



Australian Government

**Department of Health
and Aged Care**



Schedule of Pharmaceutical Benefits

Summary of Changes

Effective 1 July 2023



Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 July 2023 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	\$8.37
	Dangerous drug fee	\$5.18
	Extemporaneously-prepared	\$10.41
	Allowable additional patient charge*	\$3.29
Additional Fees (for safety net prices):	Ready-prepared	\$1.40
	Extemporaneously-prepared	\$1.80
Patient Co-payments:	General	\$30.00
	Concessional	\$7.30
Safety Net Thresholds:	General	\$1563.50
	Concessional	\$262.80
Safety Net Card Issue Fee:		\$11.42

* 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 July 2023. The Schedule is updated on the first day of each month and is available on the internet at www.pbs.gov.au.

General Pharmaceutical Benefits

Additions

Addition – Item

13318Y	ACALABRUTINIB , acalabrutinib 100 mg tablet, 56 (<i>CALQUENCE</i>)
13325H	ACALABRUTINIB , acalabrutinib 100 mg tablet, 56 (<i>CALQUENCE</i>)
13300B	CHORIOGONADOTROPIN ALFA , choriogonadotropin alfa 250 microgram/0.5 mL injection, 0.5 mL pen device (<i>Ovidrel</i>)
13335W	FINERENONE , finerenone 10 mg tablet, 28 (<i>Kerendia</i>)
13316W	FINERENONE , finerenone 20 mg tablet, 28 (<i>Kerendia</i>)
13301C	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes (<i>Actemra Subcutaneous Injection</i>)
13306H	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices (<i>Actemra ACTPen</i>)

Addition – Brand

12041R	<i>Rilast TURBUHALER 200/6, ZA</i> – BUDESONIDE + FORMOTEROL (EFORMOTEROL) , budesonide 200 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations
12093L	<i>Rilast TURBUHALER 200/6, ZA</i> – BUDESONIDE + FORMOTEROL (EFORMOTEROL) , budesonide 200 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations
8295N	<i>BTC Candesartan, BG</i> – CANDESARTAN , candesartan cilexetil 4 mg tablet, 30
8296P	<i>BTC Candesartan, BG</i> – CANDESARTAN , candesartan cilexetil 8 mg tablet, 30
8297Q	<i>BTC Candesartan, BG</i> – CANDESARTAN , candesartan cilexetil 16 mg tablet, 30
8889W	<i>BTC Candesartan, BG</i> – CANDESARTAN , candesartan cilexetil 32 mg tablet, 30
10201X	<i>Pharmacor Ezetimibe Rosuvastatin Composite Pack, CR</i> – EZETIMIBE (&) ROSUVASTATIN , ezetimibe 10 mg tablet [30] (&) rosuvastatin 20 mg tablet [30], 60
10207F	<i>Pharmacor Ezetimibe Rosuvastatin Composite Pack, CR</i> – EZETIMIBE (&) ROSUVASTATIN , ezetimibe 10 mg tablet [30] (&) rosuvastatin 40 mg tablet [30], 60
10208G	<i>Pharmacor Ezetimibe Rosuvastatin Composite Pack, CR</i> – EZETIMIBE (&) ROSUVASTATIN , ezetimibe 10 mg tablet [30] (&) rosuvastatin 10 mg tablet [30], 60
5262Y	<i>FINGOLIS, LR</i> – FINGOLIMOD , fingolimod 500 microgram capsule, 28
8246B	<i>Noumed Irbesartan, VO</i> – IRBESARTAN , irbesartan 75 mg tablet, 30
8247C	<i>Noumed Irbesartan, VO</i> – IRBESARTAN , irbesartan 150 mg tablet, 30
8248D	<i>Noumed Irbesartan, VO</i> – IRBESARTAN , irbesartan 300 mg tablet, 30
9365X	<i>Blooms The Chemist Mirtazapine, BG</i> – MIRTAZAPINE , mirtazapine 15 mg tablet, 30
8513C	<i>Blooms The Chemist Mirtazapine, BG</i> – MIRTAZAPINE , mirtazapine 30 mg tablet, 30
8883M	<i>Blooms The Chemist Mirtazapine, BG</i> – MIRTAZAPINE , mirtazapine 45 mg tablet, 30
2242B	<i>Noumed Paroxetine, VO</i> – PAROXETINE , paroxetine 20 mg tablet, 30

Addition – Equivalence Indicator

- 12117R *Calquence, AP* – **ACALABRUTINIB**, acalabrutinib 100 mg capsule, 56
12826C *Calquence, AP* – **ACALABRUTINIB**, acalabrutinib 100 mg capsule, 56

Addition – Note

- 12117R **ACALABRUTINIB**, acalabrutinib 100 mg capsule, 56 (*Calquence*)
12826C **ACALABRUTINIB**, acalabrutinib 100 mg capsule, 56 (*Calquence*)
13258T **BUDESONIDE + FORMOTEROL (EFORMOTEROL)**, budesonide 400 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations (*Rilast TURBUHALER 400/12, Symbicort TURBUHALER 400/12*)

Deletions

Deletion – Brand

- 9012H *Alendronate plus D3-DRLA, RZ* – **ALENDRONATE + COLECALCIFEROL**, alendronate 70 mg + colecalciferol 70 microgram (2800 units) tablet, 4
9183H *Alendronate plus D3-DRLA, RZ* – **ALENDRONATE + COLECALCIFEROL**, alendronate 70 mg + colecalciferol 140 microgram (5600 units) tablet, 4
2688L *Azathioprine GH, GQ* – **AZATHIOPRINE**, azathioprine 25 mg tablet, 100
11692J *Esomeprazole SZ, HX* – **ESOMEPRAZOLE**, esomeprazole 20 mg enteric tablet, 30
11692J *Esomeprazole Sandoz, SZ* – **ESOMEPRAZOLE**, esomeprazole 20 mg enteric tablet, 30
12287Q *Esomeprazole SZ, HX* – **ESOMEPRAZOLE**, esomeprazole 20 mg enteric tablet, 30
12287Q *Esomeprazole Sandoz, SZ* – **ESOMEPRAZOLE**, esomeprazole 20 mg enteric tablet, 30
8600P *Esomeprazole SZ, HX* – **ESOMEPRAZOLE**, esomeprazole 20 mg enteric tablet, 30
8600P *Esomeprazole Sandoz, SZ* – **ESOMEPRAZOLE**, esomeprazole 20 mg enteric tablet, 30
8886Q *Esomeprazole SZ, HX* – **ESOMEPRAZOLE**, esomeprazole 20 mg enteric tablet, 30
8886Q *Esomeprazole Sandoz, SZ* – **ESOMEPRAZOLE**, esomeprazole 20 mg enteric tablet, 30
12283L *Esomeprazole SZ, HX* – **ESOMEPRAZOLE**, esomeprazole 40 mg enteric tablet, 30
12283L *Esomeprazole Sandoz, SZ* – **ESOMEPRAZOLE**, esomeprazole 40 mg enteric tablet, 30
3401B *Esomeprazole SZ, HX* – **ESOMEPRAZOLE**, esomeprazole 40 mg enteric tablet, 30
3401B *Esomeprazole Sandoz, SZ* – **ESOMEPRAZOLE**, esomeprazole 40 mg enteric tablet, 30
8601Q *Esomeprazole SZ, HX* – **ESOMEPRAZOLE**, esomeprazole 40 mg enteric tablet, 30
8601Q *Esomeprazole Sandoz, SZ* – **ESOMEPRAZOLE**, esomeprazole 40 mg enteric tablet, 30
2848X *Lamotrigine Sandoz, SZ* – **LAMOTRIGINE**, lamotrigine 25 mg tablet, 56
2849Y *Lamotrigine Sandoz, SZ* – **LAMOTRIGINE**, lamotrigine 50 mg tablet, 56
2850B *Lamotrigine Sandoz, SZ* – **LAMOTRIGINE**, lamotrigine 100 mg tablet, 56
2851C *Lamotrigine Sandoz, SZ* – **LAMOTRIGINE**, lamotrigine 200 mg tablet, 56
8607B *Sandoz Metformin, HX* – **METFORMIN**, metformin hydrochloride 1 g tablet, 90
8855C *Mirtazapine Sandoz ODT 15, SZ* – **MIRTAZAPINE**, mirtazapine 15 mg orally disintegrating tablet, 30
8856D *Mirtazapine Sandoz ODT 30, SZ* – **MIRTAZAPINE**, mirtazapine 30 mg orally disintegrating tablet, 30
8857E *Mirtazapine Sandoz ODT 45, SZ* – **MIRTAZAPINE**, mirtazapine 45 mg orally disintegrating tablet, 30
12031F *Oxycodone BNM, BZ* – **OXYCODONE**, oxycodone hydrochloride 10 mg capsule, 20
12074L *Oxycodone BNM, BZ* – **OXYCODONE**, oxycodone hydrochloride 10 mg capsule, 20
5197M *Oxycodone BNM, BZ* – **OXYCODONE**, oxycodone hydrochloride 10 mg capsule, 20
8501K *Oxycodone BNM, BZ* – **OXYCODONE**, oxycodone hydrochloride 10 mg capsule, 20
8829Q *Pravastatin Sandoz, SZ* – **PRAVASTATIN**, pravastatin sodium 80 mg tablet, 30
9240H *Pravastatin Sandoz, SZ* – **PRAVASTATIN**, pravastatin sodium 80 mg tablet, 30
10551H *Rizatriptan-AU, DZ* – **RIZATRIPTAN**, rizatriptan 10 mg orally disintegrating tablet, 2
8355R *Telmisartan GH, GQ* – **TELMISARTAN**, telmisartan 40 mg tablet, 28

Deletion – Equivalence Indicator

12031F	<i>OxyNorm, MF</i> – OXYCODONE , oxycodone hydrochloride 10 mg capsule, 20
12074L	<i>OxyNorm, MF</i> – OXYCODONE , oxycodone hydrochloride 10 mg capsule, 20
5197M	<i>OxyNorm, MF</i> – OXYCODONE , oxycodone hydrochloride 10 mg capsule, 20
8501K	<i>OxyNorm, MF</i> – OXYCODONE , oxycodone hydrochloride 10 mg capsule, 20

Deletion – Note

8516F	FLUTICASONE PROPIONATE , fluticasone propionate 50 microgram/actuation inhalation, 120 actuations (<i>Axotide Junior, Flixotide Junior</i>)
13041J	ZANUBRUTINIB , zanubrutinib 80 mg capsule, 120 (<i>Brukinsa</i>)

Deletion – Restriction

12094M	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices (<i>Actemra ACTPen</i>)
12102Y	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes (<i>Actemra Subcutaneous Injection</i>)
13041J	ZANUBRUTINIB , zanubrutinib 80 mg capsule, 120 (<i>Brukinsa</i>)

Alterations

Alteration – Note

12029D	BUDESONIDE + FORMOTEROL (EFORMOTEROL) , budesonide 200 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations (<i>BiResp Spiromax, DuoResp Spiromax</i>)
12041R	BUDESONIDE + FORMOTEROL (EFORMOTEROL) , budesonide 200 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations (<i>Rilast TURBUHALER 200/6, Symbicort Turbuhaler 200/6</i>)
11301T	BUDESONIDE + FORMOTEROL (EFORMOTEROL) , budesonide 400 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 12 microgram/actuation powder for inhalation, 2 x 60 actuations (<i>BiResp Spiromax, DuoResp Spiromax</i>)
11198J	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL pen devices (<i>Brenzys, Enbrel</i>)
11201M	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL pen devices (<i>Brenzys, Enbrel</i>)
11220M	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL pen devices (<i>Brenzys, Enbrel</i>)
11222P	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL pen devices (<i>Brenzys, Enbrel</i>)
1964J	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL pen devices (<i>Enbrel</i>)
3447K	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL pen devices (<i>Enbrel</i>)
3450N	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL pen devices (<i>Enbrel</i>)
9455P	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL pen devices (<i>Brenzys, Enbrel</i>)
9456Q	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL pen devices (<i>Brenzys, Enbrel</i>)
9457R	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL pen devices (<i>Brenzys, Enbrel</i>)
9458T	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL pen devices (<i>Brenzys, Enbrel</i>)
9459W	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL pen devices (<i>Brenzys, Enbrel</i>)
9460X	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL pen devices (<i>Brenzys, Enbrel</i>)
9461Y	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL pen devices (<i>Brenzys, Enbrel</i>)
9462B	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL pen devices (<i>Brenzys, Enbrel</i>)
11196G	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Brenzys, Enbrel</i>)
11208X	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Brenzys, Enbrel</i>)
11219L	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Brenzys, Enbrel</i>)
11224R	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Brenzys, Enbrel</i>)
1963H	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Enbrel</i>)
3446J	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Enbrel</i>)
3449M	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Enbrel</i>)
9085E	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Brenzys, Enbrel</i>)

9086F	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Brenzys, Enbrel</i>)
9087G	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Brenzys, Enbrel</i>)
9088H	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Brenzys, Enbrel</i>)
9089J	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Brenzys, Enbrel</i>)
9090K	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Brenzys, Enbrel</i>)
9091L	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Brenzys, Enbrel</i>)
9431J	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Brenzys, Enbrel</i>)
11720W	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes (<i>Actemra Subcutaneous Injection</i>)
11721X	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes (<i>Actemra Subcutaneous Injection</i>)
11722Y	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices (<i>Actemra ACTPen</i>)
11734N	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices (<i>Actemra ACTPen</i>)
11742B	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices (<i>Actemra ACTPen</i>)
11743C	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes (<i>Actemra Subcutaneous Injection</i>)
11744D	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices (<i>Actemra ACTPen</i>)
11748H	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes (<i>Actemra Subcutaneous Injection</i>)
12083Y	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices (<i>Actemra ACTPen</i>)
12084B	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices (<i>Actemra ACTPen</i>)
12085C	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices (<i>Actemra ACTPen</i>)
12086D	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes (<i>Actemra Subcutaneous Injection</i>)
12090H	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices (<i>Actemra ACTPen</i>)
12094M	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices (<i>Actemra ACTPen</i>)
12095N	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes (<i>Actemra Subcutaneous Injection</i>)
12099T	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes (<i>Actemra Subcutaneous Injection</i>)
12102Y	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes (<i>Actemra Subcutaneous Injection</i>)
12105D	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes (<i>Actemra Subcutaneous Injection</i>)

Alteration – Restriction

11693K	ABATACEPT , abatacept 125 mg/mL injection, 4 x 1 mL pen devices (<i>Orencia ClickJect</i>)
1220F	ABATACEPT , abatacept 125 mg/mL injection, 4 x 1 mL syringes (<i>Orencia</i>)
12400P	ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes (<i>Humira, Yuflyma</i>)
12429E	ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices (<i>Humira, Yuflyma</i>)
8737W	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (<i>Amgevita, Hadlima, Hyrimoz, Idacio</i>)
9099X	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Amgevita, Hadlima, Hyrimoz, Idacio</i>)
11437Y	BARICITINIB , baricitinib 2 mg tablet, 28 (<i>Olumiant</i>)
11447L	BARICITINIB , baricitinib 4 mg tablet, 28 (<i>Olumiant</i>)
10905Y	CERTOLIZUMAB PEGOL , certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes (<i>Cimzia</i>)
11322X	CERTOLIZUMAB PEGOL , certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices (<i>Cimzia</i>)
8637N	ETANERCEPT , etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack (<i>Enbrel</i>)
9459W	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL pen devices (<i>Brenzys, Enbrel</i>)
9089J	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Brenzys, Enbrel</i>)
8516F	FLUTICASONE PROPIONATE , fluticasone propionate 50 microgram/actuation inhalation, 120 actuations (<i>Axotide Junior, Flixotide Junior</i>)
11372M	GOLIMUMAB , golimumab 50 mg/0.5 mL injection, 0.5 mL pen device (<i>Simponi</i>)
3426H	GOLIMUMAB , golimumab 50 mg/0.5 mL injection, 0.5 mL syringe (<i>Simponi</i>)

12996B	NIRMATRELVIR (&) RITONAVIR , nirmatrelvir 150 mg tablet [4] (&) ritonavir 100 mg tablet [2], 5 x 6 (<i>Paxlovid</i>)
10951J	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes (<i>Actemra Subcutaneous Injection</i>)
11565Q	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices (<i>Actemra ACTPen</i>)
11720W	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes (<i>Actemra Subcutaneous Injection</i>)
11734N	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices (<i>Actemra ACTPen</i>)
11742B	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices (<i>Actemra ACTPen</i>)
11743C	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes (<i>Actemra Subcutaneous Injection</i>)
11744D	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices (<i>Actemra ACTPen</i>)
11748H	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes (<i>Actemra Subcutaneous Injection</i>)
12083Y	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices (<i>Actemra ACTPen</i>)
12084B	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices (<i>Actemra ACTPen</i>)
12085C	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices (<i>Actemra ACTPen</i>)
12086D	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes (<i>Actemra Subcutaneous Injection</i>)
12090H	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices (<i>Actemra ACTPen</i>)
12095N	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes (<i>Actemra Subcutaneous Injection</i>)
12099T	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes (<i>Actemra Subcutaneous Injection</i>)
12105D	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes (<i>Actemra Subcutaneous Injection</i>)
10517M	TOFACITINIB , tofacitinib 5 mg tablet, 56 (<i>Xeljanz</i>)
11989B	UPADACITINIB , upadacitinib 15 mg modified release tablet, 28 (<i>Rinvoq</i>)

