



Australian Government

Department of Health and Ageing

SCHEDULE OF PHARMACEUTICAL BENEFITS

SUMMARY OF CHANGES

EFFECTIVE 1 June 2011

PHARMACEUTICAL BENEFITS

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 June 2011. The Schedule is updated on the first day of each month and is available on the Internet at www.pbs.gov.au.

Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 June 2011 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	\$6.42
	Dangerous drug fee	\$2.71
	Extemporaneously-prepared	\$8.46
	Allowable additional patient charge*	\$3.92
Additional Fees (for safety net prices):	Ready-prepared	\$1.07
	Extemporaneously-prepared	\$1.41
Patient Co-payments:	General	\$34.20
	Concessional	\$5.60
Safety Net Thresholds:	General	\$1317.20
	Concessional	\$336.00
Safety Net Card Issue Fee:		\$8.58

*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

Additions

Additions – Items

8969C	Calcium Folate , Injection equivalent to 1000 mg folinic acid in 100 mL (<i>Calcium Folate Ebewe</i>)
8986Y	Docetaxel , Solution concentrate for I.V. infusion 20 mg in 1 mL (<i>Taxotere</i>)
8987B	Docetaxel , Solution concentrate for I.V. infusion 20 mg in 2 mL (<i>DBL Docetaxel Concentrated Injection</i>)
8988C	Docetaxel , Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL with solvent (<i>Taxotere</i>)
8989D	Docetaxel , Solution concentrate for I.V. infusion 80 mg in 4 mL (<i>Taxotere</i>)
8990E	Docetaxel , Solution concentrate for I.V. infusion 80 mg in 8 mL (<i>DBL Docetaxel Concentrated Injection</i>)
8991F	Docetaxel , Injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL with solvent (<i>Taxotere</i>)
8992G	Docetaxel , Solution concentrate for I.V. infusion 160 mg in 16 mL (<i>DBL Docetaxel Concentrated Injection</i>)
8976K	Phenoxymethylpenicillin , Powder for oral liquid 125 mg (as potassium) per 5 mL, 100 mL (<i>Phenoxymethyl- penicillin-AFT</i>)
5024K	Phenoxymethylpenicillin , Powder for oral liquid 125 mg (as potassium) per 5 mL, 100 mL (<i>Phenoxymethyl- penicillin-AFT</i>) (Dental)
8977L	Phenoxymethylpenicillin , Powder for oral liquid 250 mg (as potassium) per 5 mL, 100 mL (<i>Phenoxymethyl- penicillin-AFT</i>)
5029Q	Phenoxymethylpenicillin , Powder for oral liquid 250 mg (as potassium) per 5 mL, 100 mL (<i>Phenoxymethyl- penicillin-AFT</i>) (Dental)
8972F	Risedronate Sodium , Tablet 35 mg (enteric coated) (<i>Actonel EC</i>)
8973G	Risedronate Sodium and Calcium Carbonate , Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium) (<i>Actonel EC Combi</i>)
8974H	Risedronate Sodium and Calcium Carbonate with Colecalciferol , Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms (<i>Actonel EC Combi D</i>)
8983T	Saxagliptin , Tablet 5 mg (as hydrochloride) (<i>Onglyza</i>)
8984W	Sirolimus , Tablet 0.5 mg (<i>Rapamune</i>)
8978M	Telmisartan with Amlodipine , Tablet 40 mg-5 mg (as besylate) (<i>Twynsta</i>)
8979N	Telmisartan with Amlodipine , Tablet 40 mg-10 mg (as besylate) (<i>Twynsta</i>)
8980P	Telmisartan with Amlodipine , Tablet 80 mg-5 mg (as besylate) (<i>Twynsta</i>)
8981Q	Telmisartan with Amlodipine , Tablet 80 mg-10 mg (as besylate) (<i>Twynsta</i>)

Additions – Brands

1889K	<i>Amoxycillin generichealth 500, GQ</i> – Amoxycillin , Capsule 500 mg
3300Q	<i>Amoxycillin generichealth 500, GQ</i> – Amoxycillin , Capsule 500 mg (Dental)
8220P	<i>Citalopram Pfizer, FZ; Pharmacor Citalo 20, MI</i> – Citalopram Hydrobromide , Tablet 20 mg (base)
8703C	<i>Citalopram Pfizer, FZ</i> – Citalopram Hydrobromide , Tablet 40 mg (base)
8358X	<i>Clopidogrel RBX, RA</i> – Clopidogrel , Tablet 75 mg (as hydrogen sulfate)
8487Q	<i>Implanon NXT, MK</i> – Etonogestrel , Subcutaneous implant 68 mg
8694N	<i>Pioglitazone Sandoz, SZ</i> – Pioglitazone , Tablet 15 mg (as hydrochloride)
8695P	<i>Pioglitazone Sandoz, SZ</i> – Pioglitazone , Tablet 30 mg (as hydrochloride)
8696Q	<i>Pioglitazone Sandoz, SZ</i> – Pioglitazone , Tablet 45 mg (as hydrochloride)
8621R	<i>Risedro once a week, QA</i> – Risedronate Sodium , Tablet 35 mg
8288F	<i>APO-Salbutamol, TX</i> – Salbutamol Sulfate , Oral pressurised inhalation 100 micrograms (base) per dose (200 doses), CFC-free formulation

