



Australian Government

Department of Health



Schedule of Pharmaceutical Benefits

Summary of Changes

Effective 1 April 2016



Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 April 2016 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	\$6.93
	Dangerous drug fee	\$2.91
	Extemporaneously-prepared	\$8.97
	Allowable additional patient charge*	\$4.33
Additional Fees (for safety net prices):	Ready-prepared	\$1.17
	Extemporaneously-prepared	\$1.53
Patient Co-payments:	General	\$38.30
	Concessional	\$6.20
Safety Net Thresholds:	General	\$1475.70
	Concessional	\$372.00
Safety Net Card Issue Fee:		\$9.61

* 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 April 2016. The Schedule is updated on the first day of each month and is available on the internet at www.pbs.gov.au.

Prescriber Bag

Additions

Addition – Brand

3472R *Dexamethasone Mylan, AF* – **DEXAMETHASONE SODIUM PHOSPHATE**, DEXAMETHASONE SODIUM PHOSPHATE Injection equivalent to 4 mg dexamethasone phosphate in 1 mL, 5

Deletions

Deletion – Brand

3472R *Dexamethasone, AF* – **DEXAMETHASONE SODIUM PHOSPHATE**, DEXAMETHASONE SODIUM PHOSPHATE Injection equivalent to 4 mg dexamethasone phosphate in 1 mL, 5

3496B *Salbutamol-GA, GN* – **SALBUTAMOL**, salbutamol 2.5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules

3497C *Salbutamol-GA, GN* – **SALBUTAMOL**, salbutamol 5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules

General Pharmaceutical Benefits

Additions

Addition – Item

10683G **AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT PHENYLALANINE**, amino acid formula with fat, carbohydrate without phenylalanine tablet: modified release, 4 x 110 g (*PKU Easy Microtabs*)

10715Y **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN**, amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 30 x 18 g sachets (*GA1 Anamix Junior*)

10693T **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE**, amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 30 x 36 g sachets (*HCU Anamix Junior*)

10730R **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, THREONINE AND VALINE AND LOW IN ISOLEUCINE**, amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid: powder for, 30 x 18 g sachets (*MMA/PA Anamix Junior*)

10736C **CITRULLINE**, citrulline 1 g tablet, 300 (*Citrulline Easy*)

10700E **GLUCOSE INDICATOR BLOOD**, glucose indicator blood strip: diagnostic, 50 (*2in1 smart glucose test strips*)

10724K **GLUCOSE INDICATOR BLOOD**, glucose indicator blood strip: diagnostic, 50 (*2in1 smart glucose test strips*)

10732W **ITRACONAZOLE**, itraconazole 50 mg capsule, 60 (*Lozanoc*)

10687L **NADROPARIN**, nadroparin calcium 1900 anti-Xa international units/0.2 mL injection, 2 x 0.2 mL syringes (*Fraxiparine*)

10735B **NADROPARIN**, nadroparin calcium 1900 anti-Xa international units/0.2 mL injection, 2 x 0.2 mL syringes (*Fraxiparine*)

10686K	NADROPARIN , nadroparin calcium 2850 anti-Xa international units/0.3 mL injection, 2 x 0.3 mL syringes (<i>Fraxiparine</i>)
10701F	NADROPARIN , nadroparin calcium 2850 anti-Xa international units/0.3 mL injection, 2 x 0.3 mL syringes (<i>Fraxiparine</i>)
10685J	NADROPARIN , nadroparin calcium 3800 anti-Xa international units/0.4 mL injection, 2 x 0.4 mL syringes (<i>Fraxiparine</i>)
10717C	NADROPARIN , nadroparin calcium 3800 anti-Xa international units/0.4 mL injection, 2 x 0.4 mL syringes (<i>Fraxiparine</i>)
10716B	NADROPARIN , nadroparin calcium 5700 anti-Xa international units/0.6 mL injection, 2 x 0.6 mL syringes (<i>Fraxiparine</i>)
10718D	NADROPARIN , nadroparin calcium 5700 anti-Xa international units/0.6 mL injection, 2 x 0.6 mL syringes (<i>Fraxiparine</i>)
10734Y	NADROPARIN , nadroparin calcium 7600 anti-Xa international units/0.8 mL injection, 2 x 0.8 mL syringes (<i>Fraxiparine</i>)
10740G	NADROPARIN , nadroparin calcium 7600 anti-Xa international units/0.8 mL injection, 2 x 0.8 mL syringes (<i>Fraxiparine</i>)
10702G	NADROPARIN , nadroparin calcium 9500 anti-Xa international units/mL injection, 2 x 1 mL syringes (<i>Fraxiparine</i>)
10733X	NADROPARIN , nadroparin calcium 9500 anti-Xa international units/mL injection, 2 x 1 mL syringes (<i>Fraxiparine</i>)
10706L	NADROPARIN , nadroparin calcium 11 400 anti-Xa international units/0.6 mL injection, 2 x 0.6 mL syringes (<i>Fraxiparine Forte</i>)
10725L	NADROPARIN , nadroparin calcium 15 200 anti-Xa international units/0.8 mL injection, 2 x 0.8 mL syringes (<i>Fraxiparine Forte</i>)
10707M	NADROPARIN , nadroparin calcium 19 000 anti-Xa international units/mL injection, 2 x 1 mL syringes (<i>Fraxiparine Forte</i>)
10731T	NETUPITANT + PALONOSETRON , netupitant 300 mg + palonosetron 500 microgram capsule, 1 (<i>Akynzeo</i>)
10703H	RITUXIMAB , rituximab 1.4 g/11.7 mL injection, 11.7 mL vial (<i>Mabthera SC</i>)
10709P	RITUXIMAB , rituximab 1.4 g/11.7 mL injection, 11.7 mL vial (<i>Mabthera SC</i>)
10719E	RITUXIMAB , rituximab 1.4 g/11.7 mL injection, 11.7 mL vial (<i>Mabthera SC</i>)
10742J	RITUXIMAB , rituximab 1.4 g/11.7 mL injection, 11.7 mL vial (<i>Mabthera SC</i>)
10694W	SUMATRIPTAN , SUMATRIPTAN Tablet 50 mg (base) (fast disintegrating), 4 (<i>Imigran FDT</i>)
10682F	TRASTUZUMAB , trastuzumab 600 mg/5 mL injection, 5 mL vial (<i>Herceptin SC</i>)
10721G	TRASTUZUMAB , trastuzumab 600 mg/5 mL injection, 5 mL vial (<i>Herceptin SC</i>)

Addition – Brand

8702B	<i>Citalopram AN, EF</i> – CITALOPRAM , citalopram 10 mg tablet, 28
10234P	<i>APO-Desvenlafaxine MR, TX</i> – DESVENLAFAXINE , desvenlafaxine 50 mg tablet: modified release, 28 tablets
10245F	<i>APO-Desvenlafaxine MR, TX</i> – DESVENLAFAXINE , desvenlafaxine 100 mg tablet: modified release, 28 tablets
2509C	<i>Dexamethasone Mylan, AF</i> – DEXAMETHASONE SODIUM PHOSPHATE , DEXAMETHASONE SODIUM PHOSPHATE Injection equivalent to 4 mg dexamethasone phosphate in 1 mL, 5
1291Y	<i>Dexamethasone Mylan, AF</i> – DEXAMETHASONE SODIUM PHOSPHATE , DEXAMETHASONE SODIUM PHOSPHATE Injection equivalent to 8 mg dexamethasone phosphate in 2 mL, 5
1394J	<i>Lenest 30 ED, AF</i> – ETHINYLOESTRADIOL + LEVONORGESTREL , ethinyloestradiol 30 microgram + levonorgestrel 150 microgram tablet [84] (&) inert substance tablet [28], 112 [4 x 28]
8816B	<i>Modafin, RW</i> – MODAFINIL , modafinil 100 mg tablet, 60
8787L	<i>Risperidone AMNEAL, EF</i> – RISPERIDONE , risperidone 500 microgram tablet, 60
8869T	<i>Risperidone AMNEAL, EF</i> – RISPERIDONE , risperidone 500 microgram tablet, 60
3169T	<i>Risperidone AMNEAL, EF</i> – RISPERIDONE , risperidone 1 mg tablet, 60
8789N	<i>Risperidone AMNEAL, EF</i> – RISPERIDONE , risperidone 1 mg tablet, 60
3170W	<i>Risperidone AMNEAL, EF</i> – RISPERIDONE , risperidone 2 mg tablet, 60
9079W	<i>Risperidone AMNEAL, EF</i> – RISPERIDONE , risperidone 2 mg tablet, 60

3171X	<i>Risperidone AMNEAL, EF</i> – RISPERIDONE , risperidone 3 mg tablet, 60
3172Y	<i>Risperidone AMNEAL, EF</i> – RISPERIDONE , risperidone 4 mg tablet, 60

Addition – Equivalence Indicator

8816B	<i>Modavigil, TB</i> – MODAFINIL , modafinil 100 mg tablet, 60
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Deletions

Deletion – Item

5561Q	CARMELLOSE SODIUM + GLYCEROL , carmellose sodium 0.5% + glycerol 0.9% eye drops, 30 x 0.4 mL unit doses (<i>Optive</i>)(Optometrical)
9307W	CARMELLOSE SODIUM + GLYCEROL , carmellose sodium 0.5% + glycerol 0.9% eye drops, 30 x 0.4 mL unit doses (<i>Optive</i>)
3065H	PINDOLOL , pindolol 15 mg tablet, 50 (<i>Visken 15</i>)

Deletion – Brand

8179L	<i>Anastrozole-GA, GN</i> – ANASTROZOLE , anastrozole 1 mg tablet, 30
8179L	<i>Anzole, UA</i> – ANASTROZOLE , anastrozole 1 mg tablet, 30
8200N	<i>Zitrocin, GN</i> – AZITHROMYCIN , azithromycin 500 mg tablet, 2
8336R	<i>Zitrocin, GN</i> – AZITHROMYCIN , azithromycin 500 mg tablet, 2
8114C	<i>Dostan, GN</i> – CABERGOLINE , cabergoline 500 microgram tablet, 8
8115D	<i>Dostan, GN</i> – CABERGOLINE , cabergoline 500 microgram tablet, 2
8393R	<i>Cobasol, GN</i> – CABERGOLINE , cabergoline 1 mg tablet, 30
8394T	<i>Cobasol, GN</i> – CABERGOLINE , cabergoline 2 mg tablet, 30
3094W	<i>Cilex, GN</i> – CEPHALEXIN , cephalexin 125 mg/5 mL oral liquid: powder for, 100 mL
3319Q	<i>Cilex, GN</i> – CEPHALEXIN , cephalexin 125 mg/5 mL oral liquid: powder for, 100 mL (Dental)
3095X	<i>Cilex, GN</i> – CEPHALEXIN , cephalexin 250 mg/5 mL oral liquid: powder for, 100 mL
3320R	<i>Cilex, GN</i> – CEPHALEXIN , cephalexin 250 mg/5 mL oral liquid: powder for, 100 mL (Dental)
9354H	<i>Clopidogrel Actavis, UA</i> – CLOPIDOGREL , clopidogrel 75 mg tablet, 28
2509C	<i>Dexamethsone, AF</i> – DEXAMETHASONE SODIUM PHOSPHATE , DEXAMETHASONE SODIUM PHOSPHATE Injection equivalent to 4 mg dexamethasone phosphate in 1 mL, 5
1291Y	<i>Dexamethsone, AF</i> – DEXAMETHASONE SODIUM PHOSPHATE , DEXAMETHASONE SODIUM PHOSPHATE Injection equivalent to 8 mg dexamethasone phosphate in 2 mL, 5
1370D	<i>Enalapril-GA, GN</i> – ENALAPRIL , enalapril maleate 5 mg tablet, 30
1368B	<i>Enalapril-GA, GN</i> – ENALAPRIL , enalapril maleate 10 mg tablet, 30
1369C	<i>Enalapril-GA, GN</i> – ENALAPRIL , enalapril maleate 20 mg tablet, 30
1834M	<i>Gabapentin-GA, UA</i> – GABAPENTIN , gabapentin 300 mg capsule, 100
1453L	<i>Gemfibrozil-GA, UA</i> – GEMFIBROZIL , gemfibrozil 600 mg tablet, 60
1453L	<i>Gemhexal, SZ</i> – GEMFIBROZIL , gemfibrozil 600 mg tablet, 60
1453L	<i>Jezil, GN</i> – GEMFIBROZIL , gemfibrozil 600 mg tablet, 60
9248R	<i>Gemfibrozil-GA, UA</i> – GEMFIBROZIL , gemfibrozil 600 mg tablet, 60
9248R	<i>Gemhexal, SZ</i> – GEMFIBROZIL , gemfibrozil 600 mg tablet, 60
9248R	<i>Jezil, GN</i> – GEMFIBROZIL , gemfibrozil 600 mg tablet, 60
2848X	<i>Torlemo DT 25, UA</i> – LAMOTRIGINE , lamotrigine 25 mg tablet, 56
2849Y	<i>Torlemo DT 50, UA</i> – LAMOTRIGINE , lamotrigine 50 mg tablet, 56
2850B	<i>Torlemo DT 100, UA</i> – LAMOTRIGINE , lamotrigine 100 mg tablet, 56
2851C	<i>Torlemo DT 200, UA</i> – LAMOTRIGINE , lamotrigine 200 mg tablet, 56
8245Y	<i>Letrozole Actavis, VN</i> – LETROZOLE , letrozole 2.5 mg tablet, 30