Alteration – Restriction Level

		From	To
8516F	FLUTICASONE PROPIONATE , fluticasone propionate 50 microgram/actuation inhalation, 120 actuations (<i>Axotide Junior, Flixotide Junior</i>)	authority-required	streamlined
11720W	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes (<i>Actemra Subcutaneous Injection</i>)	authority-required	streamlined
11742B	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices (<i>Actemra ACTPen</i>)	authority-required	streamlined
12084B	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices (<i>Actemra ACTPen</i>)	authority-required	streamlined
12086D	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes (<i>Actemra Subcutaneous Injection</i>)	authority-required	streamlined
12090H	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices (<i>Actemra ACTPen</i>)	authority-required	streamlined
12099T	TOCILIZUMAB , tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes (<i>Actemra Subcutaneous Injection</i>)	authority-required	streamlined

Advance Notices

1 August 2023

Deletion – Brand

8416Y	XMET Maxamum, SB – AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE , amino acid formula with vitamins and minerals without methionine powder for oral liquid, 500 g
8061G	XMTVI Maxamum, SB – AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, THREONINE AND VALINE AND LOW IN ISOLEUCINE , amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine powder for oral liquid, 500 g
8555G	PKU gel, VF – AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE , amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 30 x 24 g sachets
3078B	XPhen, Tyr Maxamum, SB – AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE , amino acid formula with vitamins and minerals without phenylalanine and tyrosine powder for oral liquid, 500 g

8310J	<i>MSUD AID III, SB</i> – AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE , amino acid formula with vitamins and minerals without valine, leucine and isoleucine powder for oral liquid, 500 g
2418G	<i>Amitriptyline Alphapharm 25, MQ</i> – AMITRIPTYLINE , amitriptyline hydrochloride 25 mg tablet, 50
1358L	<i>Dosulepin Mylan, MQ</i> – DOSULEPIN (DOTHIEPIN) , dosulepin (dothiepin) hydrochloride 75 mg tablet, 30
8397Y	<i>Teveten, GO</i> – EPROSARTAN , eprosartan 400 mg tablet, 28
8951D	<i>Teveten, GO</i> – EPROSARTAN , eprosartan 400 mg tablet, 28
11570Y	<i>Steglatro 15, MK</i> – ERTUGLIFLOZIN , ertugliflozin 15 mg tablet, 28
11571B	<i>Steglatro 15, MK</i> – ERTUGLIFLOZIN , ertugliflozin 15 mg tablet, 28
11577H	<i>Steglatro 5, MK</i> – ERTUGLIFLOZIN , ertugliflozin 5 mg tablet, 28
11585R	<i>Steglatro 5, MK</i> – ERTUGLIFLOZIN , ertugliflozin 5 mg tablet, 28
11561L	<i>Steglujan 5/100, MK</i> – ERTUGLIFLOZIN + SITAGLIPTIN , ertugliflozin 5 mg + sitagliptin 100 mg tablet, 28
11578J	<i>Steglujan 15/100, MK</i> – ERTUGLIFLOZIN + SITAGLIPTIN , ertugliflozin 15 mg + sitagliptin 100 mg tablet, 28
11579K	<i>Steglujan 5/100, MK</i> – ERTUGLIFLOZIN + SITAGLIPTIN , ertugliflozin 5 mg + sitagliptin 100 mg tablet, 28
11583P	<i>Steglujan 15/100, MK</i> – ERTUGLIFLOZIN + SITAGLIPTIN , ertugliflozin 15 mg + sitagliptin 100 mg tablet, 28
11264W	<i>Iressa, AP</i> – GEFITINIB , gefitinib 250 mg tablet, 30
8769M	<i>Iressa, AP</i> – GEFITINIB , gefitinib 250 mg tablet, 30
1441W	<i>Genoptic, VE</i> – GENTAMICIN , gentamicin 0.3% eye drops, 5 mL
5566Y	<i>Genoptic, VE</i> – GENTAMICIN , gentamicin 0.3% eye drops, 5 mL
1500Y	<i>Hydrocortisone Mylan 20, MQ</i> – HYDROCORTISONE , hydrocortisone 20 mg tablet, 60
1574W	<i>Nizoral 2%, KY</i> – KETOCONAZOLE , ketoconazole 2% shampoo, 60 mL
13030T	<i>Vitrakvi, BN</i> – LAROTRECTINIB , larotrectinib 20 mg/mL oral liquid, 100 mL
13035C	<i>Vitrakvi, BN</i> – LAROTRECTINIB , larotrectinib 20 mg/mL oral liquid, 100 mL
11890T	<i>Sinemet CR Prolonged-Release Tablets, OQ</i> – LEVODOPA + CARBIDOPA , levodopa 200 mg + carbidopa 50 mg modified release tablet, 60
12009C	<i>Anamorph, RW</i> – MORPHINE , morphine sulfate pentahydrate 30 mg tablet, 20
12067D	<i>Anamorph, RW</i> – MORPHINE , morphine sulfate pentahydrate 30 mg tablet, 20
1646P	<i>Anamorph, RW</i> – MORPHINE , morphine sulfate pentahydrate 30 mg tablet, 20
5163R	<i>Anamorph, RW</i> – MORPHINE , morphine sulfate pentahydrate 30 mg tablet, 20
8253J	<i>Rapilysin 10 U, TB</i> – RETEPLASE , reteplase 10 units (17.4 mg) injection [2 x 10 unit vials] (&) inert substance diluent [2 x 10 mL syringes], 1 pack

1 September 2023

Deletion – Brand

1818Q	<i>Methotrexate Accord, OD</i> – METHOTREXATE , methotrexate 50 mg/2 mL injection, 2 mL vial
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1 October 2023

Deletion – Brand

9022W	<i>Fenofibrate Mylan, AF</i> – FENOFIBRATE , fenofibrate 48 mg tablet, 60
9023X	<i>Fenofibrate Mylan, AF</i> – FENOFIBRATE , fenofibrate 145 mg tablet, 30
9246P	<i>Fenofibrate Mylan, AF</i> – FENOFIBRATE , fenofibrate 48 mg tablet, 60
9247Q	<i>Fenofibrate Mylan, AF</i> – FENOFIBRATE , fenofibrate 145 mg tablet, 30
9019Q	<i>Moxonidine MYL, AF</i> – MOXONIDINE , moxonidine 200 microgram tablet, 30
11798Y	<i>Jetrea RTU, IJ</i> – OCRIPLASMIN , ocriplasmin 375 microgram/0.3 mL intraocular injection, 0.3 mL vial

Highly Specialised Drugs Program (Private Hospital)

Additions

Addition – Item

13292N	ADALIMUMAB , adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes (<i>Humira</i>)
13317X	AVATROMBOPAG , avatrombopag 20 mg tablet, 30 (<i>Doptelet</i>)
13295R	ETANERCEPT , etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack (<i>Enbrel</i>)
13326J	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL pen devices (<i>Enbrel</i>)
13332Q	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Enbrel</i>)
13311N	TOCILIZUMAB , tocilizumab 80 mg/4 mL injection, 4 mL vial (<i>Actemra</i>)
13315T	TOCILIZUMAB , tocilizumab 80 mg/4 mL injection, 4 mL vial (<i>Actemra</i>)
13312P	TOCILIZUMAB , tocilizumab 200 mg/10 mL injection, 10 mL vial (<i>Actemra</i>)
13329M	TOCILIZUMAB , tocilizumab 200 mg/10 mL injection, 10 mL vial (<i>Actemra</i>)
13323F	TOCILIZUMAB , tocilizumab 400 mg/20 mL injection, 20 mL vial (<i>Actemra</i>)
13338B	TOCILIZUMAB , tocilizumab 400 mg/20 mL injection, 20 mL vial (<i>Actemra</i>)

Addition – Brand

13210G	<i>Humira</i> , VE – ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
13229G	<i>Humira</i> , VE – ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices
12784W	<i>Azacitidine Sandoz</i> , SZ – AZACITIDINE , azacitidine 100 mg injection, 1 vial
13033Y	<i>Azacitidine Sandoz</i> , SZ – AZACITIDINE , azacitidine 100 mg injection, 1 vial
13038F	<i>Azacitidine Sandoz</i> , SZ – AZACITIDINE , azacitidine 100 mg injection, 1 vial
13039G	<i>Azacitidine Sandoz</i> , SZ – AZACITIDINE , azacitidine 100 mg injection, 1 vial
13040H	<i>Azacitidine Sandoz</i> , SZ – AZACITIDINE , azacitidine 100 mg injection, 1 vial
6100C	<i>Azacitidine Sandoz</i> , SZ – AZACITIDINE , azacitidine 100 mg injection, 1 vial
6138C	<i>Azacitidine Sandoz</i> , SZ – AZACITIDINE , azacitidine 100 mg injection, 1 vial

Addition – Equivalence Indicator

12349Y	<i>Amgevita</i> , XT – ADALIMUMAB , adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe
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Alterations

Alteration – Note

12443X	ADALIMUMAB , adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes (<i>Humira</i>)
12349Y	ADALIMUMAB , adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe (<i>Amgevita</i>)
12439Q	ADALIMUMAB , adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe (<i>Amgevita</i>)
12335F	ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices (<i>Humira</i> , <i>Yuflyma</i>)
12396K	ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes (<i>Humira</i> , <i>Yuflyma</i>)
13210G	ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes (<i>Humira</i> , <i>Yuflyma</i>)
13229G	ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices (<i>Humira</i> , <i>Yuflyma</i>)
12368Y	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Amgevita</i> , <i>Hadlima</i> , <i>Hyrimoz</i> , <i>Idacio</i>)
12384T	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (<i>Amgevita</i> , <i>Hadlima</i> , <i>Hyrimoz</i> , <i>Idacio</i>)
9679K	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (<i>Amgevita</i> , <i>Hadlima</i> , <i>Hyrimoz</i> , <i>Idacio</i>)
9680L	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Amgevita</i> , <i>Hadlima</i> , <i>Hyrimoz</i> , <i>Idacio</i>)
5827Q	ELTROMBOPAG , eltrombopag 25 mg tablet, 28 (<i>Revolade</i>)
5828R	ELTROMBOPAG , eltrombopag 50 mg tablet, 28 (<i>Revolade</i>)
6367D	ETANERCEPT , etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack (<i>Enbrel</i>)
9641K	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL pen devices (<i>Enbrel</i>)
9615C	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Enbrel</i>)

9697J	ROMIPLOSTIM , romiplostim 250 microgram injection, 1 vial (<i>Nplate</i>)
9699L	ROMIPLOSTIM , romiplostim 500 microgram injection, 1 vial (<i>Nplate</i>)
10068X	TOCILIZUMAB , tocilizumab 80 mg/4 mL injection, 4 mL vial (<i>Actemra</i>)
1419Q	TOCILIZUMAB , tocilizumab 80 mg/4 mL injection, 4 mL vial (<i>Actemra</i>)
10079L	TOCILIZUMAB , tocilizumab 200 mg/10 mL injection, 10 mL vial (<i>Actemra</i>)
1423X	TOCILIZUMAB , tocilizumab 200 mg/10 mL injection, 10 mL vial (<i>Actemra</i>)
10060L	TOCILIZUMAB , tocilizumab 400 mg/20 mL injection, 20 mL vial (<i>Actemra</i>)
1464C	TOCILIZUMAB , tocilizumab 400 mg/20 mL injection, 20 mL vial (<i>Actemra</i>)

Alteration – Restriction

9621J	ABATACEPT , abatacept 250 mg injection, 1 vial (<i>Orencia</i>)
12443X	ADALIMUMAB , adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes (<i>Humira</i>)
12349Y	ADALIMUMAB , adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe (<i>Amgevita</i>)
12439Q	ADALIMUMAB , adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe (<i>Amgevita</i>)
12335F	ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices (<i>Humira</i> , <i>Yuflyma</i>)
12396K	ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes (<i>Humira</i> , <i>Yuflyma</i>)
13210G	ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes (<i>Humira</i> , <i>Yuflyma</i>)
13229G	ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices (<i>Humira</i> , <i>Yuflyma</i>)
12368Y	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Amgevita</i> , <i>Hadlima</i> , <i>Hyrimoz</i> , <i>Idacio</i>)
12384T	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (<i>Amgevita</i> , <i>Hadlima</i> , <i>Hyrimoz</i> , <i>Idacio</i>)
9679K	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (<i>Amgevita</i> , <i>Hadlima</i> , <i>Hyrimoz</i> , <i>Idacio</i>)
9680L	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Amgevita</i> , <i>Hadlima</i> , <i>Hyrimoz</i> , <i>Idacio</i>)
5827Q	ELTROMBOPAG , eltrombopag 25 mg tablet, 28 (<i>Revolade</i>)
5828R	ELTROMBOPAG , eltrombopag 50 mg tablet, 28 (<i>Revolade</i>)
6367D	ETANERCEPT , etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack (<i>Enbrel</i>)
9641K	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL pen devices (<i>Enbrel</i>)
9615C	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Enbrel</i>)
6397Q	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflixtra</i> , <i>Remicade</i> , <i>Renflexis</i>)
9697J	ROMIPLOSTIM , romiplostim 250 microgram injection, 1 vial (<i>Nplate</i>)
9699L	ROMIPLOSTIM , romiplostim 500 microgram injection, 1 vial (<i>Nplate</i>)
10068X	TOCILIZUMAB , tocilizumab 80 mg/4 mL injection, 4 mL vial (<i>Actemra</i>)
1419Q	TOCILIZUMAB , tocilizumab 80 mg/4 mL injection, 4 mL vial (<i>Actemra</i>)
9671B	TOCILIZUMAB , tocilizumab 80 mg/4 mL injection, 4 mL vial (<i>Actemra</i>)
10079L	TOCILIZUMAB , tocilizumab 200 mg/10 mL injection, 10 mL vial (<i>Actemra</i>)
1423X	TOCILIZUMAB , tocilizumab 200 mg/10 mL injection, 10 mL vial (<i>Actemra</i>)
9672C	TOCILIZUMAB , tocilizumab 200 mg/10 mL injection, 10 mL vial (<i>Actemra</i>)
10060L	TOCILIZUMAB , tocilizumab 400 mg/20 mL injection, 20 mL vial (<i>Actemra</i>)
1464C	TOCILIZUMAB , tocilizumab 400 mg/20 mL injection, 20 mL vial (<i>Actemra</i>)
9673D	TOCILIZUMAB , tocilizumab 400 mg/20 mL injection, 20 mL vial (<i>Actemra</i>)

Highly Specialised Drugs Program (Public Hospital)

Additions

Addition – Item

13293P	ADALIMUMAB , adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes (<i>Humira</i>)
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13313Q	AVATROMBOPAG , avatrombopag 20 mg tablet, 30 (<i>Doptelet</i>)
13294Q	ETANERCEPT , etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack (<i>Enbrel</i>)
13319B	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL pen devices (<i>Enbrel</i>)
13308K	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Enbrel</i>)
13304F	TOCILIZUMAB , tocilizumab 80 mg/4 mL injection, 4 mL vial (<i>Actemra</i>)
13324G	TOCILIZUMAB , tocilizumab 80 mg/4 mL injection, 4 mL vial (<i>Actemra</i>)
13305G	TOCILIZUMAB , tocilizumab 200 mg/10 mL injection, 10 mL vial (<i>Actemra</i>)
13330N	TOCILIZUMAB , tocilizumab 200 mg/10 mL injection, 10 mL vial (<i>Actemra</i>)
13299Y	TOCILIZUMAB , tocilizumab 400 mg/20 mL injection, 20 mL vial (<i>Actemra</i>)
13339C	TOCILIZUMAB , tocilizumab 400 mg/20 mL injection, 20 mL vial (<i>Actemra</i>)

Addition – Brand

13212J	<i>Humira</i> , <i>VE</i> – ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices
13228F	<i>Humira</i> , <i>VE</i> – ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes
12771E	<i>Azacitidine Sandoz</i> , <i>SZ</i> – AZACITIDINE , azacitidine 100 mg injection, 1 vial
13028Q	<i>Azacitidine Sandoz</i> , <i>SZ</i> – AZACITIDINE , azacitidine 100 mg injection, 1 vial
13036D	<i>Azacitidine Sandoz</i> , <i>SZ</i> – AZACITIDINE , azacitidine 100 mg injection, 1 vial
13042K	<i>Azacitidine Sandoz</i> , <i>SZ</i> – AZACITIDINE , azacitidine 100 mg injection, 1 vial
13044M	<i>Azacitidine Sandoz</i> , <i>SZ</i> – AZACITIDINE , azacitidine 100 mg injection, 1 vial
9597D	<i>Azacitidine Sandoz</i> , <i>SZ</i> – AZACITIDINE , azacitidine 100 mg injection, 1 vial
9598E	<i>Azacitidine Sandoz</i> , <i>SZ</i> – AZACITIDINE , azacitidine 100 mg injection, 1 vial

Addition – Equivalence Indicator

12417M	<i>Amgevita</i> , <i>XT</i> – ADALIMUMAB , adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe
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Alterations

