports detailing CRP and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

The assessment of the patient's response to the most recent course of biological medicine 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 that most recent course of treatment in this treatment cycle.

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 in the month prior to completing their current course of treatment.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to 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

Systemic juvenile idiopathic arthritis

Treatment Phase: Balance of supply - Continuing treatment

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 therapy available under Continuing treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

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).

tocilizumab 200 mg/10 mL injection, 10 mL vial

12706R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	1161.61	^a RoActemra [DZ]

tocilizumab 200 mg/10 mL injection, 10 mL vial

1481Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	203.73	^a Actemra [RO]

tocilizumab 200 mg/10 mL injection, 4 x 10 mL vials

12692B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	0.2	*1161.61	^a RoActemra [DZ]

■ TOCILIZUMAB**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tocilizumab for a patient who has severe active systemic juvenile idiopathic arthritis (sJIA).

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy, and

(ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

Once a patient has either failed or ceased to sustain an adequate response to 2 courses of treatment, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised tocilizumab therapy before they are eligible to commence another cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was approved to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

A 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, will not be considered as a treatment failure.

How to prescribe PBS-subsidised tocilizumab treatment therapy after 1 May 2012.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised tocilizumab treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received the first course of PBS-subsidised (initial or continuing) tocilizumab therapy in a treatment cycle and is deemed to have failed to respond or sustain an adequate response and the treating physician wishes to trial a second course, provided any break in therapy is less than 12 months (Initial 2 - re-trial or recommencement of treatment after a break of less than 12 months); or

(iii) a patient wishes to recommence treatment with tocilizumab following a break in PBS-subsidised therapy of less than 12 months (Initial 2 - re-trial or recommencement of treatment after a break of less than 12 months).

(iv) a patient wishes to recommence treatment following a break in PBS-subsidised tocilizumab therapy of more than 12 months (Initial 3 - recommencement of a new treatment cycle after a break of more than 12 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with tocilizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with this drug provided they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks provided 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 tocilizumab supply.

Assessments of response to a course of PBS-subsidised therapy must be conducted after a minimum of 12 weeks of treatment and no later than 4 weeks from the completion of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

For the second and subsequent courses of PBS-subsidised tocilizumab, it is recommended that a patient be assessed for response in the 4 weeks prior to completing their current course of treatment and that an application is posted to Services Australia no later than 2 weeks prior to the patient completing their current treatment course.

(3) Treatment cycle.

Once initial treatment with PBS-subsidised tocilizumab is approved, a patient deemed to have failed to respond to the first course of treatment may have a second course without having to requalify with respect to the indices of disease severity (joint count, fever and/or CRP level and platelet count), except if the patient has had a break in therapy of more than 12 months.

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 approved, within the timeframes specified in the relevant restriction.

(4) Baseline measurements to determine response.

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count submitted with the first authority application for tocilizumab.

Where a patient is deemed to have failed to respond or to sustain an adequate response to the first course of therapy in a treatment cycle, prescribers may provide new baseline measurements for the second course of treatment within that cycle. Assessment of response according to these revised baseline measurements may then occur. If new baseline measurements are not submitted with the initial application for the second course of treatment, then those submitted with the first course will be used to assess response to the second course.

(5) Recommencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised tocilizumab therapy of at least 12 months, must requalify for treatment under the Initial 3 treatment restriction.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with tocilizumab should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to Services Australia at the time treatment is ceased.

Note Pharmaceutical benefits that have the brand Actemra 400 mg injection in a pack size of 1 and pharmaceutical benefits that have the brand RoActemra 400 mg injection in a pack size of 1 or a pack size of 4 are equivalent for the purposes of substitution in the case of a shortage.