8245Y	<i>Letrozole-GA, GN – LETROZOLE</i> , letrozole 2.5 mg tablet, 30
3010K	<i>Norfloxacin-GA, GN – NORFLOXACIN</i> , norfloxacin 400 mg tablet, 14
8399C	<i>Torazole 20, VN – PANTOPRAZOLE</i> , pantoprazole 20 mg tablet: enteric, 30 tablets
8007K	<i>Torazole 40, VN – PANTOPRAZOLE</i> , pantoprazole 40 mg tablet: enteric, 30
8008L	<i>Torazole 40, VN – PANTOPRAZOLE</i> , pantoprazole 40 mg tablet: enteric, 30
1705R	<i>Cilopen VK, GN – PHENOXYMETHYLPENICILLIN</i> , phenoxymethylpenicillin 250 mg capsule, 50
1789E	<i>Cilopen VK, GN – PHENOXYMETHYLPENICILLIN</i> , phenoxymethylpenicillin 250 mg capsule, 50
3363B	<i>Cilopen VK, GN – PHENOXYMETHYLPENICILLIN</i> , phenoxymethylpenicillin 250 mg capsule, 50 (Dental)
2965C	<i>Cilopen VK, GN – PHENOXYMETHYLPENICILLIN</i> , phenoxymethylpenicillin 500 mg capsule, 50
3364C	<i>Cilopen VK, GN – PHENOXYMETHYLPENICILLIN</i> , phenoxymethylpenicillin 500 mg capsule, 50 (Dental)
2833D	<i>Pravastatin Actavis 10, UA – PRAVASTATIN</i> , pravastatin sodium 10 mg tablet, 30
9237E	<i>Pravastatin Actavis 10, UA – PRAVASTATIN</i> , pravastatin sodium 10 mg tablet, 30
2834E	<i>Pravastatin Actavis 20, UA – PRAVASTATIN</i> , pravastatin sodium 20 mg tablet, 30
9238F	<i>Pravastatin Actavis 20, UA – PRAVASTATIN</i> , pravastatin sodium 20 mg tablet, 30
8197K	<i>Pravastatin Actavis 40, UA – PRAVASTATIN</i> , pravastatin sodium 40 mg tablet, 30
9239G	<i>Pravastatin Actavis 40, UA – PRAVASTATIN</i> , pravastatin sodium 40 mg tablet, 30
8456C	<i>Quetiapine-GA, GN – QUETIAPINE</i> , quetiapine 25 mg tablet, 60
8457D	<i>Quetiapine-GA, GN – QUETIAPINE</i> , quetiapine 100 mg tablet, 90
8458E	<i>Quetiapine-GA, GN – QUETIAPINE</i> , quetiapine 200 mg tablet, 60
8580N	<i>Quetiapine-GA, GN – QUETIAPINE</i> , quetiapine 300 mg tablet, 60
1970Q	<i>Quinapril-GA, UA – QUINAPRIL</i> , quinapril 20 mg tablet, 30
8507R	<i>Rabeprazole-GA, GN – RABEPRAZOLE</i> , rabeprazole sodium 10 mg tablet: enteric, 28
9120B	<i>Ramipril-GA, GN – RAMIPRIL</i> , ramipril 1.25 mg capsule, 30
8787L	<i>Risperidone-GA, EF – RISPERIDONE</i> , risperidone 500 microgram tablet, 60
8869T	<i>Risperidone-GA, EF – RISPERIDONE</i> , risperidone 500 microgram tablet, 60
3169T	<i>Risperidone-GA, EF – RISPERIDONE</i> , risperidone 1 mg tablet, 60
8789N	<i>Risperidone-GA, EF – RISPERIDONE</i> , risperidone 1 mg tablet, 60
3170W	<i>Risperidone-GA, EF – RISPERIDONE</i> , risperidone 2 mg tablet, 60
9079W	<i>Risperidone-GA, EF – RISPERIDONE</i> , risperidone 2 mg tablet, 60
3171X	<i>Risperidone-GA, EF – RISPERIDONE</i> , risperidone 3 mg tablet, 60
3172Y	<i>Risperidone-GA, EF – RISPERIDONE</i> , risperidone 4 mg tablet, 60
2000G	<i>Salbutamol-GA, GN – SALBUTAMOL</i> , salbutamol 2.5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules
2001H	<i>Salbutamol-GA, GN – SALBUTAMOL</i> , salbutamol 5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules
2011W	<i>Simvastatin-DP, UA – SIMVASTATIN</i> , simvastatin 10 mg tablet, 30
9242K	<i>Simvastatin-DP, UA – SIMVASTATIN</i> , simvastatin 10 mg tablet, 30
2012X	<i>Simvastatin-DP, UA – SIMVASTATIN</i> , simvastatin 20 mg tablet, 30
9243L	<i>Simvastatin-DP, UA – SIMVASTATIN</i> , simvastatin 20 mg tablet, 30
8173E	<i>Simvastatin-DP, UA – SIMVASTATIN</i> , simvastatin 40 mg tablet, 30
9244M	<i>Simvastatin-DP, UA – SIMVASTATIN</i> , simvastatin 40 mg tablet, 30
8313M	<i>Simvastatin-DP, UA – SIMVASTATIN</i> , simvastatin 80 mg tablet, 30
9245N	<i>Simvastatin-DP, UA – SIMVASTATIN</i> , simvastatin 80 mg tablet, 30
5232J	<i>GA Tramadol 50mg, GN – TRAMADOL</i> , tramadol hydrochloride 50 mg capsule, 20 (Dental)
8455B	<i>GA Tramadol 50mg, GN – TRAMADOL</i> , tramadol hydrochloride 50 mg capsule, 20
8611F	<i>GA Tramadol 50mg, GN – TRAMADOL</i> , tramadol hydrochloride 50 mg capsule, 20

2791X	<i>Trandolapril-DP, GN</i> – TRANDOLAPRIL , trandolapril 500 microgram capsule, 28
2792Y	<i>Trandolapril-DP, GN</i> – TRANDOLAPRIL , trandolapril 1 mg capsule, 28
2793B	<i>Trandolapril-DP, GN</i> – TRANDOLAPRIL , trandolapril 2 mg capsule, 28
8758Y	<i>Trandolapril-DP, GN</i> – TRANDOLAPRIL , trandolapril 4 mg capsule, 28
5480K	<i>Valaciclovir GA, GN</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 30
8064K	<i>Valaciclovir GA, GN</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 42
8133C	<i>Valaciclovir GA, GN</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 10
8134D	<i>Valaciclovir GA, GN</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 30
8301X	<i>Venlexor XR, GN</i> – VENLAFAXINE , venlafaxine 75 mg capsule: modified release, 28 capsules
8302Y	<i>Venlexor XR, GN</i> – VENLAFAXINE , venlafaxine 150 mg capsule: modified release, 28 capsules

Deletion – Equivalence Indicator

8393R	<i>Cabaser, PF</i> – CABERGOLINE , cabergoline 1 mg tablet, 30
8394T	<i>Cabaser, PF</i> – CABERGOLINE , cabergoline 2 mg tablet, 30
1705R	<i>Cilicaine VK, FM</i> – PHENOXYMETHYLPENICILLIN , phenoxymethylpenicillin 250 mg capsule, 50
1789E	<i>Cilicaine VK, FM</i> – PHENOXYMETHYLPENICILLIN , phenoxymethylpenicillin 250 mg capsule, 50
3363B	<i>Cilicaine VK, FM</i> – PHENOXYMETHYLPENICILLIN , phenoxymethylpenicillin 250 mg capsule, 50 (Dental)
2965C	<i>Cilicaine VK, FM</i> – PHENOXYMETHYLPENICILLIN , phenoxymethylpenicillin 500 mg capsule, 50
3364C	<i>Cilicaine VK, FM</i> – PHENOXYMETHYLPENICILLIN , phenoxymethylpenicillin 500 mg capsule, 50 (Dental)

Alterations

Alteration – Restriction

The following items have additions, deletions or alterations to restrictions, notes and/or cautions.

5296R	ARTEMETHER + LUMEFANTRINE , artemether 20 mg + lumefantrine 120 mg tablet: dispersible, 18 (<i>Riamet 20mg/120mg Dispersible</i>)
9498X	ARTEMETHER + LUMEFANTRINE , artemether 20 mg + lumefantrine 120 mg tablet, 24 (<i>Riamet</i>)
9439T	ATOVAQUONE + PROGUANIL , atovaquone 250 mg + proguanil hydrochloride 100 mg tablet, 12 (<i>Malarone</i>)
8898H	CARMUSTINE , carmustine 7.7 mg implant, 8 (<i>Gladel</i>)
10003L	DABRAFENIB , dabrafenib 75 mg capsule, 120 (<i>Tafinlar</i>)
2846T	DABRAFENIB , dabrafenib 75 mg capsule, 120 (<i>Tafinlar</i>)
2954L	DABRAFENIB , dabrafenib 50 mg capsule, 120 (<i>Tafinlar</i>)
2963Y	DABRAFENIB , dabrafenib 50 mg capsule, 120 (<i>Tafinlar</i>)
9022W	FENOFIBRATE , fenofibrate 48 mg tablet, 60 (<i>Lipidil</i>)
9023X	FENOFIBRATE , fenofibrate 145 mg tablet, 30 (<i>Lipidil</i>)
9246P	FENOFIBRATE , fenofibrate 48 mg tablet, 60 (<i>Lipidil</i>)
9247Q	FENOFIBRATE , fenofibrate 145 mg tablet, 30 (<i>Lipidil</i>)
1471K	FLUCONAZOLE , fluconazole 50 mg capsule, 28 (<i>Diflucan, Dizole 50, Fluconazole Sandoz, Ozole</i>)
1472L	FLUCONAZOLE , fluconazole 100 mg capsule, 28 (<i>Diflucan, Dizole 100, Fluconazole Sandoz, Ozole</i>)
1473M	FLUCONAZOLE , fluconazole 100 mg/50 mL injection, 1 x 50 mL vial (<i>Fluconazole Hexal, Fluconazole Sandoz</i>)
1474N	FLUCONAZOLE , fluconazole 200 mg/100 mL injection, 1 x 100 mL vial (<i>Fluconazole Alphapharm, Fluconazole Hexal, Fluconazole Sandoz</i>)
1475P	FLUCONAZOLE , fluconazole 200 mg capsule, 28 (<i>APO-Fluconazole, Diflucan, Dizole 200, Fluconazole Sandoz, Fluzole 200, Ozole</i>)
1757L	FLUCONAZOLE , fluconazole 400 mg/200 mL injection, 1 x 200 mL bag (<i>Fluconazole Alphapharm</i>)
5446P	FLUCONAZOLE , fluconazole 50 mg/5 mL oral liquid: powder for, 35 mL (<i>Diflucan</i>)
2863Q	FLUVASTATIN , fluvastatin 80 mg tablet: modified release, 28 tablets (<i>Lescol XL</i>)
9236D	FLUVASTATIN , fluvastatin 80 mg tablet: modified release, 28 tablets (<i>Lescol XL</i>)

1453L	GEMFIBROZIL , gemfibrozil 600 mg tablet, 60 (<i>Ausgem, Chem mart Gemfibrozil, , GenRx Gemfibrozil, , Lipigem, Terry White Chemists Gemfibrozil</i>)
9248R	GEMFIBROZIL , gemfibrozil 600 mg tablet, 60 (<i>Ausgem, Chem mart Gemfibrozil, , GenRx Gemfibrozil, , Lipigem, Terry White Chemists Gemfibrozil</i>)
3426H	GOLIMUMAB , golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe (<i>Simponi</i>)
3427J	GOLIMUMAB , golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe (<i>Simponi</i>)
3428K	GOLIMUMAB , golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe (<i>Simponi</i>)
3429L	GOLIMUMAB , golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe (<i>Simponi</i>)
8196J	ITRACONAZOLE , itraconazole 100 mg capsule, 60 (<i>Sporanox</i>)
1616C	MINOCYCLINE , minocycline 50 mg tablet, 60 (<i>Akamin 50, Minomycin-50</i>)
8816B	MODAFINIL , modafinil 100 mg tablet, 60 (<i>Modafin, Modavigil</i>)
2833D	PRAVASTATIN , pravastatin sodium 10 mg tablet, 30 (<i>APO-Pravastatin, Auro-Pravastatin 10, Chem mart Pravastatin, Cholstat 10, Lipostat 10, Pharmacor Pravastat 10, Pravachol, Pravastatin AN, , Pravastatin Sandoz, Pravastatin generichealth, Pravastatin-GA 10, Terry White Chemists Pravastatin</i>)
2834E	PRAVASTATIN , pravastatin sodium 20 mg tablet, 30 (<i>APO-Pravastatin, Auro-Pravastatin 20, Chem mart Pravastatin, Cholstat 20, Cholvastin, Lipostat 20, Pharmacor Pravastat 20, Pravachol, Pravastatin AN, , Pravastatin Sandoz, Pravastatin generichealth, Pravastatin-GA 20, Terry White Chemists Pravastatin</i>)
8197K	PRAVASTATIN , pravastatin sodium 40 mg tablet, 30 (<i>APO-Pravastatin, Auro-Pravastatin 40, Chem mart Pravastatin, Cholstat 40, Cholvastin, Lipostat 40, Pharmacor Pravastat 40, Pravachol, Pravastatin AN, , Pravastatin Sandoz, Pravastatin generichealth, Pravastatin-GA 40, Terry White Chemists Pravastatin</i>)
8829Q	PRAVASTATIN , pravastatin sodium 80 mg tablet, 30 (<i>APO-Pravastatin, Auro-Pravastatin 80, Chem mart Pravastatin, Lipostat 80, Pravachol, Pravastatin AN, Pravastatin Sandoz, Pravastatin generichealth, Pravastatin-GA 80, Terry White Chemists Pravastatin</i>)
9237E	PRAVASTATIN , pravastatin sodium 10 mg tablet, 30 (<i>APO-Pravastatin, Auro-Pravastatin 10, Chem mart Pravastatin, Cholstat 10, Lipostat 10, Pharmacor Pravastat 10, Pravachol, Pravastatin AN, , Pravastatin Sandoz, Pravastatin generichealth, Pravastatin-GA 10, Terry White Chemists Pravastatin</i>)
9238F	PRAVASTATIN , pravastatin sodium 20 mg tablet, 30 (<i>APO-Pravastatin, Auro-Pravastatin 20, Chem mart Pravastatin, Cholstat 20, Cholvastin, Lipostat 20, Pharmacor Pravastat 20, Pravachol, Pravastatin AN, , Pravastatin Sandoz, Pravastatin generichealth, Pravastatin-GA 20, Terry White Chemists Pravastatin</i>)
9239G	PRAVASTATIN , pravastatin sodium 40 mg tablet, 30 (<i>APO-Pravastatin, Auro-Pravastatin 40, Chem mart Pravastatin, Cholstat 40, Cholvastin, Lipostat 40, Pharmacor Pravastat 40, Pravachol, Pravastatin AN, , Pravastatin Sandoz, Pravastatin generichealth, Pravastatin-GA 40, Terry White Chemists Pravastatin</i>)
9240H	PRAVASTATIN , pravastatin sodium 80 mg tablet, 30 (<i>APO-Pravastatin, Auro-Pravastatin 80, Chem mart Pravastatin, Lipostat 80, Pravachol, Pravastatin AN, Pravastatin Sandoz, Pravastatin generichealth, Pravastatin-GA 80, Terry White Chemists Pravastatin</i>)
1842Y	RISPERIDONE , risperidone 500 microgram tablet, 20 (<i>APO-Risperidone, Risperdal</i>)
8787L	RISPERIDONE , risperidone 500 microgram tablet, 60 (<i>Ozidal, Rispa, Rispericor 0.5, Risperidone AMNEAL, Risperidone AN, Risperidone Actavis 0.5, Risperidone GH, Risperidone Sandoz, Rispernia, Rixadone</i>)
8789N	RISPERIDONE , risperidone 1 mg tablet, 60 (<i>APO-Risperidone, Ozidal, Rispa, Risperdal, Rispericor 1, Risperidone AMNEAL, Risperidone AN, Risperidone Actavis 1, Risperidone Sandoz, Risperidone generichealth, Rispernia, Rixadone</i>)
9293D	RISPERIDONE , risperidone 1 mg/mL oral liquid, 100 mL (<i>Risperdal</i>)
2011W	SIMVASTATIN , simvastatin 10 mg tablet, 30 (<i>APO-Simvastatin, Auro-Simvastatin 10, Chem mart Simvastatin, GenRx Simvastatin, Lipex 10, Ransim, Simvacor 10, Simvar 10, Simvastatin AN, Simvastatin Sandoz, Simvastatin generichealth, , Simvastatin-GA 10, Terry White Chemists Simvastatin, Zimstat, Zocor</i>)
2012X	SIMVASTATIN , simvastatin 20 mg tablet, 30 (<i>APO-Simvastatin, Auro-Simvastatin 20, Chem mart Simvastatin, Lipex 20, Ransim, Simvacor 20, Simvar 20, Simvastatin AN, Simvastatin Sandoz, Simvastatin generichealth, , Simvastatin-GA 20, Terry White Chemists Simvastatin, Zimstat, Zocor</i>)
2013Y	SIMVASTATIN , simvastatin 5 mg tablet, 30 (<i>Simvastatin Sandoz, Zimstat</i>)
8173E	SIMVASTATIN , simvastatin 40 mg tablet, 30 (<i>APO-Simvastatin, Auro-Simvastatin 40, Chem mart Simvastatin, Lipex 40, Ransim, Simvacor 40, Simvar 40, Simvastatin AN, Simvastatin Sandoz, Simvastatin generichealth, , Simvastatin-GA 40, Terry White Chemists Simvastatin, Zimstat, Zocor</i>)
8313M	SIMVASTATIN , simvastatin 80 mg tablet, 30 (<i>APO-Simvastatin, Auro-Simvastatin 80, Chem mart Simvastatin, Lipex 80, Ransim, Simvacor 80, Simvar 80, Simvastatin AN, Simvastatin Sandoz, Simvastatin generichealth, , Simvastatin-GA 80, Terry White Chemists Simvastatin, Zimstat, Zocor</i>)