Alteration – Note

12406Y	ADALIMUMAB , adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes (<i>Humira</i>)
12417M	ADALIMUMAB , adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe (<i>Amgevita</i>)
12435L	ADALIMUMAB , adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe (<i>Amgevita</i>)
12431G	ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes (<i>Humira</i> , <i>Yuflyma</i>)
12444Y	ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices (<i>Humira</i> , <i>Yuflyma</i>)
13212J	ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices (<i>Humira</i> , <i>Yuflyma</i>)
13228F	ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes (<i>Humira</i> , <i>Yuflyma</i>)
12348X	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (<i>Amgevita</i> , <i>Hadlima</i> , <i>Hyrimoz</i> , <i>Idacio</i>)
12355G	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Amgevita</i> , <i>Hadlima</i> , <i>Hyrimoz</i> , <i>Idacio</i>)
9662M	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (<i>Amgevita</i> , <i>Hadlima</i> , <i>Hyrimoz</i> , <i>Idacio</i>)
9663N	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Amgevita</i> , <i>Hadlima</i> , <i>Hyrimoz</i> , <i>Idacio</i>)
5825N	ELTROMBOPAG , eltrombopag 25 mg tablet, 28 (<i>Revolade</i>)
5826P	ELTROMBOPAG , eltrombopag 50 mg tablet, 28 (<i>Revolade</i>)
5734T	ETANERCEPT , etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack (<i>Enbrel</i>)
5735W	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL pen devices (<i>Enbrel</i>)
5733R	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Enbrel</i>)
9696H	ROMIPLOSTIM , romiplostim 250 microgram injection, 1 vial (<i>Nplate</i>)

9698K	ROMIPLOSTIM , romiplostim 500 microgram injection, 1 vial (<i>Nplate</i>)
10077J	TOCILIZUMAB , tocilizumab 80 mg/4 mL injection, 4 mL vial (<i>Actemra</i>)
1476Q	TOCILIZUMAB , tocilizumab 80 mg/4 mL injection, 4 mL vial (<i>Actemra</i>)
10056G	TOCILIZUMAB , tocilizumab 200 mg/10 mL injection, 10 mL vial (<i>Actemra</i>)
1481Y	TOCILIZUMAB , tocilizumab 200 mg/10 mL injection, 10 mL vial (<i>Actemra</i>)
10064Q	TOCILIZUMAB , tocilizumab 400 mg/20 mL injection, 20 mL vial (<i>Actemra</i>)
1482B	TOCILIZUMAB , tocilizumab 400 mg/20 mL injection, 20 mL vial (<i>Actemra</i>)

Alteration – Restriction

5605B	ABATACEPT , abatacept 250 mg injection, 1 vial (<i>Orencia</i>)
12406Y	ADALIMUMAB , adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes (<i>Humira</i>)
12417M	ADALIMUMAB , adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe (<i>Amgevita</i>)
12435L	ADALIMUMAB , adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe (<i>Amgevita</i>)
12431G	ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes (<i>Humira</i> , <i>Yuflyma</i>)
12444Y	ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices (<i>Humira</i> , <i>Yuflyma</i>)
13212J	ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices (<i>Humira</i> , <i>Yuflyma</i>)
13228F	ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes (<i>Humira</i> , <i>Yuflyma</i>)
12348X	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (<i>Amgevita</i> , <i>Hadlima</i> , <i>Hyrimoz</i> , <i>Idacio</i>)
12355G	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Amgevita</i> , <i>Hadlima</i> , <i>Hyrimoz</i> , <i>Idacio</i>)
9662M	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (<i>Amgevita</i> , <i>Hadlima</i> , <i>Hyrimoz</i> , <i>Idacio</i>)
9663N	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Amgevita</i> , <i>Hadlima</i> , <i>Hyrimoz</i> , <i>Idacio</i>)
5825N	ELTROMBOPAG , eltrombopag 25 mg tablet, 28 (<i>Revolade</i>)
5826P	ELTROMBOPAG , eltrombopag 50 mg tablet, 28 (<i>Revolade</i>)
5734T	ETANERCEPT , etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack (<i>Enbrel</i>)
5735W	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL pen devices (<i>Enbrel</i>)
5733R	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Enbrel</i>)
5757B	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflixtra</i> , <i>Remicade</i> , <i>Renflexis</i>)
9696H	ROMIPLOSTIM , romiplostim 250 microgram injection, 1 vial (<i>Nplate</i>)
9698K	ROMIPLOSTIM , romiplostim 500 microgram injection, 1 vial (<i>Nplate</i>)
10077J	TOCILIZUMAB , tocilizumab 80 mg/4 mL injection, 4 mL vial (<i>Actemra</i>)
1476Q	TOCILIZUMAB , tocilizumab 80 mg/4 mL injection, 4 mL vial (<i>Actemra</i>)
9657G	TOCILIZUMAB , tocilizumab 80 mg/4 mL injection, 4 mL vial (<i>Actemra</i>)
10056G	TOCILIZUMAB , tocilizumab 200 mg/10 mL injection, 10 mL vial (<i>Actemra</i>)
1481Y	TOCILIZUMAB , tocilizumab 200 mg/10 mL injection, 10 mL vial (<i>Actemra</i>)
9658H	TOCILIZUMAB , tocilizumab 200 mg/10 mL injection, 10 mL vial (<i>Actemra</i>)
10064Q	TOCILIZUMAB , tocilizumab 400 mg/20 mL injection, 20 mL vial (<i>Actemra</i>)
1482B	TOCILIZUMAB , tocilizumab 400 mg/20 mL injection, 20 mL vial (<i>Actemra</i>)
9659J	TOCILIZUMAB , tocilizumab 400 mg/20 mL injection, 20 mL vial (<i>Actemra</i>)

Highly Specialised Drugs Program (Community Access)

Additions

Addition – Item

13328L	BUPRENORPHINE , buprenorphine 8 mg/0.16 mL modified release injection, 0.16 mL syringe (<i>Buvidal Weekly</i>)
13297W	BUPRENORPHINE , buprenorphine 16 mg/0.32 mL modified release injection, 0.32 mL syringe (<i>Buvidal Weekly</i>)

13296T	BUPRENORPHINE , buprenorphine 24 mg/0.48 mL modified release injection, 0.48 mL syringe (<i>Buvidal Weekly</i>)
13314R	BUPRENORPHINE , buprenorphine 32 mg/0.64 mL modified release injection, 0.64 mL syringe (<i>Buvidal Weekly</i>)
13298X	BUPRENORPHINE , buprenorphine 64 mg/0.18 mL modified release injection, 0.18 mL syringe (<i>Buvidal Monthly</i>)
13309L	BUPRENORPHINE , buprenorphine 96 mg/0.27 mL modified release injection, 0.27 mL syringe (<i>Buvidal Monthly</i>)
13320C	BUPRENORPHINE , buprenorphine 100 mg/0.5 mL modified release injection, 0.5 mL syringe (<i>Sublocade</i>)
13302D	BUPRENORPHINE , buprenorphine 128 mg/0.36 mL modified release injection, 0.36 mL syringe (<i>Buvidal Monthly</i>)
13303E	BUPRENORPHINE , buprenorphine 160 mg/0.45 mL modified release injection, 0.45 mL syringe (<i>Buvidal Monthly</i>)
13327K	BUPRENORPHINE , buprenorphine 300 mg/1.5 mL modified release injection, 1.5 mL syringe (<i>Sublocade</i>)
13310M	BUPRENORPHINE , buprenorphine 400 microgram sublingual tablet, 7 (<i>Subutex</i>)
13336X	BUPRENORPHINE , buprenorphine 2 mg sublingual tablet, 7 (<i>Subutex</i>)
13337Y	BUPRENORPHINE , buprenorphine 8 mg sublingual tablet, 7 (<i>Subutex</i>)
13322E	BUPRENORPHINE + NALOXONE , buprenorphine 2 mg + naloxone 500 microgram sublingual film, 28 (<i>Suboxone Film 2/0.5</i>)
13321D	BUPRENORPHINE + NALOXONE , buprenorphine 8 mg + naloxone 2 mg sublingual film, 28 (<i>Suboxone Film 8/2</i>)
13333R	METHADONE , methadone hydrochloride 5 mg/mL oral liquid, 1 L (<i>Aspen Methadone Syrup, Biodone Forte</i>)
13334T	METHADONE , methadone hydrochloride 5 mg/mL oral liquid, 200 mL (<i>Aspen Methadone Syrup, Biodone Forte</i>)

Addition – Brand

10284G	<i>Lamivudine/Zidovudine Viatris 150/300, AL</i> – LAMIVUDINE + ZIDOVUDINE , lamivudine 150 mg + zidovudine 300 mg tablet, 60
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Advance Notices

1 August 2023

Deletion – Brand

10336B	<i>Stocrin, MK</i> – EFAVIRENZ , efavirenz 200 mg tablet, 90
10366N	<i>Stocrin, MK</i> – EFAVIRENZ , efavirenz 600 mg tablet, 30

IVF Program

Alterations

Alteration – Note

6182J	CHORIOGONADOTROPIN ALFA , choriogonadotropin alfa 250 microgram/0.5 mL injection, 0.5 mL pen device (<i>Ovidrel</i>)
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Alteration – Restriction

6182J	CHORIOGONADOTROPIN ALFA , choriogonadotropin alfa 250 microgram/0.5 mL injection, 0.5 mL pen device (<i>Ovidrel</i>)
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Opiate Dependence Treatment Program

Deletions

Deletion – Item

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

11767H	BUPRENORPHINE , buprenorphine 96 mg/0.27 mL modified release injection, 0.27 mL syringe (<i>Buvidal Monthly</i>)
11987X	BUPRENORPHINE , buprenorphine 100 mg/0.5 mL modified release injection, 0.5 mL syringe (<i>Sublocade</i>)
11768J	BUPRENORPHINE , buprenorphine 128 mg/0.36 mL modified release injection, 0.36 mL syringe (<i>Buvidal Monthly</i>)
12981F	BUPRENORPHINE , buprenorphine 160 mg/0.45 mL modified release injection, 0.45 mL syringe (<i>Buvidal Monthly</i>)
11990C	BUPRENORPHINE , buprenorphine 300 mg/1.5 mL modified release injection, 1.5 mL syringe (<i>Sublocade</i>)
6307Y	BUPRENORPHINE , buprenorphine 400 microgram sublingual tablet, 7 (<i>Subutex</i>)
6308B	BUPRENORPHINE , buprenorphine 2 mg sublingual tablet, 7 (<i>Subutex</i>)
6309C	BUPRENORPHINE , buprenorphine 8 mg sublingual tablet, 7 (<i>Subutex</i>)
9749D	BUPRENORPHINE + NALOXONE , buprenorphine 2 mg + naloxone 500 microgram sublingual film, 28 (<i>Suboxone Film 2/0.5</i>)
9750E	BUPRENORPHINE + NALOXONE , buprenorphine 8 mg + naloxone 2 mg sublingual film, 28 (<i>Suboxone Film 8/2</i>)
6171T	METHADONE , methadone hydrochloride 5 mg/mL oral liquid, 200 mL (<i>Aspen Methadone Syrup, Biodone Forte</i>)
6172W	METHADONE , methadone hydrochloride 5 mg/mL oral liquid, 1 L (<i>Aspen Methadone Syrup, Biodone Forte</i>)

Repatriation Pharmaceutical Benefits

Additions

Addition – Item

13331P	DRESSING LIPIDOCOLLOID MODERATE EXUDATE , dressing lipidocolloid moderate exudate 10 cm x 12 cm dressing, 10 (<i>UrgoTul Lite Border 10035710</i>)
13307J	ZOPICLONE , zopiclone 7.5 mg tablet, 14 (<i>Imovane</i>)

Addition – Brand

4591P	<i>APX-Gabapentin, GX</i> – GABAPENTIN , gabapentin 100 mg capsule, 100
4592Q	<i>APX-Gabapentin, GX</i> – GABAPENTIN , gabapentin 300 mg capsule, 100
4593R	<i>APX-Gabapentin, GX</i> – GABAPENTIN , gabapentin 400 mg capsule, 100

Deletions

Deletion – Brand

2194L	<i>Alendronate plus D3-DRLA, RZ</i> – ALENDRONATE + COLECALCIFEROL , alendronate 70 mg + colecalciferol 70 microgram (2800 units) tablet, 4
2224C	<i>Alendronate plus D3-DRLA, RZ</i> – ALENDRONATE + COLECALCIFEROL , alendronate 70 mg + colecalciferol 140 microgram (5600 units) tablet, 4

Alterations

Alteration – Note

4284L	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Remicade</i>)
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Alteration – Restriction

4284L	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Remicade</i>)
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General Pharmaceutical Benefits

■ ABATACEPT

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

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

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

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

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

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

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

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

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

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

Continuing subsidy:

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

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

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

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

Balance of Supply listings:

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

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

(2) Baseline measurements to determine response.

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

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

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

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

Authority required

Severe active rheumatoid arthritis

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

Treatment criteria:

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

Clinical criteria:

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

Population criteria:

- Patient must be aged 18 years or older.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Up to a maximum of 4 repeats will be authorised.

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

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

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

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

Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application.

The prescription must be written with a maximum quantity of 4 and up to 3 repeats.

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

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

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

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

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

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

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

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

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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

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

Authority required

Severe active rheumatoid arthritis

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

Treatment criteria:

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

Clinical criteria:

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

Population criteria:

- Patient must be aged 18 years or older.

Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

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

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

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

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

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

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

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

Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application.

The prescription must be written with a maximum quantity of 4 and up to 3 repeats.

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

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

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

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

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

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

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

Authority required

Severe active rheumatoid arthritis

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

Treatment criteria:

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

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**

- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

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

Treatment criteria:

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

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**

- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.
- Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

11693K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	946.49	30.00	Orencia ClickJect [BQ]

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

1220F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	946.49	30.00	Orencia [BQ]

■ ACALABRUTINIB

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.

Note Pharmaceutical benefits that have the form acalabrutinib 100 mg capsule and acalabrutinib 100 mg tablet are equivalent for the purposes of substitution.

Authority required

Relapsed or refractory chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- Patient must have a WHO performance status of 1 or less, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be considered unsuitable for treatment or retreatment with a purine analogue, **AND**
- Patient must not have received treatment with another Bruton's tyrosine kinase (BTK) inhibitor for any line of treatment of CLL/SLL (untreated or relapsed/refractory disease); OR
- Patient must have developed intolerance to another Bruton's tyrosine kinase (BTK) inhibitor of a severity necessitating permanent treatment withdrawal when being treated for relapsed or refractory CLL/SLL.

A patient is considered unsuitable for treatment or retreatment with a purine analogue as demonstrated by at least one of the following:

- Failure to respond (stable disease or disease progression on treatment), or a progression-free interval of less than 3 years from treatment with a purine analogue-based therapy and anti-CD20-containing chemoimmunotherapy regimen after at least two cycles;
- Age is 70 years or older;
- Age is 65 years or older and the presence of comorbidities (Cumulative Illness Rating Scale of 6 or greater, or creatinine clearance of less than 70 mL/min) that might place the patient at an unacceptable risk for treatment-related toxicity with purine analogue-based therapy, provided they have received one or more prior treatment including at least two cycles of an alkylating agent-based (or purine analogue-based) anti-CD20 antibody-containing chemoimmunotherapy regimen;
- History of purine analogue-associated autoimmune anaemia or autoimmune thrombocytopenia;
- Evidence of one or more 17p chromosomal deletions demonstrated by a Medicare Benefits Schedule listed test.

Authority required

Relapsed or refractory chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Continuing treatment of relapsed or refractory CLL/SLL

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

acalabrutinib 100 mg capsule, 56

12117R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	8219.87	30.00	^a Calquence [AP]

acalabrutinib 100 mg tablet, 56

13318Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	8219.87	30.00	^a CALQUENCE [AP]

■ ACALABRUTINIB

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

Note Special Pricing Arrangements apply.

Note For the purposes of administering this restriction, current Bruton's tyrosine kinase inhibitors are: acalabrutinib, ibrutinib, zanubrutinib

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 Pharmaceutical benefits that have the form acalabrutinib 100 mg capsule and acalabrutinib 100 mg tablet are equivalent for the purposes of substitution.

Authority required

Mantle cell lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must be untreated with Bruton's tyrosine kinase inhibitor therapy; OR
- Patient must have developed intolerance to another Bruton's tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal, when treated for this PBS indication.

Authority required

Mantle cell lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition.

acalabrutinib 100 mg capsule, 56

12826C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	8219.87	30.00	^a Calquence [AP]

acalabrutinib 100 mg tablet, 56

13325H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	8219.87	30.00	^a CALQUENCE [AP]

■ ADALIMUMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

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

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

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

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

Initiating subsidy:

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

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

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

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

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same

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

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

Balance of Supply listings:

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

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

(2) Baseline measurements to determine response.

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

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

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

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

Note Biosimilar prescribing policy

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

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

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

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

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

Authority required

Severe active rheumatoid arthritis

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

Treatment criteria:

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

Clinical criteria:

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

cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR

- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) a completed authority prescription form; and

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

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

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

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

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

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

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

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

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

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

Treatment criteria:

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

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

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

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

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

(1) a completed authority prescription form; and

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

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

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

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

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

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

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

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

Treatment criteria:

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

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**

- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

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

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

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

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

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

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

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

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

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

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

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

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

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

Authority required

Severe active rheumatoid arthritis

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

Treatment criteria:

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

Clinical criteria:

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

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

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

12400P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	676.79	30.00	^a Humira [VE]	^a Yuflyma [EW]

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

8737W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	827.02	30.00	^a Amgevita [XT] ^a Hyrimoz [SZ]	^a Hadlima [RF] ^a Idacio [PK]

■ ADALIMUMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

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

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

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

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

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

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

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

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

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

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

Continuing subsidy:

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

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

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

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

Balance of Supply listings:

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

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

(2) Baseline measurements to determine response.

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

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

response must be determined on the total number of major joints.

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

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

Note Biosimilar prescribing policy

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

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

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

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

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

Authority required

Severe active rheumatoid arthritis

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

Treatment criteria:

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

Clinical criteria:

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

Population criteria:

- Patient must be at least 18 years of age.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

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

Treatment criteria:

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

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

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

Treatment criteria:

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

Clinical criteria:

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

Population criteria:

- Patient must be at least 18 years of age.