Authority required

Systemic juvenile idiopathic arthritis

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

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; OR
- Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient at the time of the initial application:

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

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

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

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

The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application:

(a) an active joint count of at least 2 active joints; and

(b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or

(c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

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

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

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

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

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes the following:

(i) the date of assessment of severe active systemic juvenile idiopathic arthritis;

(ii) details of prior treatment including dose and duration of treatment;

(iii) pathology reports detailing CRP and platelet count where appropriate.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

The assessment of the patient's response to the 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 in this treatment cycle.

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

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (retrial or recommencement of treatment after a break of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with this drug for this condition in the previous 12 months, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) 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

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

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

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

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). 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) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate.

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

The assessment of the patient's response to the most recent course of biological medicine 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 that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to 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

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break of more than 12 months)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from this drug for this condition, **AND**
- Patient must have polyarticular course disease and the condition must have (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); OR
- Patient must have refractory systemic symptoms and the condition must have (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Population criteria:

- Patient must be under 18 years of age.

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

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

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes the following:

(i) the date of assessment of severe active systemic juvenile idiopathic arthritis;

(ii) pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

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

The assessment of the patient's response to the most recent course of biological medicine 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 that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

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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Reply Paid 9826
HOBART TAS 7001

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Balance of supply for Initial treatment - Initial 1 (new patient) or Initial 2 (retiral or recommencement of treatment after a break of less than 12 months) or Initial 3 (recommencement of treatment after a break of more than 12 months)

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 (retiral or recommencement of treatment after a break of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under Initial 3 (recommencement of treatment after a break of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

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

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

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

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) 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

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

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

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

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity submitted with the initial treatment application.

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

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

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes baseline and current pathology reports detailing CRP and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

The assessment of the patient's response to the most recent course of biological medicine 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 that most recent course of treatment in this treatment cycle.

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 in the month prior to completing their current course of treatment.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to 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

Systemic juvenile idiopathic arthritis

Treatment Phase: Balance of supply - Continuing treatment

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 therapy available under Continuing treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

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).

tocilizumab 400 mg/20 mL injection, 20 mL vial

12694D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2259.08	^a RoActemra [DZ]

tocilizumab 400 mg/20 mL injection, 20 mL vial

1482B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	405.39	^a Actemra [RO]

tocilizumab 400 mg/20 mL injection, 4 x 20 mL vials

12707T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	0.2	*2259.08	^a RoActemra [DZ]

■ TOCILIZUMAB**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tocilizumab for a patient who has severe active systemic juvenile idiopathic arthritis (sJIA).

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

- continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy, and
- fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

Once a patient has either failed or ceased to sustain an adequate response to 2 courses of treatment, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised tocilizumab therapy before they are eligible to commence another cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was approved to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

A 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, will not be considered as a treatment failure.

How to prescribe PBS-subsidised tocilizumab treatment therapy after 1 May 2012.

(1) Initial treatment.

Applications for initial treatment should be made where:

- a patient has not received prior PBS-subsidised tocilizumab treatment and wishes to commence such therapy (Initial 1 - New patient); or
- a patient has received the first course of PBS-subsidised (initial or continuing) tocilizumab therapy in a treatment cycle and is deemed to have failed to respond or sustain an adequate response and the treating physician wishes to trial a second course, provided any break in therapy is less than 12 months (Initial 2 - retrial or recommencement of treatment after a break of less than 12 months); or
- a patient wishes to recommence treatment with tocilizumab following a break in PBS-subsidised therapy of less than 12 months (Initial 2 - retrial or recommencement of treatment after a break of less than 12 months).
- a patient wishes to recommence treatment following a break in PBS-subsidised tocilizumab therapy of more than 12 months (Initial 3 - recommencement of a new treatment cycle after a break of more than 12 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with tocilizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with this drug provided they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks provided 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 tocilizumab supply.

Assessments of response to a course of PBS-subsidised therapy must be conducted after a minimum of 12 weeks of treatment and no later than 4 weeks from the completion of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

For the second and subsequent courses of PBS-subsidised tocilizumab, it is recommended that a patient be assessed for response in the 4 weeks prior to completing their current course of treatment and that an application is posted to Services Australia no later than 2 weeks prior to the patient completing their current treatment course.