9241J	SIMVASTATIN , simvastatin 5 mg tablet, 30 (<i>Simvastatin Sandoz, Zimstat</i>)
9242K	SIMVASTATIN , simvastatin 10 mg tablet, 30 (<i>APO-Simvastatin, Auro-Simvastatin 10, Chem mart Simvastatin, GenRx Simvastatin, Lipex 10, Ransim, Simvacor 10, Simvar 10, Simvastatin AN, Simvastatin Sandoz, Simvastatin generichealth, , Simvastatin-GA 10, Terry White Chemists Simvastatin, Zimstat, Zocor</i>)
9243L	SIMVASTATIN , simvastatin 20 mg tablet, 30 (<i>APO-Simvastatin, Auro-Simvastatin 20, Chem mart Simvastatin, Lipex 20, Ransim, Simvacor 20, Simvar 20, Simvastatin AN, Simvastatin Sandoz, Simvastatin generichealth, , Simvastatin-GA 20, Terry White Chemists Simvastatin, Zimstat, Zocor</i>)
9244M	SIMVASTATIN , simvastatin 40 mg tablet, 30 (<i>APO-Simvastatin, Auro-Simvastatin 40, Chem mart Simvastatin, Lipex 40, Ransim, Simvacor 40, Simvar 40, Simvastatin AN, Simvastatin Sandoz, Simvastatin generichealth, , Simvastatin-GA 40, Terry White Chemists Simvastatin, Zimstat, Zocor</i>)
9245N	SIMVASTATIN , simvastatin 80 mg tablet, 30 (<i>APO-Simvastatin, Auro-Simvastatin 80, Chem mart Simvastatin, Lipex 80, Ransim, Simvacor 80, Simvar 80, Simvastatin AN, Simvastatin Sandoz, Simvastatin generichealth, , Simvastatin-GA 80, Terry White Chemists Simvastatin, Zimstat, Zocor</i>)
10382K	TRAMETINIB , trametinib 2 mg tablet, 30 (<i>Mekinist</i>)
10385N	TRAMETINIB , trametinib 500 microgram tablet, 30 (<i>Mekinist</i>)
10403M	TRAMETINIB , trametinib 500 microgram tablet, 30 (<i>Mekinist</i>)
10405P	TRAMETINIB , trametinib 2 mg tablet, 30 (<i>Mekinist</i>)

Alteration – Restriction Level

		<i>From</i>	<i>To</i>
5296R	ARTEMETHER + LUMEFANTRINE , artemether 20 mg + lumefantrine 120 mg tablet: dispersible, 18 (<i>Riamet 20mg/120mg Dispersible</i>)	authority-required	restricted
9498X	ARTEMETHER + LUMEFANTRINE , artemether 20 mg + lumefantrine 120 mg tablet, 24 (<i>Riamet</i>)	authority-required	restricted
9439T	ATOVAQUONE + PROGUANIL , atovaquone 250 mg + proguanil hydrochloride 100 mg tablet, 12 (<i>Malarone</i>)	authority-required	restricted
10003L	DABRAFENIB , dabrafenib 75 mg capsule, 120 (<i>Tafinlar</i>)	authority-required	streamlined
2846T	DABRAFENIB , dabrafenib 75 mg capsule, 120 (<i>Tafinlar</i>)	authority-required	streamlined
2954L	DABRAFENIB , dabrafenib 50 mg capsule, 120 (<i>Tafinlar</i>)	authority-required	streamlined
2963Y	DABRAFENIB , dabrafenib 50 mg capsule, 120 (<i>Tafinlar</i>)	authority-required	streamlined
1471K	FLUCONAZOLE , fluconazole 50 mg capsule, 28 (<i>Diflucan, Dizole 50, Fluconazole Sandoz, Ozole</i>)	streamlined	restricted
1472L	FLUCONAZOLE , fluconazole 100 mg capsule, 28 (<i>Diflucan, Dizole 100, Fluconazole Sandoz, Ozole</i>)	streamlined	restricted
1473M	FLUCONAZOLE , fluconazole 100 mg/50 mL injection, 1 x 50 mL vial (<i>Fluconazole Hexal, Fluconazole Sandoz</i>)	streamlined	restricted
1474N	FLUCONAZOLE , fluconazole 200 mg/100 mL injection, 1 x 100 mL vial (<i>Fluconazole Alphapharm, Fluconazole Hexal, Fluconazole Sandoz</i>)	streamlined	restricted
1475P	FLUCONAZOLE , fluconazole 200 mg capsule, 28 (<i>APO-Fluconazole, Diflucan, Dizole 200, Fluconazole Sandoz, Fluzole 200, Ozole</i>)	streamlined	restricted
1757L	FLUCONAZOLE , fluconazole 400 mg/200 mL injection, 1 x 200 mL bag (<i>Fluconazole Alphapharm</i>)	streamlined	restricted
5446P	FLUCONAZOLE , fluconazole 50 mg/5 mL oral liquid: powder for, 35 mL (<i>Diflucan</i>)	authority-required	restricted
8196J	ITRACONAZOLE , itraconazole 100 mg capsule, 60 (<i>Sporanox</i>)	streamlined	restricted
10382K	TRAMETINIB , trametinib 2 mg tablet, 30 (<i>Mekinist</i>)	authority-required	streamlined
10385N	TRAMETINIB , trametinib 500 microgram tablet, 30 (<i>Mekinist</i>)	authority-required	streamlined

10403M	TRAMETINIB , trametinib 500 microgram tablet, 30 (<i>Mekinist</i>)	authority-required	streamlined
10405P	TRAMETINIB , trametinib 2 mg tablet, 30 (<i>Mekinist</i>)	authority-required	streamlined

Alteration – Manufacturer Code

		From	To
9183H	<i>Dronalen Plus</i> – ALENDRONATE + COLECALCIFEROL , alendronate 70 mg + colecalciferol 140 microgram tablet, 4	FR	AL
9351E	<i>Dronalen Plus D-Cal</i> – ALENDRONATE + COLECALCIFEROL (&) CALCIUM CARBONATE , alendronate 70 mg + colecalciferol 140 microgram tablet [4] (&) calcium (as carbonate) 500 mg tablet [48], 1 pack	FR	AF
8855C	<i>Remeron SolTab</i> – MIRTAZAPINE , MIRTAZAPINE Tablet 15 mg (orally disintegrating), 30	FR	AF
8856D	<i>Remeron SolTab</i> – MIRTAZAPINE , MIRTAZAPINE Tablet 30 mg (orally disintegrating), 30	FR	AF
8857E	<i>Remeron SolTab</i> – MIRTAZAPINE , MIRTAZAPINE Tablet 45 mg (orally disintegrating), 30	FR	AF
1913Q	<i>Novasone</i> – MOMETASONE , mometasone furoate 0.1% (1 mg/g) cream, 15 g	FR	AF
8043H	<i>Novasone</i> – MOMETASONE , mometasone furoate 0.1% lotion, 30 mL	FR	AF
1915T	<i>Novasone</i> – MOMETASONE , mometasone furoate 0.1% ointment, 15 g	FR	AF
5295Q	<i>Aloxi</i> – PALONOSETRON , palonosetron 250 microgram/5 mL injection, 1 x 5 mL vial	TS	ZD
1952R	<i>Azilect</i> – RASAGILINE , RASAGILINE Tablet 1 mg (as mesilate), 30	LU	TB
9313E	<i>Rizatriptan Wafers-10mg</i> – RIZATRIPTAN , rizatriptan 10 mg wafer, 2	FR	AF

Alteration – Maximum Quantity

		From	To
3138E	CLINDAMYCIN , clindamycin 150 mg capsule, 24 (<i>APO-Clindamycin, Calindamin, Chem mart Clindamycin, Cleocin, Clindamycin BNM, Clindamycin-Link, Clindamyk, Dalacin C, Terry White Chemists Clindamycin</i>)	1	2
9353G	MESALAZINE , mesalazine 1.2 g tablet: modified release, 60 tablets (<i>Mezavant</i>)	1	2

Alteration – Number of Repeats

		From	To
3138E	CLINDAMYCIN , clindamycin 150 mg capsule, 24 (<i>APO-Clindamycin, Calindamin, Chem mart Clindamycin, Cleocin, Clindamycin BNM, Clindamycin-Link, Clindamyk, Dalacin C, Terry White Chemists Clindamycin</i>)	0	1
9149M	FLUCLOXACILLIN , flucloxacillin 125 mg/5 mL oral liquid: powder for, 100 mL (<i>Flucil</i>)	0	1
9150N	FLUCLOXACILLIN , flucloxacillin 250 mg/5 mL oral liquid: powder for, 100 mL (<i>Flucil</i>)	0	1

Advance Notices

1 May 2016

Deletion – Brand

2157M	<i>Mylanta P, JT</i> – ALUMINIUM HYDROXIDE WITH MAGNESIUM HYDROXIDE , ALUMINIUM HYDROXIDE with MAGNESIUM HYDROXIDE Oral suspension 200 mg-200 mg per 5 mL, 500 mL, 1
2022K	<i>Ridaura, GH</i> – AURANOFIN , AURANOFIN Capsule 3 mg, 60
2555L	<i>Petrus Pharmaceuticals Pty Ltd, PP</i> – GLYCEROL , glycerol 700 mg suppository, 12
2556M	<i>Petrus Pharmaceuticals Pty Ltd, PP</i> – GLYCEROL , glycerol 1.4 g suppository, 12
2557N	<i>Petrus Pharmaceuticals Pty Ltd, PP</i> – GLYCEROL , glycerol 2.8 g suppository, 12

2685H	<i>Camino Pro Bettermilk, QH</i> – GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS , glycomacropeptide and essential amino acids with vitamins and minerals oral liquid: powder for, 28 x 49 g sachets
1967M	<i>Micronor, JC</i> – NORETHISTERONE , norethisterone 350 microgram tablet, 112 [4 x 28]
1594X	<i>Ondaz, SZ</i> – ONDANSETRON , ondansetron 4 mg tablet, 10
1595Y	<i>Ondaz, SZ</i> – ONDANSETRON , ondansetron 8 mg tablet, 10
8224W	<i>Ondaz, SZ</i> – ONDANSETRON , ondansetron 4 mg tablet, 4
8225X	<i>Ondaz, SZ</i> – ONDANSETRON , ondansetron 8 mg tablet, 4
8410P	<i>Ondaz Zydis, SZ</i> – ONDANSETRON , ondansetron 4 mg wafer, 4
8411Q	<i>Ondaz Zydis, SZ</i> – ONDANSETRON , ondansetron 8 mg wafer, 4
8412R	<i>Ondaz Zydis, SZ</i> – ONDANSETRON , ondansetron 4 mg wafer, 10
8413T	<i>Ondaz Zydis, SZ</i> – ONDANSETRON , ondansetron 8 mg wafer, 10
8694N	<i>Pioglitazone generichealth 15, GQ</i> – PIOGLITAZONE , pioglitazone 15 mg tablet, 28
8695P	<i>Pioglitazone generichealth 30, GQ</i> – PIOGLITAZONE , pioglitazone 30 mg tablet, 28
8696Q	<i>Pioglitazone generichealth 45, GQ</i> – PIOGLITAZONE , pioglitazone 45 mg tablet, 28
2895J	<i>Stemetil, SW</i> – PROCHLORPERAZINE , prochlorperazine maleate 25 mg suppository, 5
5208D	<i>Stemetil, SW</i> – PROCHLORPERAZINE , prochlorperazine maleate 25 mg suppository, 5 (Dental)
8668F	<i>Tritace Titration Pack, SW</i> – RAMIPRIL , ramipril 2.5 mg tablet [7 tablets] (&) ramipril 5 mg tablet [21 tablets] (&) ramipril 10 mg capsule [10 capsules], 1 pack
8788M	<i>Risperdal Quicklet, JC</i> – RISPERIDONE , risperidone 500 microgram tablet: orally disintegrating, 28
8790P	<i>Risperdal Quicklet, JC</i> – RISPERIDONE , risperidone 1 mg tablet: orally disintegrating, 28
8792R	<i>Risperdal Quicklet, JC</i> – RISPERIDONE , risperidone 1 mg tablet: orally disintegrating, 28
8794W	<i>Risperdal Quicklet, JC</i> – RISPERIDONE , risperidone 2 mg tablet: orally disintegrating, 28
8870W	<i>Risperdal Quicklet, JC</i> – RISPERIDONE , risperidone 500 microgram tablet: orally disintegrating, 28
9075P	<i>Risperdal Quicklet, JC</i> – RISPERIDONE , risperidone 3 mg tablet: orally disintegrating, 28
9076Q	<i>Risperdal Quicklet, JC</i> – RISPERIDONE , risperidone 4 mg tablet: orally disintegrating, 28
9080X	<i>Risperdal Quicklet, JC</i> – RISPERIDONE , risperidone 2 mg tablet: orally disintegrating, 28
8267D	<i>Skelid, SW</i> – TILUDRONATE , tiludronate 200 mg tablet, 56

1 June 2016

Deletion – Brand

9195Y	<i>Clexane, SW</i> – ENOXAPARIN SODIUM , enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL ampoules
9196B	<i>Clexane, SW</i> – ENOXAPARIN SODIUM , enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL ampoules
1588N	<i>Orudis, SW</i> – KETOPROFEN , ketoprofen 100 mg suppository, 20
5139L	<i>Orudis, SW</i> – KETOPROFEN , ketoprofen 100 mg suppository, 20 (Dental)