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

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

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

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

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

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

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

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

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

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

Authority required

Severe active rheumatoid arthritis

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

Treatment criteria:

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

Clinical criteria:

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

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

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

12429E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	676.79	30.00	^a Humira [VE]	^a Yuflyma [EW]

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

9099X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	827.02	30.00	^a Amgevita [XT] ^a Hyrimoz [SZ]	^a Hadlima [RF] ^a Idacio [PK]

■ BARICITINIB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

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

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

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

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

Initiating subsidy:

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

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

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

prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

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

Continuing subsidy:

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

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

Balance of Supply listings:

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

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

(2) Baseline measurements to determine response.

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

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

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

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

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

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

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

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

Treatment criteria:

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

Clinical criteria:

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

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

Population criteria:

- Patient must be aged 18 years or older.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

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

Treatment criteria:

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

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

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

Treatment criteria:

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

Clinical criteria:

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

Population criteria:

- Patient must be aged 18 years or older.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

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

Treatment criteria:

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

Clinical criteria:

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

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

baricitinib 2 mg tablet, 28

11437Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1272.31	30.00	Olumiant [LY]

baricitinib 4 mg tablet, 28

11447L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1272.31	30.00	Olumiant [LY]

■ BUDESONIDE + FORMOTEROL (EFORMOTEROL)

Note Pharmaceutical benefits that have the brand BiResp Spiromax 200/6 powder for inhalation, 120 actuations, DuoResp Spiromax 200/6 powder for inhalation, 120 actuations, Symbicort Turbuhaler 200/6 powder for inhalation, 120 actuations and Rilast TURBUHALER 200/6 powder for inhalation, 120 actuations are equivalent for the purposes of substitution.

Note Patient must be aged 18 years or older.

Note This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD) or for allergen-induced or exercise-induced bronchoconstriction in the absence of asthma.

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

Authority required (STREAMLINED)

10464

Mild asthma

Clinical criteria:

- Patient must have asthma and require an anti-inflammatory reliever therapy, **AND**
- Patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA).

Device (inhaler) technique should be reviewed at each clinical visit and before initiating treatment with this medicine.

budesonide 200 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations

12029D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±1	2	..	37.00	30.00	^a BiResp Spiromax [TB]	^a DuoResp Spiromax [EV]

■ BUDESONIDE + FORMOTEROL (EFORMOTEROL)

Note Pharmaceutical benefits that have the brand BiResp Spiromax 200/6 powder for inhalation, 120 actuations, DuoResp Spiromax 200/6 powder for inhalation, 120 actuations, Symbicort Turbuhaler 200/6 powder for inhalation, 120 actuations and Rilast TURBUHALER 200/6 powder for inhalation, 120 actuations are equivalent for the purposes of substitution.

Note Patient must be aged 12 years or over.

Note This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD) or for allergen-induced or exercise-induced bronchoconstriction in the absence of asthma.

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

Authority required (STREAMLINED)

10464

Mild asthma

Clinical criteria:

- Patient must have asthma and require an anti-inflammatory reliever therapy, **AND**
- Patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA).

Device (inhaler) technique should be reviewed at each clinical visit and before initiating treatment with this medicine.

budesonide 200 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations

12041R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±1	2	..	37.00	30.00	^a Rilast TURBUHALER 200/6 [ZA]	^a Symbicort Turbuhaler 200/6 [AP]

■ BUDESONIDE + FORMOTEROL (EFORMOTEROL)

Note Pharmaceutical benefits that have the form budesonide 400 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 12 microgram/actuation powder for inhalation, 2 x 60 actuations and pharmaceutical benefits that have the form budesonide 400 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

7979

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Note Patient must be aged 18 years or older.

Note Budesonide/formoterol fumarate dihydrate powder for inhalation 400/12 microgram strength inhalers are not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

Note This product is not indicated for the initiation of treatment in asthma

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

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

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

10121

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

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

Note A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

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

budesonide 400 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations

13258T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*60.45	30.00	^a Rilast TURBUHALER 400/12 [ZA]	^a Symbicort TURBUHALER 400/12 [AP]

budesonide 400 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 12 microgram/actuation powder for inhalation, 2 x 60 actuations

11301T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±1	5	..	60.45	30.00	^a BiResp Spiromax [TB]	^a DuoResp Spiromax [EV]

▪ **CERTOLIZUMAB PEGOL**

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

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

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

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

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

Initiating subsidy:

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

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

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

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

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

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

Continuing subsidy:

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

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

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

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

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

Balance of Supply listings:

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

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

(2) Baseline measurements to determine response.

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

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

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

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

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

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

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

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

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

Treatment criteria:

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

Clinical criteria:

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

- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Authority required

Severe active rheumatoid arthritis

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

Treatment criteria:

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

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

Authority required

Severe active rheumatoid arthritis

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

Treatment criteria:

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

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

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

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

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

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

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

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

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

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

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

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

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

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

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

11322X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*3018.54	30.00	Cimzia [UC]

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

10905Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*3018.54	30.00	Cimzia [UC]

■ CHORIOGONADOTROPIN ALFA

Restricted benefit

Infertility indications other than that of Assisted Reproductive Technology

Treatment criteria:

- Patient must not be undergoing treatment with medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule, **AND**
- Patient must not be undergoing simultaneous treatment with this drug through another PBS program listing, **AND**
- Must be treated by an obstetrician/gynaecologist; OR
- Must be treated by a specialist in reproductive endocrinology/infertility; OR
- Must be treated by a urogynaecologist; OR
- Must be treated by an endocrinologist; OR
- Must be treated by a urologist.

The PBS prescription, whether it is to initiate or continue treatment, must be made out under the specialist's prescriber number.

choriogonadotropin alfa 250 microgram/0.5 mL injection, 0.5 mL pen device

13300B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	63.36	30.00	Ovidrel [SG]

■ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

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

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

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

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

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be

in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

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

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [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 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 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 a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

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

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

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

Clinical criteria:

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

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

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

AND either of the following:

- (a) 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.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

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

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

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

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 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: Continuing Treatment - balance of supply

Treatment criteria:

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

Clinical criteria:

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

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

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

3450N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	845.62	30.00	^a Enbrel [PF]

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

3449M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	845.62	30.00	^a Enbrel [PF]

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

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab and upadacitinib for adult patients with ankylosing spondylitis.

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

A patient is eligible for PBS-subsidised treatment with only 1 of the 8 biological medicines at any 1 time.

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

A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

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

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

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

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

(1) How to prescribe PBS-subsidised biological medicine treatment with adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab and upadacitinib.

(a) Initial treatment.

Applications for initial treatment should be made where:

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

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Assessment of the patient's response to treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the cessation of the most recent course of biological medicine therapy. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(2) Swapping therapy.

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

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine.

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

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response.

Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) 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 erythrocyte sedimentation rate (ESR), 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 Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Authority required

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

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

Clinical criteria:

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

Population criteria:

- Patient must be aged 18 years or older.

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

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

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

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

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

All measurements provided must be no more than 1 month old at the time of application.

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

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

Note Any queries concerning the arrangements to prescribe may be directed to 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

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

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

Treatment criteria:

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

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

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

11201M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	845.62	30.00	^a Brenzys [RF]	^a Enbrel [PF]

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

11196G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	845.62	30.00	^a Brenzys [RF]	^a Enbrel [PF]

▪ **ETANERCEPT**

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

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

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

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

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

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

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

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

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

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

Continuing subsidy:

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

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

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

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

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

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

Balance of Supply listings:

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

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

(2) Baseline measurements to determine response.

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

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

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

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

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

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

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

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

Clinical criteria:

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

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

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

Clinical criteria:

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

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

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

11220M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	845.62	30.00	^a Brenzys [RF]	^a Enbrel [PF]

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

11219L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	845.62	30.00	^a Brenzys [RF]	^a Enbrel [PF]

■ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab and upadacitinib for adult patients with ankylosing spondylitis.

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

A patient is eligible for PBS-subsidised treatment with only 1 of the 8 biological medicines at any 1 time.

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

A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

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

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

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

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

(1) How to prescribe PBS-subsidised biological medicine treatment with adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab and upadacitinib.

(a) Initial treatment.

Applications for initial treatment should be made where:

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

(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.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Assessment of the patient's response to treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the cessation of the most recent course of biological medicine therapy. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(2) Swapping therapy.

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

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine.

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

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response.

Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) 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 erythrocyte sedimentation rate (ESR), 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 Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Authority required

Ankylosing spondylitis

Treatment Phase: First continuing treatment

Clinical criteria:

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

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR

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

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

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

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

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

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

All measurements provided must be no more than 1 month old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

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

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

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

Note Any queries concerning the arrangements to prescribe may be directed to 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

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

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

Treatment criteria:

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

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

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

9456Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	845.62	30.00	^a Brenzys [RF]	^a Enbrel [PF]

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

9086F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	845.62	30.00	^a Brenzys [RF]	^a Enbrel [PF]

■ ETANERCEPT

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

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

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

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

treatment failure.

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

Initiating subsidy:

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

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

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

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

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

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

Continuing subsidy:

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

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

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

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

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

Balance of Supply listings:

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

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

(2) Baseline measurements to determine response.

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

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

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

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

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

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

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First Continuing treatment

Treatment criteria:

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

Clinical criteria:

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

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

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

Clinical criteria:

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

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

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

9460X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	845.62	30.00	^a Brenzys [RF]	^a Enbrel [PF]

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

9090K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	845.62	30.00	^a Brenzys [RF]	^a Enbrel [PF]

■ ETANERCEPT**Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

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

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

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

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

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

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

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

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

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

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

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not 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 a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be

deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or commencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

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

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

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

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

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

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Authority required

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

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

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

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

An adequate response to treatment is defined as:

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

either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

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

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

Where the most recent course of PBS-subsidised treatment with this drug was approved under the first continuing treatment restriction, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

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

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

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

Note Any queries concerning the arrangements to prescribe may be directed to 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 Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

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

Treatment criteria:

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

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

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

11198J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	845.62	30.00	^a Brenzys [RF]	^a Enbrel [PF]

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

11208X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	845.62	30.00	^a Brenzys [RF]	^a Enbrel [PF]

▪ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

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

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

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

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

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

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

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [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 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 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 a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

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

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline

measurements.

(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Authority required

Severe active juvenile idiopathic arthritis

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

Treatment criteria:

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

Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialed at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent

course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

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

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

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note Any queries concerning the arrangements to prescribe may be directed to 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 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

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

Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an 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).

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 a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change 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.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

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

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

A patient 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 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 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

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

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; OR
- Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Active joints are defined as:

(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).

All measures of joint count must be no more than 4 weeks old at the time of this 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.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

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

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

Note Any queries concerning the arrangements to prescribe may be directed to 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 1 (new patient) or Initial 2 (change or recommencement of treatment after break of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

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

Clinical criteria:

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

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

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

3447K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	845.62	30.00	^a Enbrel [PF]

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

3446J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	845.62	30.00	^a Enbrel [PF]

■ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

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

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

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

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

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

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

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

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

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

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not 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 a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

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

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

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

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

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

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

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

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Authority required

Severe psoriatic arthritis

Treatment Phase: First continuing treatment

Clinical criteria:

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

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

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

An adequate response to treatment is defined as:

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

either of the following:

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

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

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

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

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

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

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

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

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

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

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

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

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

Note Any queries concerning the arrangements to prescribe may be directed to 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 psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

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

Treatment criteria:

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

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

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

9458T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	845.62	30.00	^a Brenzys [RF]	^a Enbrel [PF]

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

9088H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	845.62	30.00	^a Brenzys [RF]	^a Enbrel [PF]

■ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

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

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

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

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

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

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

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

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

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

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

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (risankizumab only).

A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 August 2022 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

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

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

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

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

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

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

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, whole body

Clinical criteria:

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

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

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

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

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

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

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

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

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

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

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

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

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

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

Clinical criteria:

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

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

on the Department of Human Services website at www.humanservices.gov.au
 Applications for authority to prescribe should be forwarded to:
 Department of Human Services
 Complex Drugs
 Reply Paid 9826
 HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

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

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

11222P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	845.62	30.00	^a Brenzys [RF]	^a Enbrel [PF]

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

11224R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	845.62	30.00	^a Brenzys [RF]	^a Enbrel [PF]

■ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

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

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

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

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

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

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

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

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

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

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

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (risankizumab only).

A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 August 2022 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

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

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

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

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and

scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

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

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

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Whole body

Clinical criteria:

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

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

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

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

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

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

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

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

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

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

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

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

Note Any queries concerning the arrangements to prescribe may be directed to 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 chronic plaque psoriasis

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

Clinical criteria:

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

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Note Any queries concerning the arrangements to prescribe may be directed to 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 chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

Treatment criteria:

- Must be treated by a dermatologist.

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

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

9462B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	845.62	30.00	^a Brenzys [RF]	^a Enbrel [PF]

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

9431J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	845.62	30.00	^a Brenzys [RF]	^a Enbrel [PF]

■ ETANERCEPT

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

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

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

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

treatment failure.

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

Initiating subsidy:

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

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

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

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

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

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

Continuing subsidy:

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

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

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

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

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

Balance of Supply listings:

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

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

(2) Baseline measurements to determine response.

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

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

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

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

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

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

Authority required

Severe active rheumatoid arthritis

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

Treatment criteria:

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

Clinical criteria:

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

Population criteria:

- Patient must be at least 18 years of age.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

8637N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*845.63	30.00	Enbrel [PF]

■ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
- a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an

alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not 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 a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with biological medicines.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; **OR**
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR

- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**

- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

9457R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	845.62	30.00	^a Brenzys [RF]	^a Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

9087G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	845.62	30.00	^a Brenzys [RF]	^a Enbrel [PF]

▪ **ETANERCEPT**

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a

written-only authority application may not be practical in terms of providing timely access to continued treatment. Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

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HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

9459W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	845.62	30.00	^a Brenzys [RF]	^a Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

9089J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	845.62	30.00	^a Brenzys [RF]	^a Enbrel [PF]

■ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab and upadacitinib for adult patients with ankylosing spondylitis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab and upadacitinib only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 8 biological medicines at any 1 time.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised biological medicine treatment with adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab and upadacitinib.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient)

(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.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Assessment of the patient's response to treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the cessation of the most recent course of biological medicine therapy. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response.

Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) 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 erythrocyte sedimentation rate (ESR), 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 Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND
- (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
 - (ii) a completed BASDAI Assessment Form; and
 - (iii) a completed Exercise Program Self Certification Form included in the supporting information form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change 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.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

All measurements provided must be no more than 1 month old at the time of application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to 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

Authority required

Ankylosing spondylitis

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 a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - 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 patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

9455P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	845.62	30.00	^a Brenzys [RF]	^a Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

9085E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	845.62	30.00	^a Brenzys [RF]	^a Enbrel [PF]

▪ **ETANERCEPT**

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
- a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
- 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). An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (risankizumab only).

A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 August 2022 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**

- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

- (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
- (c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
 - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to Services Australia no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
 - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**

- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to Services Australia no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

- (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
- (ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a dermatologist.

Note 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).

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

9461Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	845.62	30.00	^a Brenzys [RF]	^a Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

9091L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	845.62	30.00	^a Brenzys [RF]	^a Enbrel [PF]

■ ETANERCEPT**Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines etanercept and ustekinumab for patients under 18 years of with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to etanercept and ustekinumab only. A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time. A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle. Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure. A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction. Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle. A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction. A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime. There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot. How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

- (i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naïve patient); or
- (ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or
- (iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
- (iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

Etanercept only:
After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 3) due to a disease flare with psoriasis affecting the whole body if:

- (i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or
- (ii) the patient has a current PASI score greater than 15

Etanercept only:
After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 3) due to a disease flare with psoriasis affecting the face, hand or foot if:

- (i) all subscores are rated moderate to severe; or
- (ii) 2 of the three subscores are rated severe to very severe; or
- (iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or
- (iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot,

(2) Assessment of response to initial treatment.
After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment will be used to determine eligibility for continuing treatment. and must be conducted within 8 weeks of the last administered dose. To avoid an interruption of supply for continuing treatment, the assessment should be submitted and no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment
Etanercept only:
Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of

treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.

Ustekinumab only:

Following the completion of an initial 28-week treatment course, a patient may qualify to receive up to 24 weeks per continuing treatment course provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine twice within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment must be demonstrated based on the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6A) Re-commencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept).

A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.

(6B) Re-treatment (etanercept only)

A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.

(7) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

Note No 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 To complete a 24-week course of treatment beyond this authority application, the next authority application (apart from supplies obtained under 'Balance of Supply') is to be under the 'completion of course' treatment phase. Therefore, remind the patient to return for clinical review in approximately 12 weeks to enable ample time to obtain the final 8 weeks of treatment of a 24-week treatment course.

Document the patient's baseline disease severity indices scores in their medical record, in addition to stating them in this authority application, to ensure:

- (i) the patient's response to treatment can be quantified from week 12; and
- (ii) in the event that the patient's treating clinician changes, the baseline value(s) are available to the new clinician without need to refer to a third party.

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial 1 treatment (Whole body) - biological medicine-naïve patient

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have lesions present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; and/or (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**

-
- Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:

(a) A Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of the last pre-requisite therapy.

A PASI assessment must have been completed for each pre-requisite treatment trialled, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of that pre-requisite treatment. State in this authority application, each of:

- (i) the name of each prior therapy trialled that meets the above requirements - state at least 2;
- (ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);
- (iii) the PASI score that followed each prior therapy trialled;
- (iv) the date the PASI scores were determined

State a baseline PASI score to be referenced in any future authority applications that continue treatment. This PASI score may be any of: (i) a current PASI score, (ii) a PASI score present prior to, or, after a pre-requisite non-biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial 2 treatment (Whole body) - Change of treatment

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.