3495Y	<i>APO-Salbutamol, TX</i> – Salbutamol Sulfate , Oral pressurised inhalation 100 micrograms (base) per dose (200 doses), CFC-free formulation (Emergency Drug Supply)
2011W	<i>Simvastatin Pfizer, FZ</i> – Simvastatin , Tablet 10 mg
2012X	<i>Simvastatin Pfizer, FZ</i> – Simvastatin , Tablet 20 mg
8173E	<i>Simvastatin Pfizer, FZ</i> – Simvastatin , Tablet 40 mg
8313M	<i>Simvastatin Pfizer, FZ</i> – Simvastatin , Tablet 80 mg
9242K	<i>Simvastatin Pfizer, FZ</i> – Simvastatin , Tablet 10 mg (Diff. Max. Rpts)
9243L	<i>Simvastatin Pfizer, FZ</i> – Simvastatin , Tablet 20 mg (Diff. Max. Rpts)
9244M	<i>Simvastatin Pfizer, FZ</i> – Simvastatin , Tablet 40 mg (Diff. Max. Rpts)
9245N	<i>Simvastatin Pfizer, FZ</i> – Simvastatin , Tablet 80 mg (Diff. Max. Rpts)

Additions – Bioequivalence Indicators

8487Q	<i>Implanon, SH</i> – Etonogestrel , Subcutaneous implant 68 mg
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Deletions

Deletions – Items

8192E	Dolasetron Mesylate , I.V. injection 100 mg in 5 mL – <i>Anzemet, SW</i>
8682Y	Glucose Indicator—blood , Test strips, 50 – <i>MWD Pen Sensor Strips, WF</i>
9264N	Glucose Indicator—blood , Test strips, 50 – <i>MWD Pen Sensor Strips, WF</i> (Diff. Max. Rpts)
2059J	Memantine Hydrochloride , Oral drops 10 mg per g, 50 g – <i>Ebixa, LU</i>
2063N	Sulfacetamide Sodium , Eye drops 100 mg per mL (10%), 15 mL – <i>Bleph 10, AG</i>
5530C	Sulfacetamide Sodium , Eye drops 100 mg per mL (10%), 15 mL – <i>Bleph 10, AG</i> (Optometrical)

Alterations

Alterations – Notes

8741C	Adalimumab , Injection 40 mg in 0.8 mL single use pre-filled syringe
9100Y	Adalimumab , Injection 40 mg in 0.8 mL single use pre-filled syringe
8638P	Etanercept , Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL
9090K	Etanercept , Injection 50 mg in 1 mL single use pre-filled syringe, 4
9460X	Etanercept , Injection 50 mg in 1 mL single use auto-injector, 4
3428K	Golimumab , Injection 50 mg in 0.5 mL single use pre-filled syringe
3429L	Golimumab , Injection 50 mg in 0.5 mL single use pre-filled pen

Alterations – Restrictions and Notes

8737W	Adalimumab , Injection 40 mg in 0.8 mL single use pre-filled syringe
9099X	Adalimumab , Injection 40 mg in 0.8 mL single use pre-filled syringe
3425G	Certolizumab Pegol , Injection 200 mg in 1 mL single use pre-filled syringe
5463M	Docetaxel , Solution concentrate for I.V. infusion 20 mg in 1 mL
5486R	Docetaxel , Solution concentrate for I.V. infusion 20 mg in 2 mL
8071T	Docetaxel , Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL with solvent
5464N	Docetaxel , Solution concentrate for I.V. infusion 80 mg in 4 mL
5487T	Docetaxel , Solution concentrate for I.V. infusion 80 mg in 8 mL
8074Y	Docetaxel , Injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL with solvent
8967Y	Docetaxel , Solution concentrate for I.V. infusion 160 mg in 16 mL
8637N	Etanercept , Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL
9089J	Etanercept , Injection 50 mg in 1 mL single use pre-filled syringe, 4
9459W	Etanercept , Injection 50 mg in 1 mL single use auto-injector, 4
3426H	Golimumab , Injection 50 mg in 0.5 mL single use pre-filled syringe

3427J **Golimumab**, Injection 50 mg in 0.5 mL single use pre-filled syringe

Alterations – Manufacturer's Code

		<i>From:</i>	<i>To:</i>
8282X	Milk Powder—Lactose Free Formula , Infant formula powder 900 g (S-26 LF)	WX	PF
8283Y	Milk Powder—Lactose Free Formula , Infant formula powder 900 g (S-26 LF) (Diff. Max. Rpts)	WX	PF

All items with the manufacturer code SI have changed to the code QA, with the exception of the following brand:

2593L *Ferrosig, SI — Iron Polymaltose Complex*, Injection 100 mg (iron) in 2 mL

Alterations – Brand Name and Manufacturer's Code

From:

1016L *AstraZeneca Pty Ltd, AP —Adrenaline*, Injection 1 mg in 1 mL (1 in 1,000)

To:

1016L *Link Medical Products Pty Ltd, LM— Adrenaline*, Injection 1 mg in 1 mL (1 in 1,000)

From:

3451P *AstraZeneca Pty Ltd, AP —Adrenaline*, Injection 1 mg in 1 mL (1 in 1,000) **(Emergency Drug Supply)**

To:

3451P *Link Medical Products Pty Ltd, LM —Adrenaline*, Injection 1 mg in 1 mL (1 in 1,000) **(Emergency Drug Supply)**

From:

5004J *AstraZeneca Pty Ltd, AP —Adrenaline*, Injection 1 mg in 1 mL (1 in 1,000) **(Dental)**

To:

5004J *Link Medical Products Pty Ltd, LM —Adrenaline*, Injection 1 mg in 1 mL (1 in 1,000) **(Dental)**

From:

1165H *Sigma Pharmaceuticals (Australia) Pty Ltd, SI —Dexamphetamine Sulfate*, Tablet 5 mg

To:

1165H *Aspen Pharma Pty Ltd, QA—Dexamphetamine Sulfate*, Tablet 5 mg

From:

1850J *Sigma Pharmaceuticals (Australia) Pty Ltd, SI — Phenobarbitone*, Tablet 30 mg

To:

1850J *Aspen Pharma Pty Ltd, QA—Phenobarbitone*, Tablet 30 mg

From:

2345K *Sigma Pharmaceuticals (Australia) Pty Ltd, SI —Thiotepa*, Powder for injection 15 mg

To:

2345K *Aspen Pharma Pty Ltd, QA—Thiotepa*, Powder for injection 15 mg

SECTION 100 – HIGHLY SPECIALISED DRUGS PROGRAM

Additions

Additions – Items

- 9747B **Sirolimus**, Tablet 0.5 mg (*Rapamune*) (**Public**)
 9748C **Sirolimus**, Tablet 0.5 mg (*Rapamune*) (**Private**)

Alterations

Additions – Restrictions and Notes

- 5605B **Abatacept**, Powder for I.V. infusion 250 mg (*Orencia*) (**Public**)
 9621J **Abatacept**, Powder for I.V. infusion 250 mg (*Orencia*) (**Private**)
 5757B **Infliximab**, Powder for I.V. infusion 100 mg (*Remicade*) (**Public**)
 6397Q **Infliximab**, Powder for I.V. infusion 100 mg (*Remicade*) (**Private**)
 9544H **Rituximab**, Solution for I.V. infusion 500 mg in 50 mL (*Mabthera*) (**Public**)
 9611W **Rituximab**, Solution for I.V. infusion 500 mg in 50 mL (*Mabthera*) (**Private**)
 9657G **Tocilizumab**, Concentrate for injection 80 mg in 4 mL (*Actemra*) (**Public**)
 9671B **Tocilizumab**, Concentrate for injection 80 mg in 4 mL (*Actemra*) (**Private**)
 9658H **Tocilizumab**, Concentrate for injection 200 mg in 10 mL (*Actemra*) (**Public**)
 9672C **Tocilizumab**, Concentrate for injection 200 mg in 10 mL (*Actemra*) (**Private**)
 9659J **Tocilizumab**, Concentrate for injection 400 mg in 20 mL (*Actemra*) (**Public**)
 9673D **Tocilizumab**, Concentrate for injection 400 mg in 20 mL (*Actemra*) (**Private**)

ADVANCE NOTICES

DELETIONS

Advance Notice – Deletion of Items

The following items which may be prescribed by Participating Dental Practitioners for Dental treatment only will be deleted from the Schedule of Pharmaceutical Benefits on 1 July 2011:

The deletions have been recommended by the Pharmaceutical Benefits Advisory Committee—

- 5129Y **Hydromorphone Hydrochloride**, Injection 2 mg in 1 mL, (*Dilaudid*), (**Dental**)
 5130B **Hydromorphone Hydrochloride**, Injection 10 mg in 1 mL, (*Dilaudid-HP*), (**Dental**)
 5131C **Hydromorphone Hydrochloride**, Injection 50 mg in 5 mL, (*Dilaudid-HP*), (**Dental**)
 5023J **Hydromorphone Hydrochloride**, Tablet 4 mg (modified release), (*Jurnista*), (**Dental**)
 3357Q **Hydromorphone Hydrochloride**, Tablet 8 mg (modified release), (*Jurnista*), (**Dental**)
 3358R **Hydromorphone Hydrochloride**, Tablet 16 mg (modified release), (*Jurnista*), (**Dental**)
 3367F **Hydromorphone Hydrochloride**, Tablet 32 mg (modified release), (*Jurnista*), (**Dental**)
 3368G **Hydromorphone Hydrochloride**, Tablet 64 mg (modified release), (*Jurnista*), (**Dental**)
 5246D **Morphine Sulfate**, Capsule 10 mg (containing sustained release pellets), (*Kapanol*), (**Dental**)
 5242X **Morphine Sulfate**, Capsule 100 mg (containing sustained release pellets), (*Kapanol*), (**Dental**)
 5067Q **Morphine Sulfate**, Capsule 120 mg (controlled release), (*MS Mono*), (**Dental**)
 5240T **Morphine Sulfate**, Capsule 20 mg (containing sustained release pellets), (*Kapanol*), (**Dental**)
 5064M **Morphine Sulfate**, Capsule 30 mg (controlled release), (*MS Mono*), (**Dental**)
 5241W **Morphine Sulfate**, Capsule 50 mg (containing sustained release pellets), (*Kapanol*), (**Dental**)
 5065N **Morphine Sulfate**, Capsule 60 mg (controlled release), (*MS Mono*), (**Dental**)
 5066P **Morphine Sulfate**, Capsule 90 mg (controlled release), (*MS Mono*), (**Dental**)
 5245C **Morphine Sulfate**, Sachet containing controlled release granules for oral suspension, 100 mg per

sachet, (*MS Contin Suspension 100 mg*) , (**Dental**)