Palliative Care

Additions

Addition – Item

10684H	FENTANYL , fentanyl 100 microgram tablet: orally disintegrating, 28 (<i>Fentora</i>)
10729Q	FENTANYL , fentanyl 100 microgram tablet: orally disintegrating, 4 (<i>Fentora</i>)
10697B	FENTANYL , fentanyl 200 microgram tablet: orally disintegrating, 4 (<i>Fentora</i>)
10698C	FENTANYL , fentanyl 200 microgram tablet: orally disintegrating, 28 (<i>Fentora</i>)
10737D	FENTANYL , fentanyl 400 microgram tablet: orally disintegrating, 28 (<i>Fentora</i>)
10739F	FENTANYL , fentanyl 400 microgram tablet: orally disintegrating, 4 (<i>Fentora</i>)

10713W	FENTANYL , fentanyl 600 microgram tablet: orally disintegrating, 28 (<i>Fentora</i>)
10722H	FENTANYL , fentanyl 600 microgram tablet: orally disintegrating, 4 (<i>Fentora</i>)
10723J	FENTANYL , fentanyl 800 microgram tablet: orally disintegrating, 4 (<i>Fentora</i>)
10738E	FENTANYL , fentanyl 800 microgram tablet: orally disintegrating, 28 (<i>Fentora</i>)

Advance Notices

1 May 2016

Deletion – Brand

5311M	<i>Petrus Pharmaceuticals Pty Ltd, PP</i> – GLYCEROL , glycerol 700 mg suppository, 12
5312N	<i>Petrus Pharmaceuticals Pty Ltd, PP</i> – GLYCEROL , glycerol 1.4 g suppository, 12
5313P	<i>Petrus Pharmaceuticals Pty Ltd, PP</i> – GLYCEROL , glycerol 2.8 g suppository, 12
5314Q	<i>Petrus Pharmaceuticals Pty Ltd, PP</i> – GLYCEROL , glycerol 700 mg suppository, 12
5315R	<i>Petrus Pharmaceuticals Pty Ltd, PP</i> – GLYCEROL , glycerol 1.4 g suppository, 12
5316T	<i>Petrus Pharmaceuticals Pty Ltd, PP</i> – GLYCEROL , glycerol 2.8 g suppository, 12

Highly Specialised Drugs Program (Private Hospital)

Additions

Addition – Brand

6284R	<i>Bacthecal, DZ</i> – BACLOFEN , baclofen 10 mg/5 mL injection: intrathecal, 1 x 5 mL ampoule
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Addition – Equivalence Indicator

6284R	<i>Lioresal Intrathecal, NV</i> – BACLOFEN , baclofen 10 mg/5 mL injection: intrathecal, 1 x 5 mL ampoule
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Deletions

Deletion – Brand

9607P	<i>Apomine, HH</i> – APOMORPHINE , apomorphine hydrochloride 20 mg/2 mL injection, 5 x 2 mL ampoules
9640J	<i>Apomine, HH</i> – APOMORPHINE , apomorphine hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules

Deletion – Equivalence Indicator

9607P	<i>Movapo, TD</i> – APOMORPHINE , apomorphine hydrochloride 20 mg/2 mL injection, 5 x 2 mL ampoules
9640J	<i>Movapo, TD</i> – APOMORPHINE , apomorphine hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules

Alterations

Alteration – Restriction

The following items have additions, deletions or alterations to restrictions, notes and/or cautions.

6284R	BACLOFEN , baclofen 10 mg/5 mL injection: intrathecal, 1 x 5 mL ampoule (<i>Bacthecal, Lioresal Intrathecal</i>)
9624M	NATALIZUMAB , natalizumab 300 mg/15 mL injection, 1 x 15 mL vial (<i>Tysabri</i>)
9611W	RITUXIMAB , rituximab 500 mg/50 mL injection, 1 x 50 mL vial (<i>Mabthera</i>)
1419Q	TOCILIZUMAB , tocilizumab 80 mg/4 mL injection, 1 x 4 mL vial (<i>Actemra</i>)
1423X	TOCILIZUMAB , tocilizumab 200 mg/10 mL injection, 1 x 10 mL vial (<i>Actemra</i>)
1464C	TOCILIZUMAB , tocilizumab 400 mg/20 mL injection, 1 x 20 mL vial (<i>Actemra</i>)
9671B	TOCILIZUMAB , tocilizumab 80 mg/4 mL injection, 1 x 4 mL vial (<i>Actemra</i>)
9672C	TOCILIZUMAB , tocilizumab 200 mg/10 mL injection, 1 x 10 mL vial (<i>Actemra</i>)
9673D	TOCILIZUMAB , tocilizumab 400 mg/20 mL injection, 1 x 20 mL vial (<i>Actemra</i>)

Highly Specialised Drugs Program (Public Hospital)

Additions

Addition – Brand

5617P *Bacthecal, DZ* – **BACLOFEN**, baclofen 10 mg/5 mL injection: intrathecal, 1 x 5 mL ampoule

Addition – Equivalence Indicator

5617P *Lioresal Intrathecal, NV* – **BACLOFEN**, baclofen 10 mg/5 mL injection: intrathecal, 1 x 5 mL ampoule

Deletions

Deletion – Brand

5609F *Apomine, HH* – **APOMORPHINE**, apomorphine hydrochloride 20 mg/2 mL injection, 5 x 2 mL ampoules

5610G *Apomine, HH* – **APOMORPHINE**, apomorphine hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules

Deletion – Equivalence Indicator

5609F *Movapo, TD* – **APOMORPHINE**, apomorphine hydrochloride 20 mg/2 mL injection, 5 x 2 mL ampoules

5610G *Movapo, TD* – **APOMORPHINE**, apomorphine hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules

Alterations

Alteration – Restriction

The following items have additions, deletions or alterations to restrictions, notes and/or cautions.

5617P **BACLOFEN**, baclofen 10 mg/5 mL injection: intrathecal, 1 x 5 mL ampoule (*Bacthecal, Lioresal Intrathecal*)

9505G **NATALIZUMAB**, natalizumab 300 mg/15 mL injection, 1 x 15 mL vial (*Tysabri*)

9544H **RITUXIMAB**, rituximab 500 mg/50 mL injection, 1 x 50 mL vial (*Mabthera*)

1476Q **TOCILIZUMAB**, tocilizumab 80 mg/4 mL injection, 1 x 4 mL vial (*Actemra*)

1481Y **TOCILIZUMAB**, tocilizumab 200 mg/10 mL injection, 1 x 10 mL vial (*Actemra*)

1482B **TOCILIZUMAB**, tocilizumab 400 mg/20 mL injection, 1 x 20 mL vial (*Actemra*)

9657G **TOCILIZUMAB**, tocilizumab 80 mg/4 mL injection, 1 x 4 mL vial (*Actemra*)

9658H **TOCILIZUMAB**, tocilizumab 200 mg/10 mL injection, 1 x 10 mL vial (*Actemra*)

9659J **TOCILIZUMAB**, tocilizumab 400 mg/20 mL injection, 1 x 20 mL vial (*Actemra*)

Highly Specialised Drugs Program (Community Access)

Additions

Addition – Item

10692R **ATAZANAVIR + COBICISTAT**, atazanavir 300 mg + cobicistat 150 mg tablet, 30 (*Evotaz*)

10680D **TENOFOVIR + EMTRICITABINE + ELVITEGRAVIR + COBICISTAT**, tenofovir alafenamide 10 mg + emtricitabine 200 mg + elvitegravir 150 mg + cobicistat 150 mg tablet, 30 (*Genvoya*)

Repatriation Pharmaceutical Benefits

Advance Notices

1 May 2016

Deletion – Brand

10586E *Petrus Pharmaceuticals Pty Ltd, PP* – **GLYCEROL**, glycerol 700 mg suppository, 12

10596Q *Petrus Pharmaceuticals Pty Ltd, PP* – **GLYCEROL**, glycerol 1.4 g suppository, 12

4246L *Petrus Pharmaceuticals Pty Ltd, PP* – **GLYCEROL**, glycerol 2.8 g suppository, 12

General Pharmaceutical Benefits

■ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT PHENYLALANINE

Restricted benefit

Phenylketonuria

amino acid formula with fat, carbohydrate without phenylalanine tablet: modified release, 4 x 110 g

10683G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±5	5	..	*1399.73	38.30	PKU Easy Microtabs [OH]

■ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN

Restricted benefit

Proven glutaric aciduria type 1

amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 30 x 18 g sachets

10715Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*2011.49	38.30	GA1 Anamix Junior [NU]

■ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE

Restricted benefit

Pyridoxine non-responsive homocystinuria

amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 30 x 36 g sachets

10693T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*2011.57	38.30	HCU Anamix Junior [NU]

■ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, THREONINE AND VALINE AND LOW IN ISOLEUCINE

Restricted benefit

Methylmalonic acidemia

Restricted benefit

Propionic acidemia

amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid: powder for, 30 x 18 g sachets

10730R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*2011.49	38.30	MMA/PA Anamix Junior [NU]

■ ARTEMETHER + LUMEFANTRINE

Note This drug is not PBS-subsidised for prophylaxis of malaria.

Restricted benefit

Confirmed or suspected Plasmodium falciparum malaria

Clinical criteria:

Patient must be unable to swallow a solid dosage form of artemether with lumefantrine.

artemether 20 mg + lumefantrine 120 mg tablet: dispersible, 18

5296R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	88.57	38.30	Riamet 20mg/120mg Dispersible [NV]

■ ARTEMETHER + LUMEFANTRINE

Note This drug is not PBS-subsidised for prophylaxis of malaria.

Restricted benefit

Confirmed or suspected Plasmodium falciparum malaria

artemether 20 mg + lumefantrine 120 mg tablet, 24

9498X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	88.57	38.30	Riamet [NV]

▪ ATOVAQUONE + PROGUANIL**Note** This drug is not PBS-subsidised for prophylaxis of malaria.**Note** Shared Care Model:

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

Restricted benefit

Confirmed or suspected Plasmodium falciparum malaria

Clinical criteria:

The treatment must be used where quinine containing regimens are inappropriate.

Population criteria:

Patient must be aged 3 years or older.

atovaquone 250 mg + proguanil hydrochloride 100 mg tablet, 12

9439T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	65.49	38.30	Malarone [GK]

▪ CARMUSTINE**Note** Carmustine is not PBS-subsidised for use in conjunction with PBS-subsidised temozolomide.**Restricted benefit**

Glioblastoma multiforme

Clinical criteria:

The condition must be suspected or confirmed at the time of initial surgery.

carmustine 7.7 mg implant, 8

8898H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	16670.18	38.30	Gladel [EI]

▪ CITRULLINE**Note** Citrulline is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism**Restricted benefit**

Urea cycle disorders

Clinical criteria:

The treatment must be for preventing low plasma arginine levels; OR

The treatment must be for preventing low citrulline levels.

citrulline 1 g tablet, 300

10736C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1196.73	38.30	Citrulline Easy [OH]

▪ DABRAFENIB**Note** A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.**Note** No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**Note** Special Pricing Arrangements apply.**Authority required (STREAMLINED)****6044**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

Clinical criteria:

The condition must be positive for a BRAF V600 mutation, AND

The condition must not have been treated previously with PBS subsidised therapy; OR

Patient must have developed intolerance to another BRAF inhibitor of a severity necessitating permanent treatment withdrawal, AND

Patient must have a WHO performance status of 2 or less.

dabrafenib 50 mg capsule, 120

2963Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	5888.32	38.30	Tafinlar [NV]

dabrafenib 75 mg capsule, 120

2846T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	8759.04	38.30	Tafinlar [NV]

■ DABRAFENIB

Note A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

Note A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)**6013**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug, AND

Patient must have stable or responding disease.

dabrafenib 50 mg capsule, 120

2954L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5888.32	38.30	Tafinlar [NV]

dabrafenib 75 mg capsule, 120

10003L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	8759.04	38.30	Tafinlar [NV]

■ FENOFIBRATE

Note The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

fenofibrate 145 mg tablet, 30

9023X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	39.71	38.30	Lipidil [GO]

fenofibrate 48 mg tablet, 60

9022W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	29.93	31.10	Lipidil [GO]

■ FENOFIBRATE

Note The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

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

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

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

Clinical criteria:

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

fenofibrate 145 mg tablet, 30

9247Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	11	..	39.71	38.30	Lipidil [GO]

fenofibrate 48 mg tablet, 60

9246P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	11	..	29.93	31.10	Lipidil [GO]

■ FLUCONAZOLE**Note** Shared Care Model:

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

Restricted benefit

Cryptococcal meningitis

Restricted benefit

Cryptococcal meningitis

Clinical criteria:

The treatment must be maintenance therapy, AND

Patient must be immunosuppressed.

Restricted benefit

Oropharyngeal candidiasis

Clinical criteria:

Patient must be immunosuppressed.

Restricted benefit

Oesophageal candidiasis

Clinical criteria:

Patient must be immunosuppressed.

Restricted benefit

Oropharyngeal candidiasis

Clinical criteria:

The treatment must be for prophylaxis, AND

Patient must be immunosuppressed.

Restricted benefit

Candida infections

Clinical criteria:

The condition must be serious or life-threatening.

fluconazole 100 mg capsule, 28

1472L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	38.70	38.30	^a Diflucan [PF] ^a Fluconazole Sandoz [SZ]	^a Dizole 100 [AF] ^a Ozole [RA]

fluconazole 100 mg/50 mL injection, 1 x 50 mL vial

1473M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	7	..	..	*21.63	22.80	^a Fluconazole Hexal [HX]	^a Fluconazole Sandoz [SZ]

fluconazole 200 mg capsule, 28

1475P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	65.50	38.30	^a APO-Fluconazole [TX] ^a Dizole 200 [AF] ^a Fluzole 200 [RW]	^a Diflucan [PF] ^a Fluconazole Sandoz [SZ] ^a Ozole [RA]

fluconazole 200 mg/100 mL injection, 1 x 100 mL vial

1474N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	7	..	..	*31.57	32.74	^a Fluconazole Alphapharm [AF] ^a Fluconazole Sandoz [SZ]	^a Fluconazole Hexal [HX]

fluconazole 400 mg/200 mL injection, 1 x 200 mL bag

1757L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	15.17	16.34	Fluconazole Alphapharm [AF]

fluconazole 50 mg capsule, 28

1471K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	24.95	26.12	^a Diflucan [PF] ^a Fluconazole Sandoz [SZ]	^a Dizole 50 [AF] ^a Ozole [RA]

■ FLUCONAZOLE**Note** Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical

practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Cryptococcal meningitis

Clinical criteria:

Patient must be unable to take a solid dose form of fluconazole.

Restricted benefit

Cryptococcal meningitis

Clinical criteria:

The treatment must be maintenance therapy, AND

Patient must be immunosuppressed, AND

Patient must be unable to take a solid dose form of fluconazole.

Restricted benefit

Oropharyngeal candidiasis

Clinical criteria:

Patient must be immunosuppressed, AND

Patient must be unable to take a solid dose form of fluconazole.

Restricted benefit

Oesophageal candidiasis

Clinical criteria:

Patient must be immunosuppressed, AND

Patient must be unable to take a solid dose form of fluconazole.

Restricted benefit

Oropharyngeal candidiasis

Clinical criteria:

The treatment must be for prophylaxis, AND

Patient must be immunosuppressed, AND

Patient must be unable to take a solid dose form of fluconazole.