(3) Treatment cycle.

Once initial treatment with PBS-subsidised tocilizumab is approved, a patient deemed to have failed to respond to the first course of treatment may have a second course without having to requalify with respect to the indices of disease severity (joint count, fever and/or CRP level and platelet count), except if the patient has had a break in therapy of more than 12 months.

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 approved, within the timeframes specified in the relevant restriction.

(4) Baseline measurements to determine response.

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count submitted with the first authority application for tocilizumab.

Where a patient is deemed to have failed to respond or to sustain an adequate response to the first course of therapy in a treatment cycle, prescribers may provide new baseline measurements for the second course of treatment within that cycle. Assessment of response according to these revised baseline measurements may then occur. If new baseline measurements are not submitted with the initial application for the second course of treatment, then those submitted with the first course will be used to assess response to the second course.

(5) Recommencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised tocilizumab therapy of at least 12 months, must requalify for treatment under the Initial 3 treatment restriction.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with tocilizumab should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to Services Australia at the time treatment is ceased.

Note Pharmaceutical benefits that have the brand Actemra 80 mg injection in a pack size of 1 and pharmaceutical benefits that have the brand RoActemra 80 mg injection in a pack size of 1 or a pack size of 4 are equivalent for the purposes of substitution in the case of a shortage.

Authority required

Systemic juvenile idiopathic arthritis

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

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; OR
- Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient at the time of the initial application:

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

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

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

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

The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application:

(a) an active joint count of at least 2 active joints; and

(b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or

(c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

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

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

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

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

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes the following:

-
- (i) the date of assessment of severe active systemic juvenile idiopathic arthritis;
 - (ii) details of prior treatment including dose and duration of treatment;
 - (iii) pathology reports detailing CRP and platelet count where appropriate.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised. The assessment of the patient's response to the 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 in this treatment cycle.

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

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (retial or recommencement of treatment after a break of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with this drug for this condition in the previous 12 months, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) 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

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

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

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

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). 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) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate.

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

The assessment of the patient's response to the most recent course of biological medicine 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 that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to 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

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break of more than 12 months)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from this drug for this condition, **AND**
- Patient must have polyarticular course disease and the condition must have (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); OR
- Patient must have refractory systemic symptoms and the condition must have (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Population criteria:

- Patient must be under 18 years of age.

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

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

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes the following:

(i) the date of assessment of severe active systemic juvenile idiopathic arthritis;

(ii) pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

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

The assessment of the patient's response to the most recent course of biological medicine 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 that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

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

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Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Balance of supply for Initial treatment - Initial 1 (new patient) or Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) or Initial 3 (recommencement of treatment after a break of more than 12 months)

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 (retrial or recommencement of treatment after a break of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under Initial 3 (recommencement of treatment after a break of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

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

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

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

Treatment criteria:

- Must be treated by a rheumatologist; OR
 - Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.
- An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) 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

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

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

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

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity submitted with the initial treatment application.

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

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

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes baseline and current pathology reports detailing CRP and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

The assessment of the patient's response to the most recent course of biological medicine 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 that most recent course of treatment in this treatment cycle.

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 in the month prior to completing their current course of treatment.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to 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

Systemic juvenile idiopathic arthritis

Treatment Phase: Balance of supply - Continuing treatment

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 therapy available under Continuing treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

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).

tocilizumab 80 mg/4 mL injection, 4 x 4 mL vials

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
12714E	0.2	*501.28	^a RoActemra [DZ]

tocilizumab 80 mg/4 mL injection, 4 mL vial

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
12713D	1	501.28	^a RoActemra [DZ]

tocilizumab 80 mg/4 mL injection, 4 mL vial

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
1476Q	1	82.19	^a Actemra [RO]