- 5171E **Morphine Sulfate**, Sachet containing controlled release granules for oral suspension, 20 mg per sachet, (*MS Contin Suspension 20 mg*) , (**Dental**)
- 5243Y **Morphine Sulfate**, Sachet containing controlled release granules for oral suspension, 30 mg per sachet, (*MS Contin Suspension 30 mg*) , (**Dental**)
- 5244B **Morphine Sulfate**, Sachet containing controlled release granules for oral suspension, 60 mg per sachet, (*MS Contin Suspension 60 mg*) , (**Dental**)
- 5164T **Morphine Sulfate**, Tablet 10 mg (controlled release), (*Momex SR 10, MS Contin*) , (**Dental**)
- 5167Y **Morphine Sulfate**, Tablet 100 mg (controlled release), (*Momex SR 100, MS Contin*) , (**Dental**)
- 5161P **Morphine Sulfate**, Tablet 15 mg (controlled release), (*MS Contin*) , (**Dental**)
- 5165W **Morphine Sulfate**, Tablet 30 mg (controlled release), (*Momex SR 30, MS Contin*) , (**Dental**)
- 5162Q **Morphine Sulfate**, Tablet 5 mg (controlled release), (*MS Contin*) , (**Dental**)
- 5166X **Morphine Sulfate**, Tablet 60 mg (controlled release), (*Momex SR 60, MS Contin*) , (**Dental**)
- 5198N **Oxycodone Hydrochloride**, Capsule 20 mg, (*OxyNorm*) , (**Dental**)
- 5247E **Oxycodone Hydrochloride**, Tablet 10 mg (controlled release), (*OxyContin*) , (**Dental**)
- 5015Y **Oxycodone Hydrochloride**, Tablet 15 mg (controlled release), (*OxyContin*) , (**Dental**)
- 5248F **Oxycodone Hydrochloride**, Tablet 20 mg (controlled release), (*OxyContin*) , (**Dental**)
- 5016B **Oxycodone Hydrochloride**, Tablet 30 mg (controlled release), (*OxyContin*) , (**Dental**)
- 5249G **Oxycodone Hydrochloride**, Tablet 40 mg (controlled release), (*OxyContin*) , (**Dental**)
- 5227D **Oxycodone Hydrochloride**, Tablet 5 mg (controlled release), (*OxyContin*) , (**Dental**)
- 5250H **Oxycodone Hydrochloride**, Tablet 80 mg (controlled release), (*OxyContin*) , (**Dental**)
- 5001F **Tramadol Hydrochloride**, Tablet 100 mg (once a day extended release), (*Durotram XR*) , (**Dental**)
- 5234L **Tramadol Hydrochloride**, Tablet 100 mg (twice daily sustained release), (*APO-Tramadol SR, Chem mart Tramadol SR, GA Tramadol SR 100mg, Lodam SR 100, Terry White Chemists Tramadol SR, Tramadol Sandoz SR, Tramedo SR 100, Zydol SR 100, Tramal SR 100*) , (**Dental**)
- 5235M **Tramadol Hydrochloride**, Tablet 150 mg (twice daily sustained release), (*APO-Tramadol SR, Chem mart Tramadol SR, GA Tramadol SR 150mg, Lodam SR 150, Terry White Chemists Tramadol SR, Tramadol Sandoz SR, Tramedo SR 150, Zydol SR 150, Tramal SR 150*) , (**Dental**)
- 5002G **Tramadol Hydrochloride**, Tablet 200 mg (once a day extended release), (*Durotram XR*) , (**Dental**)
- 5236N **Tramadol Hydrochloride**, Tablet 200 mg (twice daily sustained release), (*APO-Tramadol SR, Chem mart Tramadol SR, GA Tramadol SR 200mg, Lodam SR 200, Terry White Chemists Tramadol SR, Tramadol Sandoz SR, Tramedo SR 200, Zydol SR 200, Tramal SR 200*) , (**Dental**)
- 5003H **Tramadol Hydrochloride**, Tablet 300 mg (once a day extended release), (*Durotram XR*) , (**Dental**)
- 3338Q **Tramadol Hydrochloride**, Tablet 50 mg (twice daily sustained release), (*Tramal SR 50*) , (**Dental**)

Advance Notice – Deletion of Brands

The following brands will be deleted from the Schedule of Pharmaceutical Benefits on 1 July 2011:

Brand deletion requested by the manufacturer—

1358L *Prothiaden, AB* — **Dothiepin Hydrochloride**, Tablet 75 mg

Brand discontinued by the manufacturer—

8487Q *Implanon, SH* — **Etonogestrel**, Subcutaneous implant 68 mg

3010K *Norflohexal, HX* — **Norfloxacin**, Tablet 400 mg

REPATRIATION PHARMACEUTICAL BENEFITS

Additions

Additions – Brands

4444X *APO-Risedronate, TX; Chem mart Risedronate, CH; Risedro once a week, QA; Terry White Chemists Risedronate, TW – **Risedronate Sodium**, Tablet 35 mg*

Additions – Bioequivalence Indicators

4444X *Actonel Once-a-Week, SW – **Risedronate Sodium**, Tablet 35 mg*

Alterations

Alterations – Brand Name

From:

4011D *Zabel, AF – **Terbinafine**, Tablet 250 mg (as hydrochloride)*

To:

4011D *Tinasil, AF – **Terbinafine**, Tablet 250 mg (as hydrochloride)*

Alterations – Manufacturer's Code

All items with the manufacturer code SI have changed to the code QA.