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).

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

In relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:

- (i) there is an absence of an adequate response to that treatment; or
- (ii) there was an intolerance to that treatment; or
- (iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above.

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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HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial 3 treatment (Whole body, or, face/hand/foot) - Recommencement of treatment after a break in biological medicine of more than 5 years

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition for at least 5 years, if they have previously received PBS-subsidised treatment with a biological medicine for this condition and wish to commence a new treatment cycle, **AND**
- The condition must be affecting the whole body - all subsequent authority applications to this application will be made under treatment phases that feature the words 'whole body'; OR
- The condition must be limited to the face/hand/foot - all subsequent authority applications to this application will be made under treatment phases that feature the words 'face, hand, foot', **AND**
- Patient must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; OR
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.

Population criteria:

- Patient must be under 18 years of age.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

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).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Balance of supply - Initial 1, 2, 3 or 4 treatment (Whole body, or, face/hand/foot)

Treatment criteria:

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing current PBS-subsidised treatment with this biological medicine, but has received insufficient therapy with this biological medicine to complete 16 weeks treatment available under any of the initial treatment phases (regardless of the affected body area): (i) Initial 1, (ii) Initial 2, (iii) Initial 3, (iv) Initial 4.

Clinical criteria:

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- The treatment must provide no more than the balance of up to 16 weeks 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

Severe chronic plaque psoriasis

Treatment Phase: Completion of course - treatment covering weeks 16 to 24 (Whole body)

Treatment criteria:

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing current PBS-subsidised treatment with this biological medicine, with the intention to complete the remainder of a 24-week treatment course with this biological medicine.

Clinical criteria:

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must be assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, but within 8 weeks of the last administered dose, **AND**
- Patient must have demonstrated an adequate response to treatment, **AND**
- Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.

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 adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

Note Aim to conduct and submit the PASI assessment at week 12 or soon after to ensure uninterrupted supply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial 4 - Re-treatment (Whole body)

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have a documented history of severe chronic plaque psoriasis of the whole body.

Treatment criteria:

- Patient must be undergoing re-treatment with this biological medicine for this PBS indication after an initial adequate response to the most recent treatment course, but has since experienced at least one of the following: (i) a disease flare where the PASI score has worsened (increased) by at least 50%, (ii) the current PASI score has returned above 15.

Clinical criteria:

- Patient must not have failed more than once to achieve an adequate response with etanercept, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

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).

Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial 1 treatment (Face, hand, foot) - biological medicine-naive patient

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have the plaque or plaques of the face, or palm of hand or sole of foot present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:

(a) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling being rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy; or

(b) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy

State in this authority application, each of:

- (i) the name of each prior therapy trialled that meets the above requirements - state at least 2;
- (ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);
- (iii) whether failure type (a) or (b) as described above occurred for each prior therapy trialled;
- (iv) the dates that response assessments were determined

State in this authority application at least one of the following to act as a baseline measurement and be referenced in any future authority applications that continue treatment:

(v) for each of erythema, thickness and scaling, which of these are rated as severe or very severe (at least 2 must be rated as severe/very severe);

(vi) the percentage area of skin (combined area of face, hands and feet) affected by this condition (must be at least 30%) prior to treatment with biological medicine.

Where a patient has had a 12 month treatment break, the length of the break is measured from the date the most recent treatment was stopped to the date of the application to re-commence treatment.

Note 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 chronic plaque psoriasis

Treatment Phase: Initial 2 treatment (Face, hand, foot) - Change of treatment

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**

- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle, **AND**
- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction.

Population criteria:

- Patient must be under 18 years of age.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

In relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:

- (i) there is an absence of an adequate response to that treatment; or
- (ii) there was an intolerance to that treatment; or
- (iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above.

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).

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 chronic plaque psoriasis

Treatment Phase: Completion of course - treatment covering weeks 16 to 24 (Face, hand, foot)

Treatment criteria:

- Must be treated by a dermatologist, **AND**
- Patient must be undergoing current PBS-subsidised treatment with this biological medicine, with the intention to complete the remainder of a 24-week treatment course with this biological medicine.

Clinical criteria:

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must be assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, but within 8 weeks of the last administered dose, **AND**
- Patient must have demonstrated an adequate response to treatment, **AND**
- Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.

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 adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

Note Aim to conduct and submit the PASI/percentage of skin area affected assessment at week 12 or soon after to ensure uninterrupted supply.

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

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial 4 - Re-treatment (face, hand, foot)

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, **AND**
- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot.

Treatment criteria:

- Patient must be undergoing re-treatment with this biological medicine for this PBS indication after an initial adequate response to the most recent treatment course, but has since experienced at least one of the following: (i) all PASI sub-measures (redness, thickness, scaling) are rated as 'moderate' to 'severe', (ii) at least 2 of the 3 PASI sub-measures are rated as 'severe' to 'very severe', (iii) the skin area affected has increased by at least 50% since the last administered dose, (iv) the skin area affected is at least 30% of the total skin area of the face/hand/foot.

Clinical criteria:

- Patient must not have failed more than once to achieve an adequate response with etanercept, **AND**
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

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).

Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.

Note Any queries concerning the arrangements to prescribe may be directed to 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

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

1964J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	845.62	30.00	^a Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

1963H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	845.62	30.00	^a Enbrel [PF]

■ **FINERENONE**

Caution Serum electrolytes should be checked regularly

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

14097

Chronic kidney disease with Type 2 diabetes

Clinical criteria:

- Patient must have a diagnosis of chronic kidney disease, defined as abnormalities of at least one of: (i) kidney structure, (ii) kidney function, present for at least 3 months, prior to initiating treatment with this drug, **AND**
- Patient must not have known significant non-diabetic renal disease, prior to initiating treatment with this drug, **AND**
- Patient must have an estimated glomerular filtration rate of 25 mL/min/1.73 m² or greater, prior to initiating treatment with this drug, **AND**
- Patient must have a urinary albumin-to-creatinine ratio of 200 mg/g (22.6 mg/mmol) or greater, prior to initiating treatment with this drug, **AND**

- Patient must discontinue treatment with this drug prior to initiating renal replacement therapy, defined as dialysis or kidney transplant, **AND**
- Patient must be stabilised, for at least 4 weeks, on either: (i) an ACE inhibitor or (ii) an angiotensin II receptor antagonist, unless medically contraindicated, prior to initiation of combination therapy with this drug, **AND**
- The treatment must be in combination with an SGLT2i unless medically contraindicated or intolerant, **AND**
- Patient must not be receiving treatment with another selective nonsteroidal mineralocorticoid receptor antagonist, a renin inhibitor or a potassium-sparing diuretic, **AND**
- Patient must not have established heart failure with reduced ejection fraction with an indication for treatment with a mineralocorticoid receptor antagonist.

finerenone 10 mg tablet, 28

13335W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	84.04	30.00	Kerendia [BN]

finerenone 20 mg tablet, 28

13316W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	84.04	30.00	Kerendia [BN]

■ FLUTICASONE PROPIONATE

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)

14180

Asthma

Clinical criteria:

- The treatment must not be a PBS benefit where this 50 microgram strength is being initiated in a patient over the age of 6.00 years.

fluticasone propionate 50 microgram/actuation inhalation, 120 actuations

8516F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	20.40	21.80	^a Axotide Junior [TX]
			^b 4.00	24.40	21.80	^a Flixotide Junior [GK]

■ GOLIMUMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the

necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR

- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**

- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

golimumab 50 mg/0.5 mL injection, 0.5 mL pen device

11372M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1161.49	30.00	Simponi [JC]

golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

3426H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1161.49	30.00	Simponi [JC]

■ NIRMATRELVIR (&) RITONAVIR

Caution Nirmatrelvir with ritonavir has significant drug-drug interactions. Please refer to the TGA approved Paxlovid Product Information. Prescribers and dispensers should carefully review a patient's concomitant medications including over-the-counter medications, herbal supplements, and recreational drugs.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)**13759**

SARS-CoV-2 infection

Clinical criteria:

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset; OR
- The treatment must be initiated as soon as possible after a diagnosis is confirmed where asymptomatic.

Population criteria:

- Patient must be at least 70 years of age.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

Authority required (STREAMLINED)**13821**

SARS-CoV-2 infection

Clinical criteria:

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- Patient must satisfy at least one of the following criteria: (i) be moderately to severely immunocompromised with risk of progression to severe COVID-19 disease due to the immunocompromised status, (ii) has experienced past COVID-19 infection resulting in hospitalisation, **AND**
- The treatment must be initiated within 5 days of symptom onset.

Population criteria:

- Patient must be at least 18 years of age.

For the purpose of administering this restriction, 'moderately to severely immunocompromised' patients are those with:

- Any primary or acquired immunodeficiency including:
 - Haematologic neoplasms: leukaemias, lymphomas, myelodysplastic syndromes, multiple myeloma and other plasma cell disorders,
 - Post-transplant: solid organ (on immunosuppressive therapy), haematopoietic stem cell transplant (within 24 months),
 - Immunocompromised due to primary or acquired (HIV/AIDS) immunodeficiency; OR
- Any significantly immunocompromising condition(s) where, in the last 3 months the patient has received:
 - Chemotherapy or whole body radiotherapy,
 - High-dose corticosteroids (at least 20 mg of prednisone per day, or equivalent) for at least 14 days in a month, or pulse corticosteroid therapy,
 - Biological agents and other treatments that deplete or inhibit B cell or T cell function (abatacept, anti-CD20 antibodies, BTK inhibitors, JAK inhibitors, sphingosine 1-phosphate receptor modulators, anti-CD52 antibodies, anti-complement antibodies, anti-thymocyte globulin),
 - Selected conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) including mycophenolate, methotrexate, leflunomide, azathioprine, 6-mercaptopurine (at least 1.5mg/kg/day), alkylating agents (e.g. cyclophosphamide, chlorambucil), and systemic calcineurin inhibitors (e.g. cyclosporin, tacrolimus); OR
- Any significantly immunocompromising condition(s) where, in the last 12 months the patient has received an anti-CD20 monoclonal antibody treatment, but criterion 2c above is not met; OR
- Others with very high-risk conditions including Down Syndrome, cerebral palsy, congenital heart disease, thalassemia, sickle cell disease and other haemoglobinopathies; OR
- People with disability with multiple comorbidities and/or frailty.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

Authority required (STREAMLINED)

13748

SARS-CoV-2 infection

Clinical criteria:

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset.

Population criteria:

- Patient must be each of: (i) identify as Aboriginal or Torres Strait Islander, (ii) at least 30 years of age, (iii) at high risk.
- For the purpose of administering this restriction, high risk is defined as the presence of at least one of the following conditions:

1. The patient is in residential aged care
2. The patient has disability with multiple comorbidities and/or frailty
3. Neurological conditions, including stroke and dementia and demyelinating conditions
4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease
5. Heart failure, coronary artery disease, cardiomyopathies
6. Obesity (BMI greater than 30 kg/m²)
7. Diabetes type I or II, requiring medication for glycaemic control
8. Renal impairment (eGFR less than 60mL/min)
9. Cirrhosis
10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above
11. Past COVID-19 infection episode resulting in hospitalisation.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

Note The Modified Monash Model categorises an area according to geographical remoteness and town size. Details can be found at: <https://www.health.gov.au/health-topics/rural-health-workforce/classifications/mmm>

Authority required (STREAMLINED)

14187

SARS-CoV-2 infection

Clinical criteria:

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset.

Population criteria:

- Patient must be at high risk of requiring hospitalisation for COVID-19 infection, **AND**
- Patient must be at least 50 years old, but not older than 60 years; OR
- Patient must be at least 60 years old, but not older than 70 years.

For the purpose of administering this restriction, high risk is defined as the presence of at least one of the following conditions:

1. The patient is in residential aged care
2. The patient has disability with multiple comorbidities and/or frailty
3. Neurological conditions, including stroke and dementia and demyelinating conditions
4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease

5. Heart failure, coronary artery disease, cardiomyopathies
6. Obesity (BMI greater than 30 kg/m²)
7. Diabetes type I or II, requiring medication for glycaemic control
8. Renal impairment (eGFR less than 60mL/min)
9. Cirrhosis
10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above
11. Past COVID-19 infection episode resulting in hospitalisation.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

nirmatrelvir 150 mg tablet [4] (&) ritonavir 100 mg tablet [2], 5 x 6

12996B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	..	..	1114.84	30.00	Paxlovid [HD]

■ TOCILIZUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patients with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to Severe active juvenile idiopathic arthritis.

Treatment cycles:

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12 month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required (STREAMLINED)

14150

Severe active juvenile idiopathic arthritis

Treatment Phase: 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.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must be 30kg or over, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

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).

The assessment of response to treatment must be documented in the patient's medical records.

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 provided with the initial treatment application.

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 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 they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

11742B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	812.80	30.00	Actemra ACTPen [RO]

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

11720W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	812.80	30.00	Actemra Subcutaneous Injection [RO]

■ TOCILIZUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patients with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to Severe active juvenile idiopathic arthritis.

Treatment cycles:

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12 month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

14104

Severe active juvenile idiopathic arthritis

Treatment Phase: 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.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**

- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must be under 30kg, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

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).

The assessment of response to treatment must be documented in the patient's medical records.

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 provided with the initial treatment application.

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 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 they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

13306H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	812.80	30.00	Actemra ACTPen [RO]

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

13301C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	812.80	30.00	Actemra Subcutaneous Injection [RO]

■ **TOCILIZUMAB**

Note A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Active giant cell arteritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist, clinical immunologist or neurologist experienced in the management of giant cell arteritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed 52 weeks in total including initial and continuing applications.

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

11722Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	6	..	812.80	30.00	Actemra ACTPen [RO]

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

11721X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	6	..	812.80	30.00	Actemra Subcutaneous Injection [RO]

■ **TOCILIZUMAB**

Note A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Active giant cell arteritis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a rheumatologist, clinical immunologist or neurologist experienced in the management of giant cell arteritis.

Clinical criteria:

- Patient must have clinical symptoms of active giant cell arteritis in the absence of any other identifiable cause, **AND**
- Patient must have an ESR equal to or greater than 30 mm/hour within the past 6 weeks; OR
- Patient must have a CRP equal to or greater than 10 mg/L within the past 6 weeks; OR
- Patient must have active giant cell arteritis confirmed by positive temporal artery biopsy or imaging, **AND**
- Patient must have had a history of an ESR equal to or greater than 50 mm/hour or a CRP equal to or greater than 24.5 mg/L at diagnosis, **AND**
- Patient must have had temporal artery biopsy revealing features of giant cell arteritis at diagnosis; OR
- Patient must have had evidence of large-vessel vasculitis by magnetic resonance (MR) or computed tomography (CT) angiography or PET/CT; OR
- Patient must have had evidence of positive temporal artery halo sign by ultrasound (US) at diagnosis, **AND**
- The treatment must be in combination with a tapering course of corticosteroids, **AND**
- The treatment must not exceed 52 weeks in total including initial and continuing applications.

Population criteria:

- Patient must be aged 50 years or older.

Clinical symptoms of giant cell arteritis at diagnosis include unequivocal cranial symptoms of giant cell arteritis (new onset localized headache, scalp tenderness, temporal artery tenderness or decreased pulsation, ischemia related vision loss, or otherwise unexplained mouth or jaw pain upon mastication); or symptoms of polymyalgia rheumatica, defined as shoulder and/or hip girdle pain associated with inflammatory morning stiffness.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS and must include:

(a) details (dates, results, and unique identifying number/code or provider number) of evidence that the patient has active giant cell arteritis including pathology reports outlining the patient's ESR or CRP levels within the last 6 weeks, or positive temporal artery biopsy or imaging; and

(b) details (dates, results, and unique identifying number/code or provider number) of evidence that the patient has been diagnosed with giant cell arteritis with a history of an ESR equal to or greater than 50 mm/hour or a CRP equal to or greater than 24.5 mg/L at diagnosis.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- A completed authority prescription form; and
- A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

11744D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	812.80	30.00	Actemra ACTPen [RO]

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

11743C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	812.80	30.00	Actemra Subcutaneous Injection [RO]

■ TOCILIZUMAB

Caution Inadvertent muscular injection in patients aged less than 12 years may occur with the pen device.

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

Treatment cycles:

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.

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.

Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

Prescribing under the correct 'Treatment Phase' listing for the authority application.

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.

(3) Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.

(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 provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with a biological medicine 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 documented in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

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) - in a patient of any weight being administered a subcutaneous form of this biological medicine

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.

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

12094M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	812.80	30.00	Actemra ACTPen [RO]

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

12102Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	812.80	30.00	Actemra Subcutaneous Injection [RO]

■ TOCILIZUMAB

Caution Inadvertent muscular injection in patients aged less than 12 years may occur with the pen device.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

Treatment cycles:

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.

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.

Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

Prescribing under the correct 'Treatment Phase' listing for the authority application.

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.

(3) Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.

(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 provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with a biological medicine 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 documented in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required (STREAMLINED)

14088

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment in a patient weighing at least 30 kg

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.

The assessment of response to treatment must be documented in the patient's medical records.

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 provided with the initial treatment application.

The following reports must be documented in the patient's medical records where appropriate:

(a) baseline and current pathology reports detailing C-reactive protein (CRP) levels; and

(b) baseline and current pathology reports detailing platelet count.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of prescribing and must be documented in the patient's medical records.