Restricted benefit

Candida infections

Clinical criteria:

The condition must be serious or life-threatening, AND

Patient must be unable to take a solid dose form of fluconazole.

fluconazole 50 mg/5 mL oral liquid: powder for, 35 mL

5446P



Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	..	..	#66.61	38.30	Diflucan [PF]

▪ **FLUVASTATIN**

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

fluvastatin 80 mg tablet: modified release, 28 tablets

2863Q



Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	5	..	44.92	38.30	Lescol XL [NV]

▪ **FLUVASTATIN**

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

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

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

Clinical criteria:

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

fluvastatin 80 mg tablet: modified release, 28 tablets

9236D

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	11	..	44.92	38.30	Lescol XL [NV]

▪ **GEMFIBROZIL**

Note The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

gemfibrozil 600 mg tablet, 60

1453L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	20.32	21.49	^a Ausgem [RW] ^a GenRx Gemfibrozil [GX] ^a Terry White Chemists Gemfibrozil [TW]	^a Chem mart Gemfibrozil [CH] ^a Lipigem [AF]

■ GEMFIBROZIL

Note The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

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

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

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

Clinical criteria:

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

gemfibrozil 600 mg tablet, 60

9248R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	20.32	21.49	^a Ausgem [RW] ^a GenRx Gemfibrozil [GX] ^a Terry White Chemists Gemfibrozil [TW]	^a Chem mart Gemfibrozil [CH] ^a Lipigem [AF]

■ GLUCOSE INDICATOR BLOOD

glucose indicator blood strip: diagnostic, 50

10724K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*50.57	38.30	2in1 smart glucose test strips [UB]

■ GLUCOSE INDICATOR BLOOD

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

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

Restricted benefit

Blood glucose monitoring

Clinical criteria:

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

glucose indicator blood strip: diagnostic, 50

10700E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	11	..	*50.57	38.30	2in1 smart glucose test strips [UB]

■ GOLIMUMAB

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis, AND

Patient must have demonstrated an adequate response to treatment with this drug, AND

Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction, AND

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

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

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

(1) a completed authority prescription form and

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

All applications for continuing treatment with golimumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with golimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with golimumab.

If a patient fails to demonstrate a response to treatment with golimumab 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

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

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

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alpha antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

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

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

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

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

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

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided 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

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

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients 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.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe

3428K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1481.56	38.30	Simponi [JC]

golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe

3429L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1481.56	38.30	Simponi [JC]

▪ GOLIMUMAB

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have severe active rheumatoid arthritis, AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, AND

Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

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

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND

Patient must not receive more than 16 weeks of treatment under this restriction, AND

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

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

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 authority application must be made in writing and must include:

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

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications 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 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

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

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

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

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

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

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

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline 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 is provided with the initial application, the same marker will be used to determine response.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

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

disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alpha antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

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

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

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

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

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

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided 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 provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients 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.

Authority required

Severe active rheumatoid arthritis

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

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis, AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, 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.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

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

(a) a completed authority prescription form and

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

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 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

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

If a patient 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 for this condition.

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

If 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 bDMARD.

An adequate response to treatment is defined as:

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

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

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

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

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

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

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later

than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

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

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

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

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

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

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided 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 provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment

restriction for new or re-commencing patients 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.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe

3426H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1481.56	38.30	Simponi [JC]

golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe

3427J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1481.56	38.30	Simponi [JC]

■ **ITRACONAZOLE**

Note One capsule of itraconazole 50 mg (Lozanoc) is therapeutically equivalent to one 100 mg capsule of conventional itraconazole (Sporanox). The recommended dose of Lozanoc is therefore half the recommended dose for Sporanox. Lozanoc 50 mg capsules and Sporanox 100 mg capsules are not interchangeable.

Note Not for use in superficial mycoses

Note Shared Care Model:

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

Restricted benefit

Systemic aspergillosis

Restricted benefit

Systemic sporotrichosis

Restricted benefit

Systemic histoplasmosis

Restricted benefit

Disseminated pulmonary histoplasmosis infection

Treatment Phase: Treatment and maintenance therapy

Clinical criteria:

Patient must be diagnosed with acquired immunodeficiency syndrome (AIDS).

Restricted benefit

Chronic pulmonary histoplasmosis infection

Treatment Phase: Treatment and maintenance therapy

Clinical criteria:

Patient must be diagnosed with acquired immunodeficiency syndrome (AIDS).

Restricted benefit

Oropharyngeal candidiasis

Clinical criteria:

Patient must be immunosuppressed.

Restricted benefit

Oesophageal candidiasis

Clinical criteria:

Patient must be immunosuppressed.

itraconazole 100 mg capsule, 60

8196J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	222.77	38.30	Sporanox [JC]

itraconazole 50 mg capsule, 60

10732W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	150.39	38.30	Lozanoc [YN]

■ MINOCYCLINE

Caution There are concerns about the incidence of benign intracranial hypertension associated with this drug.

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

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

Restricted benefit

Severe acne

Clinical criteria:

The condition must not be responding to other tetracyclines.

minocycline 50 mg tablet, 60

1616C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	17.92	19.09	^a Akamin 50 [AF]
			^B 1.65	19.57	19.09	^a Minomycin-50 [QA]

■ MODAFINIL

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note This drug is not PBS-subsidised when used in combination with PBS-subsidised dexamphetamine sulfate.

Authority required

Narcolepsy

Treatment Phase: Initial treatment

Clinical criteria:

The treatment must be for use when therapy with dexamphetamine sulfate poses an unacceptable medical risk; OR

The treatment must be for use when intolerance to dexamphetamine sulfate is of a severity to necessitate treatment withdrawal, AND

Patient must have experienced excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months, AND

Patient must have a definite history of cataplexy; OR

Patient must have a mean sleep latency less than or equal to 10 minutes on a Multiple Sleep Latency Test (MSLT); OR

Patient must have an electroencephalographic (EEG) recording showing the pathologically rapid development of REM sleep, AND

Patient must not have any medical or psychiatric disorder that could otherwise account for the hypersomnia.

Treatment criteria:

Must be treated by a qualified sleep medicine practitioner or neurologist.

The presence of any one of the following indicates treatment with dexamphetamine sulfate poses an unacceptable medical risk:

(a) a psychiatric disorder;

(b) a cardiovascular disorder;

(c) a history of substance abuse;

(d) glaucoma;

(e) any other absolute contraindication to dexamphetamine sulfate as specified in the TGA-approved Product Information.

The MSLT must be preceded by nocturnal polysomnography. Sleep prior to the MSLT must be at least 6 hours in duration.

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

(a) a completed authority prescription form; and

(b) a completed Narcolepsy Initial PBS authority application and Supporting information form; and

(c) details of the contraindication or intolerance to dexamphetamine sulfate; and

(d) either:

(i) the result and date of the polysomnography test and Multiple Sleep Latency Test (MSLT) conducted by, or under the supervision of, a qualified sleep medicine practitioner; or

(ii) the result and date of the electroencephalograph (EEG), conducted by, or under the supervision of, a neurologist.

The polysomnography, MSLT or EEG test reports must be provided with the authority application.

Authority required

Narcolepsy

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug.

modafinil 100 mg tablet, 60

8816B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*284.57	38.30	^a Modafin [RW]	^a Modavigil [TB]

■ NADROPARIN**nadroparin calcium 11 400 anti-Xa international units/0.6 mL injection, 2 x 0.6 mL syringes**

10706L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	31.87	33.04	Fraxiparine Forte [AS]

nadroparin calcium 15 200 anti-Xa international units/0.8 mL injection, 2 x 0.8 mL syringes

10725L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	39.02	38.30	Fraxiparine Forte [AS]

nadroparin calcium 19 000 anti-Xa international units/mL injection, 2 x 1 mL syringes

10707M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	46.17	38.30	Fraxiparine Forte [AS]

nadroparin calcium 1900 anti-Xa international units/0.2 mL injection, 2 x 0.2 mL syringes

10735B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*17.59	18.76	Fraxiparine [AS]

nadroparin calcium 2850 anti-Xa international units/0.3 mL injection, 2 x 0.3 mL syringes

10686K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*21.17	22.34	Fraxiparine [AS]

nadroparin calcium 3800 anti-Xa international units/0.4 mL injection, 2 x 0.4 mL syringes

10685J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*24.73	25.90	Fraxiparine [AS]

nadroparin calcium 5700 anti-Xa international units/0.6 mL injection, 2 x 0.6 mL syringes

10716B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*31.89	33.06	Fraxiparine [AS]

nadroparin calcium 7600 anti-Xa international units/0.8 mL injection, 2 x 0.8 mL syringes

10734Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	24.72	25.89	Fraxiparine [AS]

nadroparin calcium 9500 anti-Xa international units/mL injection, 2 x 1 mL syringes

10702G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1	..	28.30	29.47	Fraxiparine [AS]

■ NADROPARIN**Restricted benefit**

Haemodialysis

nadroparin calcium 1900 anti-Xa international units/0.2 mL injection, 2 x 0.2 mL syringes

10687L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*17.59	18.76	Fraxiparine [AS]

nadroparin calcium 2850 anti-Xa international units/0.3 mL injection, 2 x 0.3 mL syringes

10701F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*21.17	22.34	Fraxiparine [AS]

nadroparin calcium 3800 anti-Xa international units/0.4 mL injection, 2 x 0.4 mL syringes

10717C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*24.73	25.90	Fraxiparine [AS]

nadroparin calcium 5700 anti-Xa international units/0.6 mL injection, 2 x 0.6 mL syringes

10718D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*31.89	33.06	Fraxiparine [AS]

nadroparin calcium 7600 anti-Xa international units/0.8 mL injection, 2 x 0.8 mL syringes

10740G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*39.03	38.30	Fraxiparine [AS]

nadroparin calcium 9500 anti-Xa international units/mL injection, 2 x 1 mL syringes

10733X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*46.19	38.30	Fraxiparine [AS]

■ NETUPITANT + PALONOSETRON

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

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

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

Authority required (STREAMLINED)**5991**

Nausea and vomiting

Clinical criteria:

The condition must be associated with cytotoxic chemotherapy being used to treat malignancy, AND

The treatment must be in combination with dexamethasone, AND

Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following agents:

altretamine; carmustine; cisplatin when a single dose constitutes a cycle of chemotherapy; cyclophosphamide at a dose of 1500 mg per square metre per day or greater; dacarbazine; procarbazine when a single dose constitutes a cycle of chemotherapy; streptozocin.

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

Authority required (STREAMLINED)**5994**

Nausea and vomiting

Clinical criteria:

The condition must be associated with cytotoxic chemotherapy being used to treat breast cancer, AND

The treatment must be in combination with dexamethasone, AND

Patient must be scheduled to be co-administered cyclophosphamide and an anthracycline.

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

netupitant 300 mg + palonosetron 500 microgram capsule, 1

10731T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	121.18	38.30	Akynzeo [ZD]

■ PRAVASTATIN**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

pravastatin sodium 10 mg tablet, 30

2833D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.27	13.44	^a APO-Pravastatin [TX] ^a Chem mart Pravastatin [CH] ^a Lipostat 10 [RF] ^a Pravastatin AN [EA] ^a Pravastatin generichealth [GQ] ^a Terry White Chemists Pravastatin [TW]	^a Auro-Pravastatin 10 [DO] ^a Cholstat 10 [AF] ^a Pharmacor Pravastat 10 [CR] ^a Pravastatin-GA 10 [ED] ^a Pravastatin Sandoz [SZ]
			^B 1.03	13.30	13.44	^a Pravachol [RW]	

pravastatin sodium 20 mg tablet, 30

2834E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.36	14.53	^a APO-Pravastatin [TX] ^a Chem mart Pravastatin [CH] ^a Cholvastin [RA] ^a Pharmacor Pravastat 20 [CR] ^a Pravastatin-GA 20 [ED] ^a Pravastatin Sandoz [SZ]	^a Auro-Pravastatin 20 [DO] ^a Cholstat 20 [AF] ^a Lipostat 20 [RF] ^a Pravastatin AN [EA] ^a Pravastatin generichealth [GQ] ^a Terry White Chemists Pravastatin [TW]
			^B 1.03	14.39	14.53	^a Pravachol [RW]	

pravastatin sodium 40 mg tablet, 30

8197K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.98	16.15	^a APO-Pravastatin [TX] ^a Chem mart Pravastatin [CH] ^a Cholvastin [RA] ^a Pharmacor Pravastat 40 [CR] ^a Pravastatin-GA 40 [ED] ^a Pravastatin Sandoz [SZ]	^a Auro-Pravastatin 40 [DO] ^a Cholstat 40 [AF] ^a Lipostat 40 [RF] ^a Pravastatin AN [EA] ^a Pravastatin generichealth [GQ] ^a Terry White Chemists Pravastatin [TW]
			^B 1.08	16.06	16.15	^a Pravachol [RW]	

pravastatin sodium 80 mg tablet, 30

8829Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.43	18.60	^a APO-Pravastatin [TX] ^a Chem mart Pravastatin [CH] ^a Pravastatin AN [EA] ^a Pravastatin generichealth [GQ] ^a Terry White Chemists Pravastatin [TW]	^a Auro-Pravastatin 80 [DO] ^a Lipostat 80 [RF] ^a Pravastatin-GA 80 [ED] ^a Pravastatin Sandoz [SZ]
			^B 1.10	18.53	18.60	^a Pravachol [RW]	

■ PRAVASTATIN

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

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

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

Clinical criteria:

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

pravastatin sodium 10 mg tablet, 30

9237E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	12.27	13.44	^a APO-Pravastatin [TX] ^a Chem mart Pravastatin [CH] ^a Lipostat 10 [RF] ^a Pravastatin AN [EA] ^a Pravastatin generichealth [GQ] ^a Terry White Chemists Pravastatin [TW]	^a Auro-Pravastatin 10 [DO] ^a Cholstat 10 [AF] ^a Pharmacor Pravastat 10 [CR] ^a Pravastatin-GA 10 [ED] ^a Pravastatin Sandoz [SZ]
			^B 1.03	13.30	13.44	^a Pravachol [RW]	

pravastatin sodium 20 mg tablet, 30

9238F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	13.36	14.53	^a APO-Pravastatin [TX] ^a Chem mart Pravastatin [CH] ^a Cholvastin [RA] ^a Pharmacor Pravastat 20 [CR] ^a Pravastatin-GA 20 [ED] ^a Pravastatin Sandoz [SZ]	^a Auro-Pravastatin 20 [DO] ^a Cholstat 20 [AF] ^a Lipostat 20 [RF] ^a Pravastatin AN [EA] ^a Pravastatin generichealth [GQ] ^a Terry White Chemists Pravastatin [TW]
			^B 1.03	14.39	14.53	^a Pravachol [RW]	

pravastatin sodium 40 mg tablet, 30

9239G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	14.98	16.15	^a APO-Pravastatin [TX] ^a Chem mart Pravastatin [CH] ^a Cholvastin [RA] ^a Pharmacor Pravastat 40 [CR] ^a Pravastatin-GA 40 [ED] ^a Pravastatin Sandoz [SZ]	^a Auro-Pravastatin 40 [DO] ^a Cholstat 40 [AF] ^a Lipostat 40 [RF] ^a Pravastatin AN [EA] ^a Pravastatin generichealth [GQ] ^a Terry White Chemists Pravastatin [TW]
			^B 1.08	16.06	16.15	^a Pravachol [RW]	

pravastatin sodium 80 mg tablet, 30

9240H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	17.43	18.60	^a APO-Pravastatin [TX] ^a Chem mart Pravastatin [CH] ^a Pravastatin AN [EA] ^a Pravastatin generichealth [GQ]	^a Auro-Pravastatin 80 [DO] ^a Lipostat 80 [RF] ^a Pravastatin-GA 80 [ED] ^a Pravastatin Sandoz [SZ]

^a Terry White Chemists
Pravastatin [TW]
^a Pravachol [RW]

^b1.10 18.53 18.60

■ RISPERIDONE

Caution In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalities) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo.