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price	Maximum	Brand Name and Manufacturer
					for Max. Qty \$	Recordable Value for Safety Net \$	

ADALIMUMAB

Note

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 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 anti-rheumatic 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) and the T-cell co-stimulation modulator (abatacept).

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

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

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 Medicare Australia 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 and tocilizumab, 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

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty	Maximum Recordable Value for Safety Net	Brand Name and Manufacturer
					\$	\$	

therapy and this assessment must be submitted to Medicare Australia 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 Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia 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 Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Rituximab patients:

A further application may be submitted to Medicare Australia 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 Medicare Australia 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 Medicare Australia 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.

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.

Note

(3) Baseline measurements to determine response.

Medicare Australia 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 Medicare Australia will assess response according to these revised baseline

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty	Maximum Recordable Value for Safety Net	Brand Name and Manufacturer
					\$	\$	

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.

(4) Patients 'grandfathered' onto PBS-subsidised treatment with certolizumab pegol, golimumab or tocilizumab.

From 1 August 2010, a patient who commenced treatment with certolizumab pegol or golimumab for severe rheumatoid arthritis prior to 1 March 2010 or tocilizumab for severe rheumatoid arthritis prior to 1 July 2009 and who was 'grandfathered' on to PBS-subsidised therapy, and who continues to receive treatment will have further applications for treatment with certolizumab pegol, golimumab or tocilizumab assessed under the continuing treatment restriction.

A patient may only qualify for PBS-subsidised treatment under the grandfather restriction (Initial 3 ('grandfather patients')) once. A maximum of 24 weeks of treatment with certolizumab pegol, golimumab or tocilizumab will be authorised under this restriction.

Authority required

Initial 1 (new patient or patient re-commencing after a break of more than 24 months)

Initial PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

- (a) have severe active rheumatoid arthritis; and
- (b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and
- (c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to 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:
 - hydroxychloroquine at a dose of at least 200 mg daily; or
 - leflunomide at a dose of at least 10 mg daily; or
 - sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:

- hydroxychloroquine at a dose of at least 200 mg daily; and/or
- leflunomide at a dose of at least 10 mg daily; and/or
- sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

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, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:

- azathioprine at a dose of at least 1 mg/kg per day; and/or
- cyclosporin at a dose of at least 2 mg/kg/day; and/or
- sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

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. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

GENERAL PHARMACEUTICAL BENEFITS

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					\$	\$	

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

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

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

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

— 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 reason this criterion cannot be satisfied.

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

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

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) a signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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 Medicare Australia 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 to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

Patients who fail to demonstrate a response to treatment with adalimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

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

Authority required

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

Initial course of PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have a documented history of severe active rheumatoid arthritis; and

(b) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

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 [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with adalimumab and who wish 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 adalimumab treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised adalimumab treatment was approved under either of the initial 1 or 2 treatment restrictions, patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
Where the most recent course of PBS-subsidised adalimumab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Patients who fail to demonstrate a response to treatment with adalimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. <u>Note</u> No applications for increased maximum quantities and/or repeats will be authorised. Applications for treatment with adalimumab where the dosing frequency exceeds 40 mg per fortnight will not be approved. <u>Note</u> Special Pricing Arrangements apply.							
8737W	Injection 40 mg in 0.8 mL pre-filled syringe	2	3	..	1774.36	34.20	Humira AB
9099X	Injection 40 mg in 0.8 mL pre-filled pen	2	3	..	1774.36	34.20	Humira AB

ADALIMUMAB

Note

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 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 anti-rheumatic 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) and the T-cell co-stimulation modulator (abatacept).

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

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

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 Medicare Australia 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.

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price	Maximum	Brand Name and Manufacturer
					for Max. Qty \$	Recordable Value for Safety Net \$	

(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 and tocilizumab, 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 Medicare Australia 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 Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia 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 Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Rituximab patients:

A further application may be submitted to Medicare Australia 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 Medicare Australia 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 Medicare Australia 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.

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.

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty	Maximum Recordable Value for Safety Net	Brand Name and Manufacturer
					\$	\$	

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.

Note

(3) Baseline measurements to determine response.

Medicare Australia 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 Medicare Australia 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.

(4) Patients 'grandfathered' onto PBS-subsidised treatment with certolizumab pegol, golimumab or tocilizumab.

From 1 August 2010, a patient who commenced treatment with certolizumab pegol or golimumab for severe rheumatoid arthritis prior to 1 March 2010 or tocilizumab for severe rheumatoid arthritis prior to 1 July 2009 and who was 'grandfathered' on to PBS-subsidised therapy, and who continues to receive treatment will have further applications for treatment with certolizumab pegol, golimumab or tocilizumab assessed under the continuing treatment restriction.

A patient may only qualify for PBS-subsidised treatment under the grandfather restriction (Initial 3 ('grandfather patients')) once. A maximum of 24 weeks of treatment with certolizumab pegol, golimumab or tocilizumab will be authorised under this restriction.

Authority required

Continuing treatment

Continuing PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:

- (a) who have a documented history of severe active rheumatoid arthritis; and
- (b) who have demonstrated an adequate response to treatment with adalimumab; and
- (c) whose most recent course of PBS-subsidised bDMARD treatment was with adalimumab.