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 prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

12084B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	812.80	30.00	Actemra ACTPen [RO]

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

12099T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	812.80	30.00	Actemra Subcutaneous Injection [RO]

■ TOCILIZUMAB

Caution Inadvertent muscular injection in patients aged less than 12 years may occur with the pen device.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

Treatment cycles:

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.

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.

Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

Prescribing under the correct 'Treatment Phase' listing for the authority application.

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.

(3) Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.

(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 provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with a biological medicine 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 documented

in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required (STREAMLINED)

14084

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment in a patient weighing less than 30 kg

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.

The assessment of response to treatment must be documented in the patient's medical records.

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 provided with the initial treatment application.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of prescribing and must be documented in the patient's medical records.

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 prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

12090H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	812.80	30.00	Actemra ACTPen [RO]

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

12086D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	812.80	30.00	Actemra Subcutaneous Injection [RO]

■ TOCILIZUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patients with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to Severe active juvenile idiopathic arthritis.

Treatment cycles:

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12 month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

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 not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

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 documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; OR
- (b) at least 4 active joints from the following list:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic arthritis; and
- (b) details of prior treatment including dose and duration of treatment.

Patients under 30 kg may receive up to 24 weeks of treatment under this restriction. Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction.

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.

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.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

An adequate response to treatment is defined as:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

Patients under 30 kg may receive up to 24 weeks of treatment under this restriction. Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the 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 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 they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints.

Active joints are defined as:

- (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).

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

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 active joints, the response must be demonstrated on the total number of active joints.

Patients under 30 kg may receive up to 24 weeks of treatment under this restriction. Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic arthritis; and
- (b) the date of the last continuing prescription.

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 details of the 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 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.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete 16 or 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 or 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 or 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions for patients 30 kg or over; OR
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions for patients under 30 kg.

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

11734N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	812.80	30.00	Actemra ACTPen [RO]

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

11748H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	812.80	30.00	Actemra Subcutaneous Injection [RO]

■ TOCILIZUMAB

Caution Inadvertent muscular injection in patients aged less than 12 years may occur with the pen device.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

Treatment cycles:

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.

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.

Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

Prescribing under the correct 'Treatment Phase' listing for the authority application.

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.

(3) Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.

(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 provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with a biological medicine 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 documented in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient weighing at least 30 kg)

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 assessment of response to prior treatment must be documented in the patient's medical records.

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 assessment of response to prior treatment must be documented in the patient's medical records.

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 documented in the patient's medical records.

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 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 information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active systemic juvenile idiopathic arthritis; and
 - (b) details of prior treatment including dose and duration of treatment.
- The following reports must be documented in the patient's medical records where appropriate:
- (a) the date of assessment of severe active systemic juvenile idiopathic arthritis;
 - (b) details of prior treatment including dose and duration of treatment; and
 - (c) the pathology reports detailing CRP and platelet count where appropriate.

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 in a patient weighing at least 30 kg)

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.

The assessment of response to treatment must be documented in the patient's medical records.

The following reports must be documented in the patient's medical records where appropriate:

(a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

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 details of the 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 prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break of more than 12 months in a patient weighing at least 30 kg)

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 at least one of: (a) an active joint count of at least 20 active (swollen and tender) joints; (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); (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 following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active systemic juvenile idiopathic arthritis.

The following reports must be documented in the patient's medical records where appropriate:

(a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.

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 details of the 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.

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

12083Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	812.80	30.00	Actemra ACTPen [RO]

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

12095N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	812.80	30.00	Actemra Subcutaneous Injection [RO]

■ TOCILIZUMAB

Caution Inadvertent muscular injection in patients aged less than 12 years may occur with the pen device.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

Treatment cycles:

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.

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.

Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

Prescribing under the correct 'Treatment Phase' listing for the authority application.

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.

(3) Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.

(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 provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with a biological medicine 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 documented in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient weighing less than 30 kg)

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 assessment of response to prior treatment must be documented in the patient's medical records.

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 assessment of response to prior treatment must be documented in the patient's medical records.

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 documented in the patient's medical records.

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 documented in the patient's medical records.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active systemic juvenile idiopathic arthritis; and
 - (b) the details of prior treatment including dose and duration of treatment.
- The following reports must be documented in the patient's medical records where appropriate:
- (a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

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.

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 in a patient weighing less than 30 kg)

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.

The assessment of response to treatment must be documented in the patient's medical records.

The following reports must be documented in the patient's medical records where appropriate:

(a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

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 details of the 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 prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of a new treatment cycle after a break of more than 12 months in a patient weighing less than 30 kg)

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 at least one of: (a) an active joint count of at least 20 active (swollen and tender) joints; (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); (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 following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active systemic juvenile idiopathic arthritis.

The following reports must be documented in the patient's medical records where appropriate:

(a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.

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 details of the 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.

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

12085C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	812.80	30.00	Actemra ACTPen [RO]

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

12105D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	812.80	30.00	Actemra Subcutaneous Injection [RO]

■ TOCILIZUMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis. Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of

more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an

application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

11565Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	812.80	30.00	Actemra ACTPen [RO]

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

10951J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	812.80	30.00	Actemra Subcutaneous Injection [RO]

■ TOFACITINIB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR

- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

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Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**

- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

tofacitinib 5 mg tablet, 56

10517M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1211.93	30.00	Xeljanz [PF]

■ UPADACITINIB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the

response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

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Or mailed to:

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Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, conducted within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count, ESR and/or CRP must be no more than 4 weeks old at the time of application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

upadacitinib 15 mg modified release tablet, 28

11989B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1272.31	30.00	Rinvoq [VE]

Highly Specialised Drugs Program (Private Hospital)

■ ABATACEPT

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply

treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment. Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion.

Up to a maximum of 4 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months).

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion.

Up to a maximum of 4 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

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Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

abatacept 250 mg injection, 1 vial

9621J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	281.27	Orencia [BQ]

■ ADALIMUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patients with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to Severe active juvenile idiopathic arthritis.

Treatment cycles:

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12 month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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 No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

14107

Severe active juvenile idiopathic arthritis

Treatment Phase: 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.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

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).

The assessment of response to treatment must be documented in the patient's medical records.

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 provided with the initial treatment application.

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 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 they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13229G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	652.03	^a Humira [VE]	^a Yuflyma [EW]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12368Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	800.83	^a Amgevita [XT] ^a Hyrimoz [SZ]	^a Hadlima [RF] ^a Idacio [PK]

■ ADALIMUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patients with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to Severe active juvenile idiopathic arthritis. Treatment cycles:

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12 month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine

therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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 No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

14107

Severe active juvenile idiopathic arthritis

Treatment Phase: 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.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

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).

The assessment of response to treatment must be documented in the patient's medical records.

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 provided with the initial treatment application.

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 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 they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13210G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	652.03	^a Humira [VE]	^a Yuflyma [EW]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	800.83	^a Amgevita [XT]	^a Hadlima [RF]

■ ADALIMUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patients with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to Severe active juvenile idiopathic arthritis.

Treatment cycles:

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12 month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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 No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

14107

Severe active juvenile idiopathic arthritis

Treatment Phase: 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.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

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).

The assessment of response to treatment must be documented in the patient's medical records.

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 provided with the initial treatment application.

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 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 they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes

13292N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	652.03	^a Humira [VE]

adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe

12349Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*800.83	^a Amgevita [XT]

■ ADALIMUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patients with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to Severe active juvenile idiopathic arthritis.

Treatment cycles:

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12 month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

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 not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

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 documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) details of prior treatment including dose and duration of treatment.

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 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.

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.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

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).

The assessment of response to treatment must be documented in the patient's medical records.

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 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the 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 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 they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active joints are defined as:

- (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).

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

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 active joints, the response must be demonstrated on the total number of active joints.

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 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic; and
- (b) the date of the last continuing prescription.

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 details of the 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 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.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient 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 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12335F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	652.03	^a Humira [VE]	^a Yuflyma [EW]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9680L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	800.83	^a Amgevita [XT] ^a Hyrimoz [SZ]	^a Hadlima [RF] ^a Idacio [PK]

■ ADALIMUMAB**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patients with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to Severe active juvenile idiopathic arthritis.

Treatment cycles:

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12 month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of to the current treatment should be

conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

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 not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

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 documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; OR
- (b) at least 4 active joints from the following list:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic arthritis; and
- (b) details of prior treatment including dose and duration of treatment.

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 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.

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.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

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).

The assessment of response to treatment must be documented in the patient's medical records.

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 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the 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 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 they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active joints are defined as:

(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).

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

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 active joints, the response must be demonstrated on the total number of active joints.

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 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic; and
- (b) the date of the last continuing prescription.

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 details of the 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 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.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient 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 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12396K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	652.03	^a Humira [VE]	^a Yuflyma [EW]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9679K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	800.83	^a Amgevita [XT] ^a Hyrimoz [SZ]	^a Hadlima [RF] ^a Idacio [PK]

■ ADALIMUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patients with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to Severe active juvenile idiopathic arthritis.

Treatment cycles:

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12 month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz or Idacio is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note 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.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

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 not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

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 documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; OR
- (b) at least 4 active joints from the following list:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic arthritis; and
- (b) details of prior treatment including dose and duration of treatment.

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 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.

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.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

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).

The assessment of response to treatment must be documented in the patient's medical records.

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 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the 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 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 they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active joints are defined as:

(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).

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

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 active joints, the response must be demonstrated on the total number of active joints.

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 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic; and

(b) the date of the last continuing prescription.

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 details of the 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 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.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient 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 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes

12443X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	652.03	^a Humira [VE]

adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe

12439Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	..	..	*800.83	^a Amgevita [XT]

■ AVATROMBOPAG

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe thrombocytopenia

Treatment Phase: Initial treatment - New patient

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The following criteria indicate failure to achieve an adequate response to corticosteroid and/or immunoglobulin therapy and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) details of a platelet count supporting the diagnosis of ITP.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
 - Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment or Grandfather treatment restriction if the patient has not had a treatment break, confirmed through a pathology report from an Approved Pathology Authority; OR
 - Patient must have changed treatment from either romiplostim or eltrombopag to this drug under the Balance of Supply/Change of Therapy restriction and demonstrated a sustained response; OR
 - Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, confirmed through a pathology report from an Approved Pathology Authority, **AND**
 - The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.
- For the purposes of this restriction, a sustained response is defined as the patient having the ability to maintain a platelet count sufficient to prevent clinically significant bleeding based on clinical assessment.
- The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug and must be documented in the patient's medical records.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Severe thrombocytopenia

Treatment Phase: Second or Subsequent Continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under first continuing or re-initiation of interrupted continuing treatment restriction, **AND**
- Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Severe thrombocytopenia

Treatment Phase: Balance of supply or change of therapy

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment restriction; OR
- Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction; OR
- Patient must have received insufficient therapy with this drug for this condition under the Second or Subsequent Continuing treatment restriction; OR
- Patient must have received insufficient therapy with this drug for this condition under the Grandfather treatment restriction; OR
- Patient must be changing therapy from romiplostim or eltrombopag to this drug for this condition, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment under this restriction.

Patients receiving treatment with romiplostim or eltrombopag may change to avatrombopag under this restriction.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Severe thrombocytopenia

Treatment Phase: Grandfather treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 July 2023, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a sustained platelet response to the non-PBS-subsidised treatment with this drug for this condition, **AND**

- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) details of a platelet count supporting the diagnosis of ITP.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following criteria indicate failure to achieve an adequate response to corticosteroid and/or immunoglobulin therapy and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The platelet count must have been no more than 4 weeks old at the time that non-PBS-subsidised treatment with this drug was initiated and must be documented in the patient's medical records.

For the purposes of this restriction, a sustained response is defined as the patient having the ability to maintain a platelet count sufficient to prevent clinically significant bleeding based on clinical assessment.

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 First Continuing treatment or Re-initiation of interrupted continuing treatment criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

avatrombopag 20 mg tablet, 30

13317X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	2649.43	Doptelet [ZO]

■ ELTROMBOPAG

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe thrombocytopenia

Treatment Phase: Initial treatment - New patient

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The following criteria indicate failure to achieve an adequate response to corticosteroid and/or immunoglobulin therapy and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) details of a platelet count supporting the diagnosis of ITP.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The platelet count must be no more than 4 weeks old at the time of application and must 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. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction if the patient has not had a treatment break, confirmed through a pathology report from an Approved Pathology Authority; OR
- Patient must have changed treatment from either romiplostim or avatrombopag to this drug under the Balance of Supply/Change of therapy restriction and demonstrated a sustained response; OR

- Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, confirmed through a pathology report from an Approved Pathology Authority, **AND**
 - The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.
- For the purposes of this restriction, a sustained response is defined as the patient having the ability to maintain a platelet count sufficient to prevent clinically significant bleeding based on clinical assessment.
- The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug and must be documented in the patient's medical records.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Severe thrombocytopenia

Treatment Phase: Second or Subsequent Continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
 - Patient must have previously received PBS-subsidised treatment with this drug for this condition under first continuing or re-initiation of interrupted continuing treatment restriction, **AND**
 - Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug, **AND**
 - The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.
- The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Severe thrombocytopenia

Treatment Phase: Balance of supply or change of therapy

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
 - The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
 - Patient must have received insufficient therapy with this drug for this condition under the Initial treatment restriction; OR
 - Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction; OR
 - Patient must have received insufficient therapy with this drug for this condition under the Second or Subsequent Continuing treatment restriction; OR
 - Patient must be changing therapy from romiplostim or avatrombopag to this drug for this condition, **AND**
 - The treatment must provide no more than the balance of up to 24 weeks treatment under this restriction.
- Patients receiving treatment with romiplostim or avatrombopag may change to eltrombopag under this restriction.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

eltrombopag 25 mg tablet, 28

5827Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1276.49	Revolade [NV]

▪ ELTROMBOPAG

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe thrombocytopenia

Treatment Phase: Initial treatment - New patient

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
 - Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy, **AND**
 - Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
 - The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.
- The following criteria indicate failure to achieve an adequate response to corticosteroid and/or immunoglobulin therapy and must be demonstrated at the time of initial application;
- (a) a platelet count of less than or equal to 20,000 million per L; OR
- (b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.
- The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:
- (a) details of a platelet count supporting the diagnosis of ITP.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The platelet count must be no more than 4 weeks old at the time of application and must 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. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
 - Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction if the patient has not had a treatment break, confirmed through a pathology report from an Approved Pathology Authority; OR
 - Patient must have changed treatment from either romiplostim or avatrombopag to this drug under the Balance of Supply/Change of therapy restriction and demonstrated a sustained response; OR
 - Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, confirmed through a pathology report from an Approved Pathology Authority, **AND**
 - The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.
- For the purposes of this restriction, a sustained response is defined as the patient having the ability to maintain a platelet count sufficient to prevent clinically significant bleeding based on clinical assessment.
The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug and must be documented in the patient's medical records.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Severe thrombocytopenia

Treatment Phase: Second or Subsequent Continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
 - Patient must have previously received PBS-subsidised treatment with this drug for this condition under first continuing or re-initiation of interrupted continuing treatment restriction, **AND**
 - Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug, **AND**
 - The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.
- The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Severe thrombocytopenia

Treatment Phase: Balance of supply or change of therapy

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment restriction; OR
- Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction; OR
- Patient must have received insufficient therapy with this drug for this condition under the Second or Subsequent Continuing treatment restriction; OR
- Patient must be changing therapy from romiplostim or avatrombopag to this drug for this condition, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment under this restriction.

Patients receiving treatment with romiplostim or avatrombopag may change to eltrombopag under this restriction.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

eltrombopag 50 mg tablet, 28

5828R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	2504.61	Revolade [NV]

▪ ETANERCEPT

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patients with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to Severe active juvenile idiopathic arthritis.

Treatment cycles:

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12 month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of to the current treatment should be

conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum number of repeats may be authorised.

Note No increase in the maximum quantity or number of units may be authorised.

Authority required (STREAMLINED)

14155

Severe active juvenile idiopathic arthritis

Treatment Phase: 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.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

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).

The assessment of response to treatment must be documented in the patient's medical records.

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 provided with the initial treatment application.

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.

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 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 they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

13295R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	395.05	Enbrel [PF]

■ ETANERCEPT

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patients with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to Severe active juvenile idiopathic arthritis.

Treatment cycles:

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12 month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Note No increase in the maximum number of repeats may be authorised.

Note No increase in the maximum quantity or number of units may be authorised.

Authority required (STREAMLINED)

14155

Severe active juvenile idiopathic arthritis

Treatment Phase: 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.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

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).

The assessment of response to treatment must be documented in the patient's medical records.

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 provided with the initial treatment application.

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.

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 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 they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

13326J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	781.71	^a Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

13332Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	781.71	^a Enbrel [PF]

▪ ETANERCEPT

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patients with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to Severe active juvenile idiopathic arthritis.

Treatment cycles:

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12 month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months

who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

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 not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

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 documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; OR
- (b) at least 4 active joints from the following list:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic arthritis; and
- (b) details of prior treatment including dose and duration of treatment.

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 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.

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.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

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).

The assessment of response to treatment must be documented in the patient's medical records.

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 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the 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 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 prescribed 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 they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active joints are defined as:

(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).

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

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 active joints, the response must be demonstrated on the total number of active joints.

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 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic arthritis; and
- (b) the date of the last continuing prescription.

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 details of the 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 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.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient 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 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

6367D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	395.05	Enbrel [PF]

▪ ETANERCEPT

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patients with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to Severe active juvenile idiopathic arthritis.

Treatment cycles:

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12 month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same

treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

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 not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

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 documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) details of prior treatment including dose and duration of treatment.

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 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.