Note Shared Care Model:

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

Authority required (STREAMLINED)

5993

Behavioural disturbances

Clinical criteria:

The condition must be characterised by psychotic symptoms and aggression, AND

Patient must have dementia of the Alzheimer type, AND

Patient must have failed to respond to non-pharmacological methods of treatment, AND

The treatment must be limited to a maximum duration of 12 weeks.

Authority required (STREAMLINED)

5916

Severe behavioural disturbances

Clinical criteria:

Patient must have autism, AND

The treatment must be under the supervision of a paediatrician or psychiatrist, AND

The treatment must be in combination with non-pharmacological measures.

Population criteria:

Patient must be under 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or ICD-10 international classification of mental and behavioural disorders.

Authority required (STREAMLINED)

5898

Severe behavioural disturbances

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have autism, AND

Patient must have been commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age, AND

The treatment must be under the supervision of a paediatrician or psychiatrist, AND

The treatment must be in combination with non-pharmacological measures.

Population criteria:

Patient must be aged 18 years or older.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or ICD-10 international classification of mental and behavioural disorders.

risperidone 1 mg tablet, 60

8789N

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	20.18	21.35	^a APO-Risperidone [TX] ^a Rispa [RW] ^a Rispericor 1 [CR] ^a Risperidone AMNEAL [EF] ^a Risperidone generichealth [GQ] ^a Rispernia [ER]	^a Ozidal [RA] ^a Risperdal [JC] ^a Risperidone Actavis 1 [ED] ^a Risperidone AN [EA] ^a Risperidone Sandoz [SZ] ^a Rixadone [AF]

risperidone 1 mg/mL oral liquid, 100 mL

9293D

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
\$1	2	..	111.88	38.30	Risperdal [JC]

■ RISPERIDONE

Caution In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalities) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo.

Note Shared Care Model:

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

Note For items 8787L and 1842Y, pharmaceutical benefits that have the form tablet 0.5 mg are equivalent for the purposes of substitution.

Authority required (STREAMLINED)**6010**

Behavioural disturbances

Clinical criteria:

The condition must be characterised by psychotic symptoms and aggression, AND

Patient must have dementia of the Alzheimer type, AND

Patient must have failed to respond to non-pharmacological methods of treatment, AND

The treatment must be limited to a maximum duration of 12 weeks.

Authority required (STREAMLINED)**5911**

Severe behavioural disturbances

Clinical criteria:

Patient must have autism, AND

The treatment must be under the supervision of a paediatrician or psychiatrist, AND

The treatment must be in combination with non-pharmacological measures.

Population criteria:

Patient must be under 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or ICD-10 international classification of mental and behavioural disorders.

Authority required (STREAMLINED)**5902**

Severe behavioural disturbances

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have autism, AND

Patient must have been commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age, AND

The treatment must be under the supervision of a paediatrician or psychiatrist, AND

The treatment must be in combination with non-pharmacological measures.

Population criteria:

Patient must be aged 18 years or older.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or ICD-10 international classification of mental and behavioural disorders.

risperidone 500 microgram tablet, 20

1842Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	2	..	*15.48	16.65	^a APO-Risperidone [TX]	^a Risperdal [JC]

risperidone 500 microgram tablet, 60

8787L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	15.48	16.65	^a Ozidal [RA] ^a Rispericor 0.5 [CR] ^a Risperidone AMNEAL [EF] ^a Risperidone GH [GQ] ^a Rispernia [ER]	^a Rispa [RW] ^a Risperidone Actavis 0.5 [ED] ^a Risperidone AN [EA] ^a Risperidone Sandoz [SZ] ^a Rixadone [AF]

■ RITUXIMAB

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

Authority required (STREAMLINED)**6011**

Relapsed or refractory Stage III or IV CD20 positive follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Maintenance therapy

Clinical criteria:

The treatment must be maintenance therapy, AND

Patient must have demonstrated a partial or complete response to re-induction treatment received immediately prior to this current Authority application, AND

Patient must not receive more than 8 cycles or 2 years duration of treatment, whichever comes first, under this restriction.

rituximab 1.4 g/11.7 mL injection, 11.7 mL vial

10709P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	7	..	2850.65	38.30	Mabthera SC [RO]

▪ RITUXIMAB

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

Authority required (STREAMLINED)**5998**

Relapsed or refractory low-grade B-cell non-Hodgkin's lymphoma

Treatment Phase: Re-induction treatment

Clinical criteria:

The treatment must be for re-induction treatment purposes only, AND

The condition must have relapsed or be refractory to treatment, AND

Patient must not receive more than 4 doses of rituximab in total, including intravenous and subcutaneous injections, and no more than 3 doses of subcutaneous rituximab under this restriction.

An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab with no more than 4 doses in total.

Authority required (STREAMLINED)**6039**

Relapsed or refractory follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Re-induction treatment

Clinical criteria:

The treatment must be for re-induction treatment purposes only, AND

The condition must have relapsed or be refractory to treatment, AND

Patient must not receive more than 4 doses of rituximab in total, including intravenous and subcutaneous injections, and no more than 3 doses of subcutaneous rituximab under this restriction.

An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab with no more than 4 doses in total.

rituximab 1.4 g/11.7 mL injection, 11.7 mL vial

10703H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	2850.65	38.30	Mabthera SC [RO]

▪ RITUXIMAB

Note A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

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

Authority required (STREAMLINED)**5992**

Stage III or IV CD20 positive follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Maintenance therapy

Clinical criteria:

Patient must have demonstrated a partial or complete response to the induction phase of treatment for previously untreated follicular B-cell Non-Hodgkin's lymphoma, received immediately prior to this current Authority application, AND

The treatment must be maintenance therapy, AND

Patient must not receive more than 12 doses or 2 years duration of treatment, whichever comes first, under this restriction.

rituximab 1.4 g/11.7 mL injection, 11.7 mL vial

10742J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	11	..	2850.65	38.30	Mabthera SC [RO]

▪ RITUXIMAB

Note A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

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

Authority required (STREAMLINED)**5980**

Previously untreated CD20 positive diffuse large B-cell non-Hodgkin's lymphoma

Treatment Phase: Induction treatment

Clinical criteria:

The treatment must be in combination with chemotherapy, AND

The condition must be previously untreated, AND

The condition must be symptomatic, AND

The treatment must be for induction treatment purposes only, AND

Patient must not receive more than 8 doses of rituximab in total, including intravenous and subcutaneous injections, and no more than 7 doses of subcutaneous rituximab under this restriction.

An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab with no more than 8 doses in total.

Authority required (STREAMLINED)**6040**

Previously untreated Stage III or IV CD20 positive follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Induction treatment

Clinical criteria:

The treatment must be in combination with chemotherapy, AND

The condition must be previously untreated, AND

The condition must be symptomatic, AND

The treatment must be for induction treatment purposes only, AND

Patient must not receive more than 8 doses of rituximab in total, including intravenous and subcutaneous injections, and no more than 7 doses of subcutaneous rituximab under this restriction.

An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab with no more than 8 doses in total.

rituximab 1.4 g/11.7 mL injection, 11.7 mL vial

10719E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	6	..	2850.65	38.30	Mabthera SC [RO]

■ SIMVASTATIN**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

simvastatin 10 mg tablet, 30

2011W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	11.90	13.07	^a APO-Simvastatin [TX] ^a Chem mart Simvastatin [CH] ^a Ransim [RA] ^a Simvar 10 [RW] ^a Simvastatin-GA 10 [ED] ^a Simvastatin Sandoz [SZ] ^a Zimstat [AF]	^a Auro-Simvastatin 10 [DO] ^a GenRx Simvastatin [GX] ^a Simvacor 10 [CR] ^a Simvastatin AN [EA] ^a Simvastatin generichealth [GQ] ^a Terry White Chemists Simvastatin [TW]
			^B 4.00	15.90	13.07	^a Lipex 10 [FR]	^a Zocor [MK]

simvastatin 20 mg tablet, 30

2012X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.57	13.74	^a APO-Simvastatin [TX] ^a Chem mart Simvastatin [CH] ^a Simvacor 20 [CR] ^a Simvastatin AN [EA] ^a Simvastatin generichealth [GQ] ^a Terry White Chemists Simvastatin [TW]	^a Auro-Simvastatin 20 [DO] ^a Ransim [RA] ^a Simvar 20 [RW] ^a Simvastatin-GA 20 [ED] ^a Simvastatin Sandoz [SZ] ^a Zimstat [AF]
			^B 4.00	16.57	13.74	^a Lipex 20 [FR]	^a Zocor [MK]

simvastatin 40 mg tablet, 30

8173E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.51	14.68	^a APO-Simvastatin [TX] ^a Chem mart Simvastatin [CH] ^a Simvacor 40 [CR] ^a Simvastatin AN [EA] ^a Simvastatin generichealth [GQ] ^a Terry White Chemists Simvastatin [TW]	^a Auro-Simvastatin 40 [DO] ^a Ransim [RA] ^a Simvar 40 [RW] ^a Simvastatin-GA 40 [ED] ^a Simvastatin Sandoz [SZ] ^a Zimstat [AF]
			^B 4.00	17.51	14.68	^a Lipex 40 [FR]	^a Zocor [MK]

simvastatin 5 mg tablet, 30

2013Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	11.50	12.67	^a Simvastatin Sandoz [SZ]	^a Zimstat [AF]

simvastatin 80 mg tablet, 30

8313M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.85	16.02	^a APO-Simvastatin [TX] ^a Chem mart Simvastatin [CH] ^a Simvacor 80 [CR] ^a Simvastatin AN [EA]	^a Auro-Simvastatin 80 [DO] ^a Ransim [RA] ^a Simvar 80 [RW] ^a Simvastatin-GA 80 [ED]

					^a Simvastatin generichealth [GQ]	^a Simvastatin Sandoz [SZ]
					^a Terry White Chemists Simvastatin [TW]	^a Zimstat [AF]
	^B 4.00	18.85	16.02		^a Lipex 80 [FR]	^a Zocor [MK]

■ SIMVASTATIN

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

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

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

Clinical criteria:

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

simvastatin 10 mg tablet, 30

9242K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	11.90	13.07	^a APO-Simvastatin [TX] ^a Chem mart Simvastatin [CH] ^a Ransim [RA] ^a Simvar 10 [RW] ^a Simvastatin-GA 10 [ED] ^a Simvastatin Sandoz [SZ] ^a Zimstat [AF]	^a Auro-Simvastatin 10 [DO] ^a GenRx Simvastatin [GX] ^a Simvacor 10 [CR] ^a Simvastatin AN [EA] ^a Simvastatin generichealth [GQ] ^a Terry White Chemists Simvastatin [TW]
	^B 4.00	15.90	13.07			^a Lipex 10 [FR]	^a Zocor [MK]

simvastatin 20 mg tablet, 30

9243L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	12.57	13.74	^a APO-Simvastatin [TX] ^a Chem mart Simvastatin [CH] ^a Simvacor 20 [CR] ^a Simvastatin AN [EA] ^a Simvastatin generichealth [GQ] ^a Terry White Chemists Simvastatin [TW]	^a Auro-Simvastatin 20 [DO] ^a Ransim [RA] ^a Simvar 20 [RW] ^a Simvastatin-GA 20 [ED] ^a Simvastatin Sandoz [SZ] ^a Zimstat [AF]
	^B 4.00	16.57	13.74			^a Lipex 20 [FR]	^a Zocor [MK]

simvastatin 40 mg tablet, 30

9244M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	13.51	14.68	^a APO-Simvastatin [TX] ^a Chem mart Simvastatin [CH] ^a Simvacor 40 [CR] ^a Simvastatin AN [EA] ^a Simvastatin generichealth [GQ] ^a Terry White Chemists Simvastatin [TW]	^a Auro-Simvastatin 40 [DO] ^a Ransim [RA] ^a Simvar 40 [RW] ^a Simvastatin-GA 40 [ED] ^a Simvastatin Sandoz [SZ] ^a Zimstat [AF]
	^B 4.00	17.51	14.68			^a Lipex 40 [FR]	^a Zocor [MK]

simvastatin 5 mg tablet, 30

9241J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	11.50	12.67	^a Simvastatin Sandoz [SZ]	^a Zimstat [AF]

simvastatin 80 mg tablet, 30

9245N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	14.85	16.02	^a APO-Simvastatin [TX] ^a Chem mart Simvastatin [CH] ^a Simvacor 80 [CR] ^a Simvastatin AN [EA] ^a Simvastatin generichealth [GQ] ^a Terry White Chemists Simvastatin [TW]	^a Auro-Simvastatin 80 [DO] ^a Ransim [RA] ^a Simvar 80 [RW] ^a Simvastatin-GA 80 [ED] ^a Simvastatin Sandoz [SZ] ^a Zimstat [AF]
	^B 4.00	18.85	16.02			^a Lipex 80 [FR]	^a Zocor [MK]

■ SUMATRIPTAN

Caution Selective serotonin (5HT₁) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

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

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

Note Pharmaceutical benefits that have the form sumatriptan tablet 50 mg (as succinate) and pharmaceutical benefits that have the form sumatriptan tablet (fast disintegrating) 50 mg (as succinate) are equivalent for the purposes of substitution.

Note Continuing Therapy Only:

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

Restricted benefit

Migraine attack

Clinical criteria:

The condition must have usually failed to respond to analgesics in the past.

SUMATRIPTAN Tablet 50 mg (base) (fast disintegrating), 4

10694W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	^B 3.56	20.90	18.51	^a Imigran FDT [AS]

■ TRAMETINIB

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

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

Note Special Pricing Arrangements apply.

Note MANAGED ENTRY SCHEME

This medicine has been listed on the PBS via a Managed Entry Scheme (MES). This MES provides a mechanism to address the uncertainty over the size of the additional clinical benefit of this medicine while providing early access to those patients for whom there is a high clinical need.

Information about the benefits of this medicine in clinical practice will be collected, analysed and presented to the Pharmaceutical Benefits Advisory Committee (PBAC) for consideration in the near future.

Prescribers and patients must be aware that if a drug listed via a MES does not prove as beneficial in clinical practice as appeared in the clinical data presented to the PBAC, it may subsequently have its restriction modified, or may be removed from the PBS by the Commonwealth or at the request of the sponsor.

In the case of trametinib, the relevant information is being collected from an ongoing clinical trial outside the PBS.