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:

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

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

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST

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Monday to Friday).								
All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.								
Patients who fail to demonstrate a response to treatment with adalimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.								
Note								
No applications for increased maximum quantities and/or repeats will be authorised.								
Applications for treatment with adalimumab where the dosing frequency exceeds 40 mg per fortnight will not be approved.								
Note								
Special Pricing Arrangements apply.								
8741C	Injection 40 mg in 0.8 mL pre-filled syringe	2	5	..	1774.36	34.20	Humira	AB
9100Y	Injection 40 mg in 0.8 mL pre-filled pen	2	5	..	1774.36	34.20	Humira	AB
ADRENALINE								
1016L NP	Injection 1 mg in 1 mL (1 in 1,000)	5	1	..	20.34	21.41	Link Medical Products Pty Ltd	LM
3451P NP	Injection 1 mg in 1 mL (1 in 1,000)	5	..	..	20.34	21.41	Link Medical Products Pty Ltd	LM
5004J	Injection 1 mg in 1 mL (1 in 1,000) (Dental)	5	..	..	20.34	21.41	Link Medical Products Pty Ltd	LM
AMOXYCILLIN								
1889K NP,MW	Capsule 500 mg	20	1	..	10.45	11.52	^a Alphamox 500	AF
							^a Amoxycillin-GA	GM
							^a Amoxycillin generichealth 500	GQ
							^a Amoxycillin Ranbaxy	RA
							^a Amoxycillin Sandoz	SZ
							^a APO-Amoxycillin	TX
							^a Chem mart Amoxycillin	CH
							^a Cilamox	QA
							^a GenRx Amoxycillin	GX
							^a Terry White Chemists Amoxycillin	TW
				^B 1.35	11.80	11.52	^a Amoxil	GK
3300Q	Capsule 500 mg (Dental)	20	..	..	10.45	11.52	^a Alphamox 500	AF
							^a Amoxycillin-GA	GM
							^a Amoxycillin generichealth 500	GQ
							^a Amoxycillin Ranbaxy	RA
							^a Amoxycillin Sandoz	SZ
							^a APO-Amoxycillin	TX
							^a Chem mart Amoxycillin	CH
							^a Cilamox	QA
							^a GenRx Amoxycillin	GX
							^a Terry White Chemists Amoxycillin	TW
				^B 1.35	11.80	11.52	^a Amoxil	GK

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty	Maximum Recordable Value for Safety Net	Brand Name and Manufacturer
					\$	\$	
8969C	CALCIUM FOLINATE Injection equivalent to 1000 mg folinic acid in 100 mL	1	1	..	258.72	34.20	Calcium Folate Ebewe

CERTOLIZUMAB PEGOL

Note

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

Further prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe certolizumab pegol should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 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 anti-rheumatic 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) and the T-cell co-stimulation modulator (abatacept).

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

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

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 Medicare Australia 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.

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price	Maximum Recordable Value for Safety Net	Brand Name and Manufacturer
					for Max. Qty \$	\$	
	Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 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 Medicare Australia 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 Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia 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 Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Rituximab patients:

A further application may be submitted to Medicare Australia 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 Medicare Australia 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 Medicare Australia 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.

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.

GENERAL PHARMACEUTICAL BENEFITS

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					\$	\$	

Note

(3) Baseline measurements to determine response.

Medicare Australia 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 Medicare Australia 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.

(4) Patients 'grandfathered' onto PBS-subsidised treatment with certolizumab pegol, golimumab or tocilizumab.

From 1 August 2010, a patient who commenced treatment with certolizumab pegol or golimumab for severe rheumatoid arthritis prior to 1 March 2010 or tocilizumab for severe rheumatoid arthritis prior to 1 July 2009 and who was 'grandfathered' on to PBS-subsidised therapy, and who continues to receive treatment will have further applications for treatment with certolizumab pegol, golimumab or tocilizumab assessed under the continuing treatment restriction.

A patient may only qualify for PBS-subsidised treatment under the grandfather restriction (Initial 3 ('grandfather patients')) once. A maximum of 24 weeks of treatment with certolizumab pegol, golimumab or tocilizumab will be authorised under this restriction.

Authority required

Initial 1 (new patient or patient re-commencing after a break of more than 24 months)

Initial PBS-subsidised treatment with certolizumab pegol, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

- (a) have severe active rheumatoid arthritis; and
- (b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and
- (c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to 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:
 - hydroxychloroquine at a dose of at least 200 mg daily; or
 - leflunomide at a dose of at least 10 mg daily; or
 - sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:

- hydroxychloroquine at a dose of at least 200 mg daily; and/or
- leflunomide at a dose of at least 10 mg daily; and/or
- sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

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, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:

- azathioprine at a dose of at least 1 mg/kg per day; and/or
- cyclosporin at a dose of at least 2 mg/kg/day; and/or
- sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

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.

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					\$	\$	

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. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

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

- (i) a total active joint count of at least 20 active (swollen and tender) joints; or
- (ii) at least 4 active joints from the following list of major joints:
 - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - 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 reason this criterion cannot be satisfied.

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

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

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
- (3) a signed patient acknowledgement.

A maximum of 18 to 20 weeks of treatment depending on the dosage regimen will be authorised under this restriction.

Where fewer than 5 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 18 or 20 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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 Medicare Australia 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 to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with certolizumab pegol.

Patients who fail to demonstrate a response to treatment with certolizumab pegol under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Authority required

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

Initial course of PBS-subsidised treatment with certolizumab pegol, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

- (a) have a documented history of severe active rheumatoid arthritis; and
- (b) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

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 [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with certolizumab pegol and who wish 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 certolizumab pegol treatment, within the timeframes specified below.