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.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

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).

The assessment of response to treatment must be documented in the patient's medical records.

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 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the 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 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 prescribed 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 they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active joints are defined as:

- (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).

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

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 active joints, the response must be demonstrated on the total number of active joints.

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 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic arthritis; and
- (b) the date of the last continuing prescription.

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 details of the 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 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.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient 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 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

9641K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	781.71	^a Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

9615C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	781.71	^a Enbrel [PF]

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Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be

subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 22 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

Population criteria:

- Patient must be aged 18 years or older.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed within 4 weeks prior to completing their current course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Population criteria:

- Patient must be aged 18 years or older.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

infliximab 100 mg injection, 1 vial

6397Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	272.03	^a Inflectra [PF] ^a Renflexis [OQ]	^a Remicade [JC]

▪ ROMIPLOSTIM

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe thrombocytopenia

Treatment Phase: Initial treatment - New patient

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The following criteria indicate failure to achieve an adequate response to corticosteroid and/or immunoglobulin therapy and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The medical practitioner should request 1 vial of the appropriate strength, to titrate therapy based on the weight of the patient. A maximum of 5 repeats will be authorised.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment, may be requested under the Balance of supply or change of therapy restriction. The total period of treatment authorised under this restriction must not exceed 24 weeks.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) details of a platelet count supporting the diagnosis of ITP.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The platelet count must be no more than 4 weeks old at the time of application and must 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. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction if the patient has not had a treatment break, confirmed through a pathology report from an Approved Pathology Authority; OR
- Patient must have changed treatment from either eltrombopag or avatrombopag to this drug under the Balance of Supply/Change of therapy restriction and demonstrated a sustained response; OR
- Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, confirmed through a pathology report from an Approved Pathology Authority, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

For the purposes of this restriction, a sustained response is defined as the patient having the ability to maintain a platelet count sufficient to prevent clinically significant bleeding based on clinical assessment.

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug and must be documented in the patient's medical records.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Severe thrombocytopenia

Treatment Phase: Second or Subsequent Continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under first continuing or re-initiation of interrupted continuing treatment restriction, **AND**
- Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Severe thrombocytopenia

Treatment Phase: Balance of supply or change of therapy

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
 - The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
 - Patient must have received insufficient therapy with this drug for this condition under the Initial treatment restriction; OR
 - Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction; OR
 - Patient must have received insufficient therapy with this drug for this condition under the Second or Subsequent Continuing treatment restriction; OR
 - Patient must be changing therapy from eltrombopag or avatrombopag to this drug for this condition, **AND**
 - The treatment must provide no more than the balance of up to 24 weeks treatment under this restriction.
- Patients receiving treatment with eltrombopag or avatrombopag may change to romiplostim under this restriction.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

romiplostim 250 microgram injection, 1 vial

9697J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	522.25	Nplate [AN]

romiplostim 500 microgram injection, 1 vial

9699L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1036.14	Nplate [AN]

■ TOCILIZUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patients with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to Severe active juvenile idiopathic arthritis.

Treatment cycles:

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12 month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate

response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

14082

Severe active juvenile idiopathic arthritis

Treatment Phase: 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.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

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).

The assessment of response to treatment must be documented in the patient's medical records.

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 provided with the initial treatment application.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority approval is required 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.

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 they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

tocilizumab 80 mg/4 mL injection, 4 mL vial

13311N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*179.33	Actemra [RO]

tocilizumab 200 mg/10 mL injection, 10 mL vial

13312P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	220.25	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

13338B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	429.98	Actemra [RO]

■ TOCILIZUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

Treatment cycles:

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.

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.

Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

Prescribing under the correct 'Treatment Phase' listing for the authority application.

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.

(3) Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.

(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 provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with a biological medicine 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 documented in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

14179

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.

The assessment of response to treatment must be documented in the patient's medical records.

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 provided with the initial treatment application.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of prescribing and must be documented in the patient's medical records.

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 approval is required 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 prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

tocilizumab 200 mg/10 mL injection, 10 mL vial

13329M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*432.13	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

13323F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*851.59	Actemra [RO]

■ TOCILIZUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

Treatment cycles:

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.

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.

Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

Prescribing under the correct 'Treatment Phase' listing for the authority application.

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.

(3) Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.

(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 provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with a biological medicine 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 documented in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

14179

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.

The assessment of response to treatment must be documented in the patient's medical records.

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 provided with the initial treatment application.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of prescribing and must be documented in the patient's medical records.

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 approval is required 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 prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

tocilizumab 80 mg/4 mL injection, 4 mL vial

13315T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	5	..	*350.29	Actemra [RO]

■ TOCILIZUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

Treatment cycles:

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.

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.

Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

Prescribing under the correct 'Treatment Phase' listing for the authority application.

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.

(3) Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.

(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 provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with a biological medicine 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 documented in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

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 assessment of response to prior treatment must be documented in the patient's medical records.

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 assessment of response to prior treatment must be documented in the patient's medical records.

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 documented in the patient's medical records.

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 documented in the patient's medical records.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active systemic juvenile idiopathic arthritis; and
- (b) the details of prior treatment including dose and duration of treatment.

The following reports must be documented in the patient's medical records where appropriate:

- (a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

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 approval is required for each strength requested.

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.

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.

The assessment of response to treatment must be documented in the patient's medical records.

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 approval is required for each strength requested.

The following reports must be documented in the patient's medical records where appropriate:

- (a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to retial or recommence therapy with this drug, must be accompanied by details of the 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 prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

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 at least one of: (a) an active joint count of at least 20 active (swollen and tender) joints; (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); 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 following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active systemic juvenile idiopathic arthritis.

The following reports must be documented in the patient's medical records where appropriate:

(a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

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 approval is required for each strength requested.

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 details of the 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.

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.

tocilizumab 80 mg/4 mL injection, 4 mL vial

1419Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	94.56	Actemra [RO]

tocilizumab 200 mg/10 mL injection, 10 mL vial

1423X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	220.25	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

1464C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	429.98	Actemra [RO]

■ TOCILIZUMAB**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patients with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to Severe active juvenile idiopathic arthritis.

Treatment cycles:

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12 month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

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 not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

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 documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; OR
- (b) at least 4 active joints from the following list:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic arthritis; and
- (b) details of prior treatment including dose and duration of treatment.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority approval is required 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.

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.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**

- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

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).

The assessment of response to treatment must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority approval is required 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 change 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 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 they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active joints are defined as:

- (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).

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

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 active joints, the response must be demonstrated on the total number of active joints.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority approval is required for each strength requested. Up to a maximum of 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic arthritis; and
- (b) the date of the last continuing prescription.

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 details of the 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 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.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient 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 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

tocilizumab 80 mg/4 mL injection, 4 mL vial

10068X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	94.56	Actemra [RO]

tocilizumab 200 mg/10 mL injection, 10 mL vial

10079L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	220.25	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

10060L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	429.98	Actemra [RO]

■ TOCILIZUMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**

- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**

- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 5 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

tocilizumab 80 mg/4 mL injection, 4 mL vial

9671B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	94.56	Actemra [RO]

tocilizumab 200 mg/10 mL injection, 10 mL vial

9672C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	220.25	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

9673D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	429.98	Actemra [RO]

Highly Specialised Drugs Program (Public Hospital)

▪ ABATACEPT

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply

treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment. Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion.

Up to a maximum of 4 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months).

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion.

Up to a maximum of 4 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

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Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

abatacept 250 mg injection, 1 vial

5605B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	262.40	Orencia [BQ]

■ ADALIMUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patients with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to Severe active juvenile idiopathic arthritis.

Treatment cycles:

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12 month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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 No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

14136

Severe active juvenile idiopathic arthritis

Treatment Phase: 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.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

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).

The assessment of response to treatment must be documented in the patient's medical records.

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 provided with the initial treatment application.

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 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 they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13228F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	618.90	^a Humira [VE]	^a Yuflyma [EW]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

12348X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	761.98	^a Amgevita [XT] ^a Hyrimoz [SZ]	^a Hadlima [RF] ^a Idacio [PK]

■ ADALIMUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patients with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to Severe active juvenile idiopathic arthritis. Treatment cycles:

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12 month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine

therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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 No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

14136

Severe active juvenile idiopathic arthritis

Treatment Phase: 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.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

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).

The assessment of response to treatment must be documented in the patient's medical records.

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 provided with the initial treatment application.

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 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 they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13212J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	618.90	^a Humira [VE]	^a Yuflyma [EW]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	761.98	^a Amgevita [XT]	^a Hadlima [RF]

■ ADALIMUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patients with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to Severe active juvenile idiopathic arthritis.

Treatment cycles:

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12 month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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 No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

14136

Severe active juvenile idiopathic arthritis

Treatment Phase: 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.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

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).

The assessment of response to treatment must be documented in the patient's medical records.

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 provided with the initial treatment application.

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 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 they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes

13293P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	618.90	^a Humira [VE]

adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe

12417M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*761.98	^a Amgevita [XT]

■ ADALIMUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patients with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to Severe active juvenile idiopathic arthritis.

Treatment cycles:

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12 month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

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 not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

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 documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) details of prior treatment including dose and duration of treatment.

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 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.

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.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

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).

The assessment of response to treatment must be documented in the patient's medical records.

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 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the 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 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 they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active joints are defined as:

- (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).

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

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 active joints, the response must be demonstrated on the total number of active joints.

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 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic; and
- (b) the date of the last continuing prescription.

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 details of the 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 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.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient 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 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12431G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	618.90	^a Humira [VE]	^a Yuflyma [EW]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9662M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	761.98	^a Amgevita [XT] ^a Hyrimoz [SZ]	^a Hadlima [RF] ^a Idacio [PK]

■ ADALIMUMAB**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patients with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to Severe active juvenile idiopathic arthritis.

Treatment cycles:

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12 month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of to the current treatment should be

conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

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 not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

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 documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; OR
- (b) at least 4 active joints from the following list:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic arthritis; and
- (b) details of prior treatment including dose and duration of treatment.

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 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.

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.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

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).

The assessment of response to treatment must be documented in the patient's medical records.

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 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the 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 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 they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active joints are defined as:

(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).

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

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 active joints, the response must be demonstrated on the total number of active joints.

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 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic; and
- (b) the date of the last continuing prescription.

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 details of the 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 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.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient 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 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12444Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	618.90	^a Humira [VE]	^a Yuflyma [EW]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9663N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	761.98	^a Amgevita [XT] ^a Hyrimoz [SZ]	^a Hadlima [RF] ^a Idacio [PK]

■ ADALIMUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patients with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to Severe active juvenile idiopathic arthritis.

Treatment cycles:

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12 month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz or Idacio is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note 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.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

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 not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

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 documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; OR
- (b) at least 4 active joints from the following list:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic arthritis; and
- (b) details of prior treatment including dose and duration of treatment.

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 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.

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.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

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).

The assessment of response to treatment must be documented in the patient's medical records.

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 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the 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 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 they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active joints are defined as:

(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).

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

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 active joints, the response must be demonstrated on the total number of active joints.

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 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic; and

(b) the date of the last continuing prescription.

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 details of the 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 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.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient 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 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes

12406Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	618.90	^a Humira [VE]

adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe

12435L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	..	..	*761.98	^a Amgevita [XT]

■ AVATROMBOPAG

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe thrombocytopenia

Treatment Phase: Initial treatment - New patient

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The following criteria indicate failure to achieve an adequate response to corticosteroid and/or immunoglobulin therapy and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) details of a platelet count supporting the diagnosis of ITP.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
 - Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment or Grandfather treatment restriction if the patient has not had a treatment break, confirmed through a pathology report from an Approved Pathology Authority; OR
 - Patient must have changed treatment from either romiplostim or eltrombopag to this drug under the Balance of Supply/Change of Therapy restriction and demonstrated a sustained response; OR
 - Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, confirmed through a pathology report from an Approved Pathology Authority, **AND**
 - The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.
- For the purposes of this restriction, a sustained response is defined as the patient having the ability to maintain a platelet count sufficient to prevent clinically significant bleeding based on clinical assessment.
- The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug and must be documented in the patient's medical records.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Severe thrombocytopenia

Treatment Phase: Second or Subsequent Continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under first continuing or re-initiation of interrupted continuing treatment restriction, **AND**
- Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Severe thrombocytopenia

Treatment Phase: Balance of supply or change of therapy

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment restriction; OR
- Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction; OR
- Patient must have received insufficient therapy with this drug for this condition under the Second or Subsequent Continuing treatment restriction; OR
- Patient must have received insufficient therapy with this drug for this condition under the Grandfather treatment restriction; OR
- Patient must be changing therapy from romiplostim or eltrombopag to this drug for this condition, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment under this restriction.

Patients receiving treatment with romiplostim or eltrombopag may change to avatrombopag under this restriction.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Severe thrombocytopenia

Treatment Phase: Grandfather treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 July 2023, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a sustained platelet response to the non-PBS-subsidised treatment with this drug for this condition, **AND**

- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) details of a platelet count supporting the diagnosis of ITP.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following criteria indicate failure to achieve an adequate response to corticosteroid and/or immunoglobulin therapy and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The platelet count must have been no more than 4 weeks old at the time that non-PBS-subsidised treatment with this drug was initiated and must be documented in the patient's medical records.

For the purposes of this restriction, a sustained response is defined as the patient having the ability to maintain a platelet count sufficient to prevent clinically significant bleeding based on clinical assessment.

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 First Continuing treatment or Re-initiation of interrupted continuing treatment criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

avatrombopag 20 mg tablet, 30

13313Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	2601.06	Doptelet [ZO]

■ ELTROMBOPAG

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe thrombocytopenia

Treatment Phase: Initial treatment - New patient

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The following criteria indicate failure to achieve an adequate response to corticosteroid and/or immunoglobulin therapy and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) details of a platelet count supporting the diagnosis of ITP.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The platelet count must be no more than 4 weeks old at the time of application and must 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. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction if the patient has not had a treatment break, confirmed through a pathology report from an Approved Pathology Authority; OR
- Patient must have changed treatment from either romiplostim or avatrombopag to this drug under the Balance of Supply/Change of therapy restriction and demonstrated a sustained response; OR

- Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, confirmed through a pathology report from an Approved Pathology Authority, **AND**
 - The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.
- For the purposes of this restriction, a sustained response is defined as the patient having the ability to maintain a platelet count sufficient to prevent clinically significant bleeding based on clinical assessment.
- The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug and must be documented in the patient's medical records.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Severe thrombocytopenia

Treatment Phase: Second or Subsequent Continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
 - Patient must have previously received PBS-subsidised treatment with this drug for this condition under first continuing or re-initiation of interrupted continuing treatment restriction, **AND**
 - Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug, **AND**
 - The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.
- The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Severe thrombocytopenia

Treatment Phase: Balance of supply or change of therapy

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
 - The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
 - Patient must have received insufficient therapy with this drug for this condition under the Initial treatment restriction; OR
 - Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction; OR
 - Patient must have received insufficient therapy with this drug for this condition under the Second or Subsequent Continuing treatment restriction; OR
 - Patient must be changing therapy from romiplostim or avatrombopag to this drug for this condition, **AND**
 - The treatment must provide no more than the balance of up to 24 weeks treatment under this restriction.
- Patients receiving treatment with romiplostim or avatrombopag may change to eltrombopag under this restriction.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

eltrombopag 25 mg tablet, 28

5825N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1228.12	Revolade [NV]

▪ ELTROMBOPAG

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe thrombocytopenia

Treatment Phase: Initial treatment - New patient

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
 - Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy, **AND**
 - Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
 - The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.
- The following criteria indicate failure to achieve an adequate response to corticosteroid and/or immunoglobulin therapy and must be demonstrated at the time of initial application;
- (a) a platelet count of less than or equal to 20,000 million per L; OR
- (b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.
- The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:
- (a) details of a platelet count supporting the diagnosis of ITP.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The platelet count must be no more than 4 weeks old at the time of application and must 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. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
 - Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction if the patient has not had a treatment break, confirmed through a pathology report from an Approved Pathology Authority; OR
 - Patient must have changed treatment from either romiplostim or avatrombopag to this drug under the Balance of Supply/Change of therapy restriction and demonstrated a sustained response; OR
 - Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, confirmed through a pathology report from an Approved Pathology Authority, **AND**
 - The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.
- For the purposes of this restriction, a sustained response is defined as the patient having the ability to maintain a platelet count sufficient to prevent clinically significant bleeding based on clinical assessment.
The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug and must be documented in the patient's medical records.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Severe thrombocytopenia

Treatment Phase: Second or Subsequent Continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
 - Patient must have previously received PBS-subsidised treatment with this drug for this condition under first continuing or re-initiation of interrupted continuing treatment restriction, **AND**
 - Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug, **AND**
 - The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.
- The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Severe thrombocytopenia

Treatment Phase: Balance of supply or change of therapy

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment restriction; OR
- Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction; OR
- Patient must have received insufficient therapy with this drug for this condition under the Second or Subsequent Continuing treatment restriction; OR
- Patient must be changing therapy from romiplostim or avatrombopag to this drug for this condition, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment under this restriction.

Patients receiving treatment with romiplostim or avatrombopag may change to eltrombopag under this restriction.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

eltrombopag 50 mg tablet, 28

5826P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	2456.24	Revolade [NV]

▪ ETANERCEPT

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patients with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to Severe active juvenile idiopathic arthritis.

Treatment cycles:

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12 month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of to the current treatment should be

conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum number of repeats may be authorised.

Note No increase in the maximum quantity or number of units may be authorised.

Authority required (STREAMLINED)

14154

Severe active juvenile idiopathic arthritis

Treatment Phase: 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.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

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).