Details of these arrangements are included in an information sheet that must be provided by the prescribing doctor to each patient receiving PBS-subsidy for this medicine.

For more information on Managed Entry Schemes, please visit

<http://www.pbs.gov.au/info/publication/factsheets/shared/framework-for-introduction-of-managed-entry-scheme-for-PBAC-submissions>.

For more information on the PBAC's consideration of this medicine and its MES, please visit

<http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2014-11/trametinib-psd-11-2014>

Authority required (STREAMLINED)

6021

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

Clinical criteria:

Patient must be receiving PBS-subsidised dabrafenib concomitantly for this condition, AND

Patient must not have had progressive disease when treated with a BRAF inhibitor.

trametinib 2 mg tablet, 30

10382K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	8759.04	38.30	Mekinist [NV]

trametinib 500 microgram tablet, 30

10403M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	3	..	*6605.97	38.30	Mekinist [NV]

■ TRAMETINIB

Note A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

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

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

Note Special Pricing Arrangements apply.

Note MANAGED ENTRY SCHEME

This medicine has been listed on the PBS via a Managed Entry Scheme (MES). This MES provides a mechanism to address the uncertainty over the size of the additional clinical benefit of this medicine while providing early access to those patients for whom there is a high clinical need.

Information about the benefits of this medicine in clinical practice will be collected, analysed and presented to the Pharmaceutical Benefits Advisory Committee (PBAC) for consideration in the near future.

Prescribers and patients must be aware that if a drug listed via a MES does not prove as beneficial in clinical practice as appeared in the clinical data presented to the PBAC, it may subsequently have its restriction modified, or may be removed from the PBS by the Commonwealth or at the request of the sponsor.

In the case of trametinib, the relevant information is being collected from an ongoing clinical trial outside the PBS.

Details of these arrangements are included in an information sheet that must be provided by the prescribing doctor to each patient receiving PBS-subsidy for this medicine.

For more information on Managed Entry Schemes, please visit

<http://www.pbs.gov.au/info/publication/factsheets/shared/framework-for-introduction-of-managed-entry-scheme-for-PBAC-submissions>.

For more information on the PBAC's consideration of this medicine and its MES, please visit

<http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2014-11/trametinib-psd-11-2014>

Authority required (STREAMLINED)

6029

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug, AND

Patient must be receiving PBS-subsidised dabrafenib concomitantly for this condition, AND

Patient must have stable or responding disease.

trametinib 2 mg tablet, 30

10405P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	8759.04	38.30	Mekinist [NV]

trametinib 500 microgram tablet, 30

10385N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*6605.97	38.30	Mekinist [NV]

▪ **TRASTUZUMAB**

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Locally advanced HER2 positive breast cancer

Treatment Phase: Initial treatment (3 weekly regimen)

Clinical criteria:

Patient must commence treatment concurrently with neoadjuvant chemotherapy, AND

The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, AND

Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.

HER2 positivity must be demonstrated by in situ hybridisation (ISH).

Authority applications for initial treatment must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Early Breast Cancer - PBS Supporting Information Form which includes:

(i) a copy of the pathology report from an Approved Pathology Authority confirming the presence of HER2 gene amplification by in situ hybridisation (ISH); and

(ii) a copy of the signed patient acknowledgement form.

Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

Authority required

Early HER2 positive breast cancer

Treatment Phase: Initial treatment (3 weekly regimen)

Clinical criteria:

Patient must commence treatment concurrently with adjuvant chemotherapy, AND

Patient must have undergone surgery, AND

The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, AND

Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.

HER2 positivity must be demonstrated by in situ hybridisation (ISH).

Authority applications for initial treatment must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Early Breast Cancer - PBS Supporting Information Form which includes:

- (i) a copy of the pathology report from an Approved Pathology Authority confirming the presence of HER2 gene amplification by in situ hybridisation (ISH); and
(ii) a copy of the signed patient acknowledgement form.

Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

Authority required

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion, AND

The treatment must not be in combination with nab-paclitaxel, AND

The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Authority applications for initial treatment must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Late stage metastatic breast cancer Initial PBS authority application form which includes a copy of the pathology report from an Approved Pathology Authority confirming evidence of HER2 gene amplification in the primary tumour or a metastatic lesion by in situ hybridisation (ISH) and tick a box to state the patient has Stage IV disease.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

Note No applications for increased maximum quantities will be authorised.

Note No applications for increased repeats will be authorised.

Note Special Pricing Arrangements apply.

trastuzumab 600 mg/5 mL injection, 5 mL vial

10721G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	2942.72	38.30	Herceptin SC [RO]

▪ **TRASTUZUMAB**

Authority required

Early HER2 positive breast cancer

Treatment Phase: Continuing treatment (3 weekly regimen)

Clinical criteria:

Patient must have previously received treatment with PBS-subsidised trastuzumab, AND

The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, AND

Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.

Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, at 3 monthly intervals during treatment.

Where a patient has a break in trastuzumab therapy of more than 1 week but less than 6 weeks from when the last dose was due, authority approval will be granted for a new loading dose.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Locally advanced HER2 positive breast cancer

Treatment Phase: Continuing treatment (3 weekly regimen)

Clinical criteria:

Patient must have previously received treatment with PBS-subsidised trastuzumab, AND

The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, AND

Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.

Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, at 3 monthly intervals during treatment.

Where a patient has a break in trastuzumab therapy of more than 1 week but less than 6 weeks from when the last dose was due, authority approval will be granted for a new loading dose.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug for this condition, AND

The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Where a patient has a break in trastuzumab therapy of more than 1 week from when the last dose was due, authority approval will be granted for a new loading dose.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), at 3 monthly intervals during treatment.

Note No applications for increased maximum quantities will be authorised.

Note No applications for increased repeats will be authorised.

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

Note Special Pricing Arrangements apply.

Authority required

HER2 positive breast cancer

Treatment Phase: Grandfathering treatment

Clinical criteria:

Patient must have previously received non-PBS-subsidised treatment with this drug for this condition before 1 July 2015, AND

The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), at 3 monthly intervals during treatment.

Note No applications for increased maximum quantities will be authorised.

Note No applications for increased repeats will be authorised.

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

Note Special Pricing Arrangements apply.

trastuzumab 600 mg/5 mL injection, 5 mL vial

10682F

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	3	..	2942.72	38.30	Herceptin SC [RO]

Palliative Care

■ FENTANYL

Caution The risk of drug dependence is high.

Note Shared Care Model:

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

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

Authority required

Breakthrough pain

Treatment Phase: Initial treatment for dose titration

Clinical criteria:

Patient must have cancer, AND

Patient must have pain directly attributable to cancer, AND

Patient must be assessed as receiving adequate management of their persistent pain with opioids, AND

Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; OR

The treatment must be used as short acting opioids are considered clinically inappropriate; OR

Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.

Treatment criteria:

Patient must be undergoing palliative care.

fentanyl 100 microgram tablet: orally disintegrating, 4

10729Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*71.84	38.30	Fentora [TB]

fentanyl 200 microgram tablet: orally disintegrating, 4

10697B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*71.84	38.30	Fentora [TB]

fentanyl 400 microgram tablet: orally disintegrating, 4

10739F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*71.84	38.30	Fentora [TB]

fentanyl 600 microgram tablet: orally disintegrating, 4

10722H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*71.84	38.30	Fentora [TB]

fentanyl 800 microgram tablet: orally disintegrating, 4

10723J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*71.84	38.30	Fentora [TB]

■ FENTANYL

Caution The risk of drug dependence is high.

Note Shared Care Model:

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

Note For first continuing supply, applications for increased repeats for up to 3 months' supply may be authorised.

Note Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.

Note Telephone approvals are limited to 1 months' therapy.

Authority required

Breakthrough pain

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have cancer, AND

Patient must have pain directly attributable to cancer, AND

Patient must be assessed as receiving adequate management of their persistent pain with opioids, AND

Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; OR

The treatment must be used as short acting opioids are considered clinically inappropriate; OR

Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.

Treatment criteria:

Patient must be undergoing palliative care.

fentanyl 100 microgram tablet: orally disintegrating, 28

10684H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*430.80	38.30	Fentora [TB]

fentanyl 200 microgram tablet: orally disintegrating, 28

10698C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*430.80	38.30	Fentora [TB]

fentanyl 400 microgram tablet: orally disintegrating, 28

10737D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*430.80	38.30	Fentora [TB]

fentanyl 600 microgram tablet: orally disintegrating, 28

10713W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*430.80	38.30	Fentora [TB]

fentanyl 800 microgram tablet: orally disintegrating, 28

10738E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*430.80	38.30	Fentora [TB]

Highly Specialised Drugs Program (Private Hospital)

■ BACLOFEN

Authority required

Severe chronic spasticity

Clinical criteria:

Patient must have failed to respond to treatment with oral antispastic agents; OR

Patient must have had unacceptable side effects to treatment with oral antispastic agents, AND

Patient must have chronic spasticity of cerebral origin.

Authority required

Severe chronic spasticity

Clinical criteria:

Patient must have failed to respond to treatment with oral antispastic agents; OR

Patient must have had unacceptable side effects to treatment with oral antispastic agents, AND

Patient must have chronic spasticity due to multiple sclerosis.

Authority required

Severe chronic spasticity

Clinical criteria:

Patient must have failed to respond to treatment with oral antispastic agents; OR

Patient must have had unacceptable side effects to treatment with oral antispastic agents, AND

Patient must have chronic spasticity due to spinal cord injury.

Authority required

Severe chronic spasticity

Clinical criteria:

Patient must have failed to respond to treatment with oral antispastic agents; OR

Patient must have had unacceptable side effects to treatment with oral antispastic agents, AND

Patient must have chronic spasticity due to spinal cord disease.

baclofen 10 mg/5 mL injection: intrathecal, 1 x 5 mL ampoule

6284R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	10	..	..	*1293.23	^a Bacthecal [DZ]	^a Lioresal Intrathecal [NV]

■ NATALIZUMAB

Caution Progressive multifocal leukoencephalopathy has been reported with this drug.

Authority required

Clinically definite relapsing-remitting multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

The treatment must be as monotherapy, AND

Patient must be ambulatory (without assistance or support), AND

Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years, AND

The condition must be confirmed by magnetic resonance imaging of the brain and/or spinal cord; OR

Patient must be deemed unsuitable for magnetic resonance imaging due to the risk of physical (not psychological) injury to the patient.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a neurologist.

The date of the magnetic resonance imaging scan must be included in the patient's medical notes, unless written certification is provided, in the patient's medical notes, by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient.

Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.

Authority required

Clinically definite relapsing-remitting multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

The treatment must be as monotherapy, AND

Patient must have previously been issued with an authority prescription for this drug, AND

Patient must not show continuing progression of disability while on treatment with this drug, AND

Patient must have demonstrated compliance with, and an ability to tolerate, this therapy.

Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.

natalizumab 300 mg/15 mL injection, 1 x 15 mL vial

9624M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1536.57	Tysabri [BD]

▪ **RITUXIMAB**

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

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

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a

minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

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

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

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

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

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

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided 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 provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment

restriction for new or re-commencing patients 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.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have severe active rheumatoid arthritis, AND

Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist, AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, AND

Patient must not have failed previous PBS-subsidised treatment with rituximab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

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

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND

Patient must not receive more than 2 infusions of rituximab 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.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

For the purposes of this restriction 'TNF' alfa antagonist means adalimumab, certolizumab pegol, etanercept, golimumab and infliximab.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

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 authority application must be made in writing and must include:

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

Assessment of a patient's response to an initial course of treatment must be made at least 12 weeks after the first infusion so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services within 4 weeks of the date it was conducted. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

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

A patient who fails to demonstrate a response to rituximab treatment and who qualifies to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

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

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

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

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

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

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

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

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline 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 is provided with the initial application, the same marker will be used to determine response

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;

(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;

(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Authority required

Severe active rheumatoid arthritis

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

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis, AND

Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist, AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, AND

Patient must not receive more than 2 infusions of rituximab 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.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

For the purposes of this restriction 'TNF' alfa antagonist means adalimumab, certolizumab pegol, etanercept, golimumab and infliximab.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

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

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

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

Applications for a patient who has received PBS-subsidised treatment with rituximab 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 rituximab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised rituximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response at least 12 weeks after the first infusion. This assessment must be submitted no later than 4 weeks from the date of the assessment.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted within 4 weeks of assessment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

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

If a patient fails to demonstrate a response to a treatment with rituximab and who qualify to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

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).

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis, AND

Patient must have demonstrated an adequate response to treatment with this drug, AND

Patient must have received this drug as the most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition, AND

Patient must not receive more than 2 infusions of rituximab 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.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

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

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

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

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted within 4 weeks of assessment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

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

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).

rituximab 500 mg/50 mL injection, 1 x 50 mL vial

9611W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1945.85	Mabthera [RO]

▪ TOCILIZUMAB

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have severe active rheumatoid arthritis, AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, AND

Patient must not have failed previous PBS-subsidised treatment with tocilizumab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the

Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

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 authority application must be made in writing and must include:

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

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.

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

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

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

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

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

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

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

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

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline 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 is provided with the initial application, the same marker will be used to determine response.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

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

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

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

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

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

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

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

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided 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 provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients 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.

Authority required

Severe active rheumatoid arthritis

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

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis, AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, 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 rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

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

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

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

At the time of 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.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab 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 tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

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

If 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 bDMARD.

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).

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

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

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

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

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

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

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

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

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the

commencement of treatment with each initial treatment application must be provided 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 provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients 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.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

Clinical criteria:

Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs

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Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis, AND

Patient must have demonstrated an adequate response to treatment with tocilizumab, AND

Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

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

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

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

At the time of 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.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to demonstrate a response to treatment with tocilizumab 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

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Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

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

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alpha antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

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

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

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

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

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

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided 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 provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients 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.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

Clinical criteria:

Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

tocilizumab 200 mg/10 mL injection, 1 x 10 mL vial

9672C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	357.31	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 1 x 20 mL vial

9673D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	704.03	Actemra [RO]

tocilizumab 80 mg/4 mL injection, 1 x 4 mL vial

9671B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	148.32	Actemra [RO]

■ TOCILIZUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tocilizumab for a patient who has severe active systemic juvenile idiopathic arthritis (SJIA).

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

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

(ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

Once a patient has either failed or ceased to respond to 2 courses of treatment, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised tocilizumab therapy before they are eligible to receive further PBS-subsidised tocilizumab therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was stopped to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

A patient who was receiving PBS-subsidised tocilizumab treatment immediately prior to 1 May 2012 is considered to be in their first cycle as of 1 May 2012. A patient who has had a break in tocilizumab treatment of at least 12 months immediately prior to making a new application, on or after 1 May 2012, will commence a new treatment cycle.

A patient who has failed their first course of tocilizumab in a treatment cycle and who has a break in therapy of less than 12 months may commence a second course of treatment within the same treatment cycle.

A patient who has failed their first course of tocilizumab in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

(1) How to prescribe PBS-subsidised tocilizumab therapy after 1 May 2012.

(a) Initial treatment.