A maximum of 18 to 20 weeks of treatment depending on the dosage regimen will be authorised under this restriction.

Where fewer than 5 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 18 or 20 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised certolizumab pegol treatment was approved under either of the initial 1 or 2 treatment restrictions,

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					\$	\$	
patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.							

Where the most recent course of PBS-subsidised certolizumab pegol treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients who fail to demonstrate a response to treatment with certolizumab pegol under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Authority required

Initial 3 ('grandfather' patients)

Initial PBS-subsidised supply for continuing treatment with certolizumab pegol, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of an adult who:

- (a) has a documented history of severe active rheumatoid arthritis; and
- (b) was receiving treatment with certolizumab pegol prior to 1 March 2010; and
- (c) has demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with certolizumab pegol; and
- (d) is receiving treatment with certolizumab pegol at the time of application.

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

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

The same indices of disease severity used to establish baseline at the commencement of treatment with a bDMARD must be used for assessment of all continuing applications.

The assessment of the patient's response to a continuing course of therapy must be made within 4 weeks prior to completion of that course and posted to Medicare Australia 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 criterion.

A maximum of 24 weeks of treatment with certolizumab pegol will be approved under this criterion.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only.

Patients who fail to demonstrate a response to treatment with certolizumab pegol under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Authority required

Continuing treatment

Continuing PBS-subsidised treatment with certolizumab pegol, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:

- (a) who have a documented history of severe active rheumatoid arthritis; and
- (b) who have demonstrated an adequate response to treatment with certolizumab pegol; and
- (c) whose most recent course of PBS-subsidised bDMARD treatment was with certolizumab pegol.

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:

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

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

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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					\$	\$	

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

Patients who fail to demonstrate a response to treatment with certolizumab pegol under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note

Special Pricing Arrangements apply.

3425G	Injection 200 mg in 1 mL single use pre-filled syringe	2	5	..	1708.64	34.20	Cimzia	UC
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CITALOPRAM HYDROBROMIDE

Restricted benefit

Major depressive disorders.

8220P NP	Tablet 20 mg (base)	28	5	..	22.12	23.19	^a	APO-Citalopram	TX
							^a	Celapram	AF
							^a	Celica	RA
							^a	Chem mart	CH
							^a	Citalopram	GM
							^a	Ciazil	BF
							^a	Citalobell	CR
							^a	Citalopram 20	GQ
							^a	Citalopram	FZ
							^a	generichealth	SZ
							^a	Citalopram Pfizer	GX
							^a	Citalopram Sandoz	MI
							^a	GenRx Citalopram	QA
							^a	Pharmacor	TW
							^a	Citalo 20	
							^a	Talam	
							^a	Terry White Chemists	
							^a	Citalopram	
8703C NP	Tablet 40 mg (base)	28	5	..	32.99	34.06	^B 4.45	Cipramil	LU
							^a	APO-Citalopram	TX
							^a	Celapram	AF
							^a	Citalopram Pfizer	FZ
							^a	Citalopram Sandoz	SZ
							^a	GenRx Citalopram	GX

CLOPIDOGREL

Authority required (STREAMLINED)

1719

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients with a history of symptomatic cerebrovascular ischaemic episodes while on therapy with low-dose aspirin;

1720

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding;

1721

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or NSAIDs;

1722

Prevention of recurrence of myocardial infarction or unstable angina in patients with a history of symptomatic cardiac ischaemic events while on therapy with low-dose aspirin;

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
1723							
Prevention of recurrence of myocardial infarction or unstable angina in patients where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding;							
1724							
Prevention of recurrence of myocardial infarction or unstable angina in patients where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or NSAIDs.							
Note							
Not for prophylaxis of DVT or peripheral arterial disease.							
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							
Clopidogrel (as besilate) 75 mg tablets have been established to be bioequivalent to clopidogrel (as hydrogen sulfate) 75 mg tablets.							
8358X NP	Tablet 75 mg (as hydrogen sulfate)	28	5	..	70.30	34.20	^a APO-Clopidogrel TX
						^a Chem mart CH	
						^a Clopidogrel RA	
						^a Clopidogrel RBX SZ	
						^a Clopidogrel Sandoz SZ	
						^a Clopidogrel Winthrop WA	
						^a Iscover BQ	
						^a Piax AF	
						^a Plavix SW	
						^a Terry White Chemists TW Clopidogrel	
DEXAMPHETAMINE SULFATE							
Note							
Care must be taken to comply with the provisions of State/Territory law when prescribing dexamphetamine.							
Authority required							
Use in attention deficit hyperactivity disorder, in accordance with State/Territory law;							
Narcolepsy.							
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.							
1165H NP	Tablet 5 mg	100	5	..	18.19	19.26	Aspen Pharma Pty Ltd QA
DOCETAXEL							
Authority required							
Adjuvant treatment of node-positive breast cancer in combination with an anthracycline and cyclophosphamide;							
Advanced breast cancer after failure of prior therapy;							
Advanced metastatic ovarian cancer after failure of prior therapy which includes a platinum compound;							
Locally advanced or metastatic non-small cell lung cancer.							
Authority required							
Treatment of androgen independent (hormone refractory) metastatic carcinoma of the prostate in a patient with a Karnofsky performance-status score of at least 60%. Docetaxel must be used as first-line chemotherapy and administered in three weekly cycles.							
Note							
A maximum of 10 cycles of treatment with docetaxel will be authorised under this restriction.							
Note							
The 20 mg solution concentrates for I.V. infusion and solution for I.V. infusion (after reconstitution) are bioequivalent.							
5463M	Solution concentrate for I.V. infusion 20 mg in 1 mL	2	..	..	*651.16	34.20	^a Taxotere SW
5486R	Solution concentrate for I.V. infusion 20 mg in 2 mL	2	..	..	*651.16	34.20	^a DBL Docetaxel Concentrated HH

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8071T	Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL with solvent	2	..	..	*651.16	34.20	a	Injection Docetaxel Ebewe IT
							a	Taxotere SW

DOCETAXEL

Authority required

Neoadjuvant treatment of a patient with a WHO performance status of 1 or less, with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx, in combination with cisplatin and fluorouracil.