The assessment of response to treatment must be documented in the patient's medical records.

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 provided with the initial treatment application.

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.

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 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 they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

13294Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	371.81	Enbrel [PF]

■ ETANERCEPT

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patients with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to Severe active juvenile idiopathic arthritis.

Treatment cycles:

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12 month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Note No increase in the maximum number of repeats may be authorised.

Note No increase in the maximum quantity or number of units may be authorised.

Authority required (STREAMLINED)

14154

Severe active juvenile idiopathic arthritis

Treatment Phase: 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.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

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).

The assessment of response to treatment must be documented in the patient's medical records.

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 provided with the initial treatment application.

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.

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 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 they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

13319B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	743.60	^a Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

13308K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	743.60	^a Enbrel [PF]

▪ ETANERCEPT

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patients with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to Severe active juvenile idiopathic arthritis.

Treatment cycles:

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12 month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months

who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

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 not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

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 documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; OR
- (b) at least 4 active joints from the following list:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic arthritis; and
- (b) details of prior treatment including dose and duration of treatment.

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 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.

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.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

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).

The assessment of response to treatment must be documented in the patient's medical records.

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 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the 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 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 prescribed 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 they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active joints are defined as:

(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).

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

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 active joints, the response must be demonstrated on the total number of active joints.

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 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic arthritis; and
- (b) the date of the last continuing prescription.

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 details of the 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 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.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or commencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or commencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

5734T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	371.81	Enbrel [PF]

▪ ETANERCEPT

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patients with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to Severe active juvenile idiopathic arthritis.

Treatment cycles:

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12 month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same

treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

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 not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

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 documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) details of prior treatment including dose and duration of treatment.

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 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.

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.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

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).

The assessment of response to treatment must be documented in the patient's medical records.

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 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the 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 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 prescribed 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 they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active joints are defined as:

- (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).

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

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 active joints, the response must be demonstrated on the total number of active joints.

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 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic arthritis; and
- (b) the date of the last continuing prescription.

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 details of the 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 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.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient 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 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

5735W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	743.60	^a Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL syringes

5733R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	743.60	^a Enbrel [PF]

■ INFILIXIMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be

subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 22 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

Population criteria:

- Patient must be aged 18 years or older.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed within 4 weeks prior to completing their current course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Population criteria:

- Patient must be aged 18 years or older.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

infliximab 100 mg injection, 1 vial

5757B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	253.52	^a Inflectra [PF] ^a Renflexis [OQ]	^a Remicade [JC]

▪ ROMIPLOSTIM

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe thrombocytopenia

Treatment Phase: Initial treatment - New patient

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The following criteria indicate failure to achieve an adequate response to corticosteroid and/or immunoglobulin therapy and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The medical practitioner should request 1 vial of the appropriate strength, to titrate therapy based on the weight of the patient. A maximum of 5 repeats will be authorised.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment, may be requested under the Balance of supply or change of therapy restriction. The total period of treatment authorised under this restriction must not exceed 24 weeks.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) details of a platelet count supporting the diagnosis of ITP.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The platelet count must be no more than 4 weeks old at the time of application and must 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. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction if the patient has not had a treatment break, confirmed through a pathology report from an Approved Pathology Authority; OR
- Patient must have changed treatment from either eltrombopag or avatrombopag to this drug under the Balance of Supply/Change of therapy restriction and demonstrated a sustained response; OR
- Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, confirmed through a pathology report from an Approved Pathology Authority, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

For the purposes of this restriction, a sustained response is defined as the patient having the ability to maintain a platelet count sufficient to prevent clinically significant bleeding based on clinical assessment.

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug and must be documented in the patient's medical records.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Severe thrombocytopenia

Treatment Phase: Second or Subsequent Continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under first continuing or re-initiation of interrupted continuing treatment restriction, **AND**
- Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Severe thrombocytopenia

Treatment Phase: Balance of supply or change of therapy

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
 - The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
 - Patient must have received insufficient therapy with this drug for this condition under the Initial treatment restriction; OR
 - Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction; OR
 - Patient must have received insufficient therapy with this drug for this condition under the Second or Subsequent Continuing treatment restriction; OR
 - Patient must be changing therapy from eltrombopag or avatrombopag to this drug for this condition, **AND**
 - The treatment must provide no more than the balance of up to 24 weeks treatment under this restriction.
- Patients receiving treatment with eltrombopag or avatrombopag may change to romiplostim under this restriction.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

romiplostim 250 microgram injection, 1 vial

9696H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	494.12	Nplate [AN]

romiplostim 500 microgram injection, 1 vial

9698K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	988.24	Nplate [AN]

■ TOCILIZUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patients with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to Severe active juvenile idiopathic arthritis.

Treatment cycles:

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12 month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate

response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

14164

Severe active juvenile idiopathic arthritis

Treatment Phase: 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.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

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).

The assessment of response to treatment must be documented in the patient's medical records.

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 provided with the initial treatment application.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority approval is required 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.

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 they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

tocilizumab 80 mg/4 mL injection, 4 mL vial

13324G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*164.38	Actemra [RO]

tocilizumab 200 mg/10 mL injection, 10 mL vial

13305G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	203.73	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

13339C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	405.39	Actemra [RO]

■ TOCILIZUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

Treatment cycles:

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.

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.

Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

Prescribing under the correct 'Treatment Phase' listing for the authority application.

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.

(3) Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.

(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 provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with a biological medicine 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 documented in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

14093

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.

The assessment of response to treatment must be documented in the patient's medical records.

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 provided with the initial treatment application.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of prescribing and must be documented in the patient's medical records.

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 approval is required 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 prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

tocilizumab 200 mg/10 mL injection, 10 mL vial

13330N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*407.46	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

13299Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*810.78	Actemra [RO]

■ TOCILIZUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

Treatment cycles:

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.

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.

Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

Prescribing under the correct 'Treatment Phase' listing for the authority application.

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.

(3) Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.

(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 provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with a biological medicine 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 documented in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

14093

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.

The assessment of response to treatment must be documented in the patient's medical records.

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 provided with the initial treatment application.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of prescribing and must be documented in the patient's medical records.

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 approval is required 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 prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

tocilizumab 80 mg/4 mL injection, 4 mL vial

13304F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	5	..	*328.76	Actemra [RO]

■ TOCILIZUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

Treatment cycles:

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.

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.

Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

Prescribing under the correct 'Treatment Phase' listing for the authority application.

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.

(3) Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.

(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 provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with a biological medicine 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 documented in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

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 assessment of response to prior treatment must be documented in the patient's medical records.

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 assessment of response to prior treatment must be documented in the patient's medical records.

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 documented in the patient's medical records.

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 documented in the patient's medical records.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active systemic juvenile idiopathic arthritis; and
- (b) the details of prior treatment including dose and duration of treatment.

The following reports must be documented in the patient's medical records where appropriate:

- (a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

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 approval is required for each strength requested.

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.

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.

The assessment of response to treatment must be documented in the patient's medical records.

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 approval is required for each strength requested.

The following reports must be documented in the patient's medical records where appropriate:

- (a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to retial or recommence therapy with this drug, must be accompanied by details of the 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 prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

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 at least one of: (a) an active joint count of at least 20 active (swollen and tender) joints; (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); 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 following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active systemic juvenile idiopathic arthritis.

The following reports must be documented in the patient's medical records where appropriate:

(a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

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 approval is required for each strength requested.

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 details of the 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.

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.

tocilizumab 80 mg/4 mL injection, 4 mL vial

1476Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	82.19	Actemra [RO]

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	Actemra [RO]

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	Actemra [RO]

■ TOCILIZUMAB**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patients with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to Severe active juvenile idiopathic arthritis.

Treatment cycles:

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12 month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

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 not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

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 documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; OR
- (b) at least 4 active joints from the following list:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic arthritis; and
- (b) details of prior treatment including dose and duration of treatment.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority approval is required 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.

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.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**

- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

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).

The assessment of response to treatment must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority approval is required 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 change 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 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 they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active joints are defined as:

- (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).

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

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 active joints, the response must be demonstrated on the total number of active joints.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority approval is required for each strength requested. Up to a maximum of 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic arthritis; and
- (b) the date of the last continuing prescription.

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 details of the 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 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.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient 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 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

tocilizumab 80 mg/4 mL injection, 4 mL vial

10077J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	82.19	Actemra [RO]

tocilizumab 200 mg/10 mL injection, 10 mL vial

10056G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	203.73	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

10064Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	405.39	Actemra [RO]

■ TOCILIZUMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy.

Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not provided with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Indicate where this has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**

- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**

- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 5 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

tocilizumab 80 mg/4 mL injection, 4 mL vial

9657G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	82.19	Actemra [RO]

tocilizumab 200 mg/10 mL injection, 10 mL vial

9658H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	203.73	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

9659J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	405.39	Actemra [RO]

Highly Specialised Drugs Program (Community Access)

■ BUPRENORPHINE

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

14157

Opioid dependence

Clinical criteria:

- The treatment must be within a framework of medical, social and psychological treatment.
- A medical practitioner must request a quantity sufficient for up to 28 days of supply per dispensing according to the patient's daily dose. Up to 2 repeats will be authorised. A medical practitioner must not request the maximum listed quantity or number of repeats if lesser quantity or repeats are sufficient for the patient's needs.

buprenorphine 400 microgram sublingual tablet, 7

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13310M	4	2	..	*35.47	30.00	Subutex [IR]

NP

buprenorphine 2 mg sublingual tablet, 7

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13336X	12	2	..	*119.39	30.00	Subutex [IR]

NP

buprenorphine 8 mg sublingual tablet, 7

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13337Y	16	2	..	*412.75	30.00	Subutex [IR]

NP

■ BUPRENORPHINE

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

14139

Opioid dependence

Treatment criteria:

- Must be treated by a health care professional.

Clinical criteria:

- The treatment must be within a framework of medical, social and psychological treatment, **AND**
- Patient must be stabilised on one of the following prior to commencing treatment with this drug for this condition: (i) weekly prolonged release buprenorphine (Buvidal Weekly) (ii) sublingual buprenorphine (iii) buprenorphine/naloxone.

buprenorphine 160 mg/0.45 mL modified release injection, 0.45 mL syringe

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13303E	1	2	..	378.71	30.00	Buvidal Monthly [UR]

NP

buprenorphine 128 mg/0.36 mL modified release injection, 0.36 mL syringe

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13302D	1	2	..	378.71	30.00	Buvidal Monthly [UR]

NP

buprenorphine 64 mg/0.18 mL modified release injection, 0.18 mL syringe

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13298X 	1	2	..	378.71	30.00	Buvidal Monthly [UR]

buprenorphine 96 mg/0.27 mL modified release injection, 0.27 mL syringe

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13309L 	1	2	..	378.71	30.00	Buvidal Monthly [UR]

■ BUPRENORPHINE

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)**14138**

Opioid dependence

Treatment criteria:

- Must be treated by a health care professional.

Clinical criteria:

- The treatment must be within a framework of medical, social and psychological treatment, **AND**
- Patient must be stabilised on sublingual buprenorphine or buprenorphine/naloxone prior to commencing treatment with this drug for this condition.

buprenorphine 100 mg/0.5 mL modified release injection, 0.5 mL syringe

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13320C 	±1	2	..	378.71	30.00	Sublocade [IR]

buprenorphine 300 mg/1.5 mL modified release injection, 1.5 mL syringe

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13327K 	±1	2	..	378.71	30.00	Sublocade [IR]

■ BUPRENORPHINE

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)**14075**

Opioid dependence

Treatment criteria:

- Must be treated by a health care professional.

Clinical criteria:

- The treatment must be within a framework of medical, social and psychological treatment.

buprenorphine 16 mg/0.32 mL modified release injection, 0.32 mL syringe

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13297W 	4	2	..	*378.71	30.00	Buvidal Weekly [UR]

buprenorphine 24 mg/0.48 mL modified release injection, 0.48 mL syringe

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13296T 	4	2	..	*378.71	30.00	Buvidal Weekly [UR]

buprenorphine 8 mg/0.16 mL modified release injection, 0.16 mL syringe

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13328L 	4	2	..	*378.71	30.00	Buvidal Weekly [UR]

■ BUPRENORPHINE

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note No increase in the maximum number of repeats may be authorised.

Note No increase in the maximum quantity or number of units may be authorised.

Authority required (STREAMLINED)

14075

Opioid dependence

Treatment criteria:

- Must be treated by a health care professional.

Clinical criteria:

- The treatment must be within a framework of medical, social and psychological treatment.

buprenorphine 32 mg/0.64 mL modified release injection, 0.64 mL syringe

13314R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	2	..	*378.71	30.00	Buvidal Weekly [UR]

▪ **BUPRENORPHINE + NALOXONE**

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

14074

Opioid dependence

Clinical criteria:

- The treatment must be within a framework of medical, social and psychological treatment.

A medical practitioner must request a quantity sufficient for up to 28 days of supply per dispensing according to the patient's daily dose. Up to 2 repeats will be authorised. A medical practitioner must not request the maximum listed quantity or number of repeats if lesser quantity or repeats are sufficient for the patient's needs.

buprenorphine 2 mg + naloxone 500 microgram sublingual film, 28

13322E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	2	..	*157.70	30.00	Suboxone Film 2/0.5 [IR]

buprenorphine 8 mg + naloxone 2 mg sublingual film, 28

13321D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	2	..	*509.43	30.00	Suboxone Film 8/2 [IR]

▪ **METHADONE**

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

14178

Opioid dependence

Clinical criteria:

- The treatment must be within a framework of medical, social and psychological treatment.

A medical practitioner must request a quantity (in millilitres) sufficient for up to 28 days of supply per dispensing according to the patient's daily dose. Up to 2 repeats will be authorised. A medical practitioner must not request the maximum listed quantity or number of repeats if lesser quantity or repeats are sufficient for the patient's needs.

methadone hydrochloride 5 mg/mL oral liquid, 1 L

13333R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	0.84	2	..	*44.62	30.00	^a Aspen Methadone Syrup [AS]	^a Biodone Forte [MW]

methadone hydrochloride 5 mg/mL oral liquid, 200 mL

13334T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4.2	2	..	*50.09	30.00	^a Aspen Methadone Syrup [AS]	^a Biodone Forte [MW]

IVF Treatment Program

▪ CHORIOGONADOTROPIN ALFA

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

14124

Assisted Reproductive Technology

Clinical criteria:

- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

Treatment criteria:

- Patient must not be undergoing simultaneous treatment with this drug through another PBS program listing.

choriogonadotropin alfa 250 microgram/0.5 mL injection, 0.5 mL pen device

6182J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	59.22	30.00	Ovidrel [SG]

Repatriation Pharmaceutical Benefits Scheme

■ DRESSING LIPIDOCOLLOID MODERATE EXUDATE

13331P dressing lipidocolloid moderate exudate 10 cm x 12 cm dressing, 10

13331P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	80.25	7.30	UrgoTul Lite Border 10035710 [UG]

■ INFLIXIMAB

Note Any queries concerning the arrangements to prescribe infliximab, or requests for forms, may be directed to the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) on 1800 552 580.

Written applications for authority to prescribe infliximab should be forwarded to:

Reply Paid 9998

Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC)

Department of Veterans' Affairs

GPO Box 9998

BRISBANE QLD 4001

Authority required

Rheumatoid arthritis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a consultant physician.

Population criteria:

- Patient must be an adult.

Clinical criteria:

- Patient must have active rheumatoid arthritis, **AND**
- Patient must have a specific accepted war-caused or service-related disability of refractory rheumatoid arthritis, **AND**
- Patient must have a proven raised erythrocyte sedimentation rate (ESR) and/or C-reactive protein (CRP) level, **AND**
- Patient must have proven erosive rheumatoid arthritis without end-stage disease, **AND**
- Patient must have failed an adequate trial of methotrexate and 2 other disease modifying anti-rheumatic drugs (such as sulfasalazine, hydroxychloroquine, leflunomide or ciclosporin), unless these drugs were contraindicated or intolerance developed, **AND**
- Patient must have no history of active tuberculosis requiring treatment in the last 3 years, **AND**
- Patient must have no history of opportunistic infection in the last 2 months, **AND**
- The treatment must be in combination with methotrexate, **AND**
- The treatment must be for the reduction of signs and symptoms and prevention of structural joint damage, **AND**
- Patient must not be pregnant or breastfeeding, **AND**
- Patient must be using an effective form of contraception if female and of child-bearing age.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Infliximab (Remicade) RPBS Authority Application - Supporting Information form (contact the VAPAC on 1800 552 580 for a copy of the form).

Authority required

Rheumatoid arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a consultant physician.

Clinical criteria:

- Patient must have a specific accepted war-caused or service-related disability of refractory rheumatoid arthritis, **AND**
- Patient must have previously been issued with an authority prescription for this drug for the treatment of this condition, **AND**

- Patient must have demonstrated an improvement in ESR and/or CRP level following the initial 3 dose course of therapy, **AND**
- Patient must have achieved an ACR20 (American College of Rheumatology) response by 14 weeks after the commencement of the initial course of therapy, **AND**
- The treatment must be in combination with methotrexate.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Infliximab (Remicade) RPBS Authority Application - Supporting Information form (contact the VAPAC on 1800 552 580 for a copy of the form).

infliximab 100 mg injection, 1 vial

4284L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	285.56	7.30	Remicade [JC]

▪ **ZOPICLONE**

Restricted benefit

Insomnia

Clinical criteria:

- The treatment must be for the short-term.

zopiclone 7.5 mg tablet, 14

13307J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	20.37	7.30	Imovane [SW]