Applications for initial treatment should be made where:

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

(ii) a patient wishes to recommence treatment with tocilizumab following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received the first course of PBS-subsidised (initial or continuing) tocilizumab therapy in a treatment cycle and is deemed to have failed to respond or sustain a response and the treating physician wishes to trial a second course, provided any break in therapy is less than 12 months (Initial 2); or

(iv) a patient wishes to recommence treatment with tocilizumab following a break in PBS-subsidised therapy of less than 12 months (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab for that course.

For second and subsequent courses of PBS-subsidised tocilizumab, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with tocilizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with tocilizumab providing they have demonstrated an adequate response to treatment. The patient

remains eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted tocilizumab supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

(2) Treatment cycle.

Once initial treatment with PBS-subsidised tocilizumab is approved, a patient deemed to have failed to respond to the first course of treatment may have a second course without having to requalify with respect to the indices of disease severity (joint count, fever and/or CRP level and platelet count) or the prior therapy requirements, except if the patient has had a break in therapy of more than 12 months.

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

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the relevant baseline measurements of the joint count, fever and/or CRP level and platelet count submitted with the first authority application for tocilizumab.

Where a patient is deemed to have failed to respond or to sustain a response to the first course of therapy in a treatment cycle, prescribers may provide new baseline measurements for the second course of treatment within that cycle. The Department of Human Services will assess response according to these revised baseline measurements. If new baseline measurements are not submitted with the initial application for the second course of treatment, then those submitted with the first course will be used by the Department of Human Services to assess response to the second course.

(4) Recommencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised tocilizumab therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with tocilizumab should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

Clinical criteria:

Patient must have been diagnosed with systemic juvenile idiopathic arthritis, AND

Patient must have received no prior PBS-subsidised treatment with tocilizumab for this condition; OR

Patient must not have received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months, 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 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 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; 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:

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

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

The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application:

-
- (a) an active joint count of at least 2 active joints; and
(b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or
(c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).
The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

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

- (1) completed authority prescription form(s); and
- (2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the date of assessment of severe active systemic juvenile idiopathic arthritis;
 - (ii) details of prior treatment including dose and duration of treatment;
 - (iii) pathology reports detailing CRP and platelet count where appropriate; and
- (3) an acknowledgement signed by a parent or authorised guardian.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month 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 months supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to 2 courses of treatment in a treatment cycle they will not be eligible to receive further PBS-subsidised tocilizumab therapy in that treatment cycle. A patient may retrial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

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

Note Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 4 weeks from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

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

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

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (retrial or recommencement of treatment after a break of less than 12 months)

Clinical criteria:

Patient must have a documented history of systemic juvenile idiopathic arthritis, AND

Patient must have received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months, AND

Patient must not have failed to demonstrate an adequate response to PBS-subsidised therapy with tocilizumab for this condition more than once in the current treatment cycle, 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.

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

- (1) completed authority prescription form(s); and
- (2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate.

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 months supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

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

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to that course of treatment with tocilizumab.

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.

If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may retrial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

Note Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 4 weeks from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

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

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

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) - balance of supply

Clinical criteria:

Patient must have received insufficient therapy under the Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy under the Initial 2 (retrial or recommencement of treatment after a break of less 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.

Treatment criteria:

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of systemic juvenile idiopathic arthritis, AND

Patient must have demonstrated an adequate response to their most recent course of PBS-subsidised treatment with tocilizumab, AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

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

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

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

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

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity submitted with the initial treatment application.

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

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

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes baseline and current pathology reports detailing CRP and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month 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 months supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the most recent prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with tocilizumab.

Patients are eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may retrial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

Note An assessment of the patient's response to a continuing course of therapy should be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

tocilizumab 200 mg/10 mL injection, 1 x 10 mL vial

1423X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	357.31	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 1 x 20 mL vial

1464C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	704.03	Actemra [RO]

tocilizumab 80 mg/4 mL injection, 1 x 4 mL vial

1419Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	148.32	Actemra [RO]

Highly Specialised Drugs Program (Public Hospital)

■ BACLOFEN

Authority required (STREAMLINED)

6000

Severe chronic spasticity

Clinical criteria:

Patient must have failed to respond to treatment with oral antispastic agents; OR

Patient must have had unacceptable side effects to treatment with oral antispastic agents, AND

Patient must have chronic spasticity of cerebral origin.

Authority required (STREAMLINED)

6003

Severe chronic spasticity

Clinical criteria:

Patient must have failed to respond to treatment with oral antispastic agents; OR

Patient must have had unacceptable side effects to treatment with oral antispastic agents, AND

Patient must have chronic spasticity due to multiple sclerosis.

Authority required (STREAMLINED)

5990

Severe chronic spasticity

Clinical criteria:

Patient must have failed to respond to treatment with oral antispastic agents; OR

Patient must have had unacceptable side effects to treatment with oral antispastic agents, AND

Patient must have chronic spasticity due to spinal cord injury.

Authority required (STREAMLINED)

6051

Severe chronic spasticity

Clinical criteria:

Patient must have failed to respond to treatment with oral antispastic agents; OR

Patient must have had unacceptable side effects to treatment with oral antispastic agents, AND

Patient must have chronic spasticity due to spinal cord disease.

baclofen 10 mg/5 mL injection: intrathecal, 1 x 5 mL ampoule

5617P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	10	..	..	*1246.30	^a Bacthecal [DZ]	^a Lioresal Intrathecal [NV]

■ NATALIZUMAB

Caution Progressive multifocal leukoencephalopathy has been reported with this drug.

Authority required (STREAMLINED)

6043

Clinically definite relapsing-remitting multiple sclerosis

Clinical criteria:

The treatment must be as monotherapy, AND

Patient must be ambulatory (without assistance or support), AND

Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years, AND

The condition must be confirmed by magnetic resonance imaging of the brain and/or spinal cord; OR

Patient must be deemed unsuitable for magnetic resonance imaging due to the risk of physical (not psychological) injury to the patient.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a neurologist.

The date of the magnetic resonance imaging scan must be included in the patient's medical notes, unless written certification is provided, in the patient's medical notes, by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient.

Treatment with this drug must cease if there is continuing progression of disability whilst the patient is being treated with this drug.

For continued treatment the patient must demonstrate compliance with, and an ability to tolerate, this drug.

Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.

natalizumab 300 mg/15 mL injection, 1 x 15 mL vial

9505G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1489.64	Tysabri [BD]

▪ **RITUXIMAB**

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

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

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient

will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

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

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

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

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

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

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided 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 provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients 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.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have severe active rheumatoid arthritis, AND

Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist, AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, AND

Patient must not have failed previous PBS-subsidised treatment with rituximab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

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

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND

Patient must not receive more than 2 infusions of rituximab 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.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

For the purposes of this restriction 'TNF' alfa antagonist means adalimumab, certolizumab pegol, etanercept, golimumab and infliximab.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

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 authority application must be made in writing and must include:

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

Assessment of a patient's response to an initial course of treatment must be made at least 12 weeks after the first infusion so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services within 4 weeks of the date it was conducted. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

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

A patient who fails to demonstrate a response to rituximab treatment and who qualifies to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

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

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

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

(b) at least 4 active joints from the following list of major joints:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline 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 is provided with the initial application, the same marker will be used to determine response

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Authority required

Severe active rheumatoid arthritis

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

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis, AND

Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist, AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, AND

Patient must not receive more than 2 infusions of rituximab 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.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

For the purposes of this restriction 'TNF' alfa antagonist means adalimumab, certolizumab pegol, etanercept, golimumab and infliximab.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

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

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

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

Applications for a patient who has received PBS-subsidised treatment with rituximab 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 rituximab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised rituximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response at least 12 weeks after the first infusion. This assessment must be submitted no later than 4 weeks from the date of the assessment.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted within 4 weeks of assessment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

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

If a patient fails to demonstrate a response to a treatment with rituximab and who qualify to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

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).

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis, AND

Patient must have demonstrated an adequate response to treatment with this drug, AND

Patient must have received this drug as the most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition, AND

Patient must not receive more than 2 infusions of rituximab 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.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

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

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

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

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted within 4 weeks of assessment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

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

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).

rituximab 500 mg/50 mL injection, 1 x 50 mL vial

9544H

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
1	..	..	1898.92	Mabthera [RO]

■ TOCILIZUMAB

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have severe active rheumatoid arthritis, AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, AND

Patient must not have failed previous PBS-subsidised treatment with tocilizumab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

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

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine,

leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

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 authority application must be made in writing and must include:

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

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.

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

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

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

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

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

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline 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 is provided with the initial application, the same marker will be used to determine response.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists

(adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF- α antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF- α antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

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

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

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

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

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

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided 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 provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients 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.

Authority required

Severe active rheumatoid arthritis

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

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis, AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, 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 rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

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

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

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

At the time of 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.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab 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 tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

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

If 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 bDMARD.

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).

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

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Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

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

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alpha antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the

dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

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

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

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

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

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

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided 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 provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients 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.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

Clinical criteria:

Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs

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Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis, AND

Patient must have demonstrated an adequate response to treatment with tocilizumab, AND

Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

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

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

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

At the time of 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.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to demonstrate a response to treatment with tocilizumab 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:

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

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New

baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

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

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

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

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

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

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided 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 provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients 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.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

Clinical criteria:

Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to

Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

tocilizumab 200 mg/10 mL injection, 1 x 10 mL vial

9658H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	336.90	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 1 x 20 mL vial

9659J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	670.29	Actemra [RO]

tocilizumab 80 mg/4 mL injection, 1 x 4 mL vial

9657G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	135.95	Actemra [RO]

■ TOCILIZUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tocilizumab for a patient who has severe active systemic juvenile idiopathic arthritis (sJIA).

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

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

(ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

Once a patient has either failed or ceased to respond to 2 courses of treatment, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised tocilizumab therapy before they are eligible to receive further PBS-subsidised tocilizumab therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was stopped to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

A patient who was receiving PBS-subsidised tocilizumab treatment immediately prior to 1 May 2012 is considered to be in their first cycle as of 1 May 2012. A patient who has had a break in tocilizumab treatment of at least 12 months immediately prior to making a new application, on or after 1 May 2012, will commence a new treatment cycle.

A patient who has failed their first course of tocilizumab in a treatment cycle and who has a break in therapy of less than 12 months may commence a second course of treatment within the same treatment cycle.

A patient who has failed their first course of tocilizumab in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

(1) How to prescribe PBS-subsidised tocilizumab therapy after 1 May 2012.

(a) Initial treatment.

Applications for initial treatment should be made where:

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

(ii) a patient wishes to recommence treatment with tocilizumab following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received the first course of PBS-subsidised (initial or continuing) tocilizumab therapy in a treatment cycle and is deemed to have failed to respond or sustain a response and the treating physician wishes to trial a second course, provided any break in therapy is less than 12 months (Initial 2); or

(iv) a patient wishes to recommence treatment with tocilizumab following a break in PBS-subsidised therapy of less than 12 months (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab for that course.

For second and subsequent courses of PBS-subsidised tocilizumab, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

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

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted tocilizumab supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient

will be deemed to have failed to respond to treatment with tocilizumab.

(2) Treatment cycle.

Once initial treatment with PBS-subsidised tocilizumab is approved, a patient deemed to have failed to respond to the first course of treatment may have a second course without having to requalify with respect to the indices of disease severity (joint count, fever and/or CRP level and platelet count) or the prior therapy requirements, except if the patient has had a break in therapy of more than 12 months.

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

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the relevant baseline measurements of the joint count, fever and/or CRP level and platelet count submitted with the first authority application for tocilizumab.

Where a patient is deemed to have failed to respond or to sustain a response to the first course of therapy in a treatment cycle, prescribers may provide new baseline measurements for the second course of treatment within that cycle. The Department of Human Services will assess response according to these revised baseline measurements. If new baseline measurements are not submitted with the initial application for the second course of treatment, then those submitted with the first course will be used by the Department of Human Services to assess response to the second course.

(4) Recommencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised tocilizumab therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with tocilizumab should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

Clinical criteria:

Patient must have been diagnosed with systemic juvenile idiopathic arthritis, AND

Patient must have received no prior PBS-subsidised treatment with tocilizumab for this condition; OR

Patient must not have received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months, 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 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 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; 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:

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

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

The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application:

(a) an active joint count of at least 2 active joints; and

(b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or

(c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of

methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

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

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

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes the following:

(i) the date of assessment of severe active systemic juvenile idiopathic arthritis;

(ii) details of prior treatment including dose and duration of treatment;

(iii) pathology reports detailing CRP and platelet count where appropriate; and

(3) an acknowledgement signed by a parent or authorised guardian.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month 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 months supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to 2 courses of treatment in a treatment cycle they will not be eligible to receive further PBS-subsidised tocilizumab therapy in that treatment cycle. A patient may retrial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

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

Note Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 4 weeks from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

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

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

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (retrial or recommencement of treatment after a break of less than 12 months)

Clinical criteria:

Patient must have a documented history of systemic juvenile idiopathic arthritis, AND

Patient must have received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months, AND

Patient must not have failed to demonstrate an adequate response to PBS-subsidised therapy with tocilizumab for this condition more than once in the current treatment cycle, 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.

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

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

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate.

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 months supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

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

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to that course of treatment with tocilizumab.

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.

If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may retrial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

Note Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 4 weeks from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

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

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

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (retial or recommencement of treatment after a break of less than 12 months) - balance of supply

Clinical criteria:

Patient must have received insufficient therapy under the Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy under the Initial 2 (retial or recommencement of treatment after a break of less 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.

Treatment criteria:

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of systemic juvenile idiopathic arthritis, AND

Patient must have demonstrated an adequate response to their most recent course of PBS-subsidised treatment with tocilizumab, AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

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

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

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

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

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity submitted with the initial treatment application.

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

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

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes baseline and current pathology reports detailing CRP and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month 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 months supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the most recent prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with tocilizumab.

Patients are eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may retrial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

Note An assessment of the patient's response to a continuing course of therapy should be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

tocilizumab 200 mg/10 mL injection, 1 x 10 mL vial

1481Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	336.90	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 1 x 20 mL vial

1482B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	670.29	Actemra [RO]

tocilizumab 80 mg/4 mL injection, 1 x 4 mL vial

1476Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	135.95	Actemra [RO]

Highly Specialised Drugs Program (Community Access)

▪ ATAZANAVIR + COBICISTAT

Authority required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must be antiretroviral treatment naive, AND

The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received PBS-subsidised therapy for HIV infection, AND

The treatment must be in combination with other antiretroviral agents.

atazanavir 300 mg + cobicistat 150 mg tablet, 30

10692R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1116.35	38.30	Evotaz [BQ]

▪ TENOFOVIR + EMTRICITABINE + ELVITEGRAVIR + COBICISTAT

Authority required (STREAMLINED)

4522

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must be antiretroviral treatment naive.

Authority required (STREAMLINED)

4470

HIV infection

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received PBS-subsidised therapy for HIV infection.

tenofovir alafenamide 10 mg + emtricitabine 200 mg + elvitegravir 150 mg + cobicistat 150 mg tablet, 30

10680D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*2016.63	38.30	Genvoya [GI]