Note

The carcinoma can be considered inoperable for technical or organ preservation reasons.

Authority required

Adjuvant treatment of node-positive breast cancer in combination with an anthracycline and cyclophosphamide;

Advanced breast cancer after failure of prior therapy;

Advanced metastatic ovarian cancer after failure of prior therapy which includes a platinum compound;

Locally advanced or metastatic non-small cell lung cancer.

Authority required

Treatment of androgen independent (hormone refractory) metastatic carcinoma of the prostate in a patient with a Karnofsky performance-status score of at least 60%. Docetaxel must be used as first-line chemotherapy and administered in three weekly cycles.

Note

A maximum of 10 cycles of treatment with docetaxel will be authorised under this restriction.

Note

The 80 mg solution concentrates for I.V. infusion and solution for I.V. infusion (after reconstitution) are bioequivalent.

5464N	Solution concentrate for I.V. infusion 80 mg in 4 mL	1	..	..	1280.83	34.20	a	Taxotere	SW
5487T	Solution concentrate for I.V. infusion 80 mg in 8 mL	1	..	..	1280.83	34.20	a	DBL Docetaxel Concentrated Injection	HH
8074Y	Injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL with solvent	1	..	..	1280.83	34.20	a	Docetaxel Ebewe IT	SW
							a	Taxotere	

DOCETAXEL

Authority required

Neoadjuvant treatment of a patient with a WHO performance status of 1 or less, with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx, in combination with cisplatin and fluorouracil.

Note

The carcinoma can be considered inoperable for technical or organ preservation reasons.

Authority required

Adjuvant treatment of node-positive breast cancer in combination with an anthracycline and cyclophosphamide;

Advanced breast cancer after failure of prior therapy;

Advanced metastatic ovarian cancer after failure of prior therapy which includes a platinum compound;

Locally advanced or metastatic non-small cell lung cancer.

Authority required

Treatment of androgen independent (hormone refractory) metastatic carcinoma of the prostate in a patient with a Karnofsky performance-status score of at least 60%. Docetaxel must be used as first-line chemotherapy and administered in three weekly cycles.

Note

A maximum of 10 cycles of treatment with docetaxel will be authorised under this restriction.

8967Y	Solution concentrate for I.V. infusion 160 mg in 16 mL	1	..	..	2457.26	34.20		DBL Docetaxel Concentrated Injection	HH
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GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
DOCETAXEL							
<u>Authority required</u>							
Treatment of HER2 positive early breast cancer in combination with trastuzumab.							
<u>Authority required</u>							
Adjuvant treatment of operable breast cancer in combination with cyclophosphamide.							
<u>Note</u>							
A maximum of four cycles of treatment will be authorised under this restriction.							
<u>Note</u>							
The 20 mg solution concentrates for I.V. infusion and solution for I.V. infusion (after reconstitution) are bioequivalent.							
8986Y	Solution concentrate for I.V. infusion 20 mg in 1 mL	2	..	..	*651.16	34.20 ^a	Taxotere SW
8987B	Solution concentrate for I.V. infusion 20 mg in 2 mL	2	..	..	*651.16	34.20 ^a	DBL Docetaxel Concentrated Injection HH
8988C	Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL with solvent	2	..	..	*651.16	34.20 ^a	Taxotere SW
DOCETAXEL							
<u>Authority required</u>							
Treatment of HER2 positive early breast cancer in combination with trastuzumab.							
<u>Authority required</u>							
Adjuvant treatment of operable breast cancer in combination with cyclophosphamide.							
<u>Note</u>							
A maximum of four cycles of treatment will be authorised under this restriction.							
<u>Note</u>							
The 80 mg solution concentrates for I.V. infusion and solution for I.V. infusion (after reconstitution) are bioequivalent.							
8989D	Solution concentrate for I.V. infusion 80 mg in 4 mL	1	..	..	1280.83	34.20 ^a	Taxotere SW
8990E	Solution concentrate for I.V. infusion 80 mg in 8 mL	1	..	..	1280.83	34.20 ^a	DBL Docetaxel Concentrated Injection HH
8991F	Injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL with solvent	1	..	..	1280.83	34.20 ^a	Taxotere SW
DOCETAXEL							
<u>Authority required</u>							
Treatment of HER2 positive early breast cancer in combination with trastuzumab.							
<u>Authority required</u>							
Adjuvant treatment of operable breast cancer in combination with cyclophosphamide.							
<u>Note</u>							
A maximum of four cycles of treatment will be authorised under this restriction.							
8992G	Solution concentrate for I.V. infusion 160 mg in 16 mL	1	..	..	2457.26	34.20	DBL Docetaxel Concentrated Injection HH

ETANERCEPT

Note

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty	Maximum Recordable Value for Safety Net	Brand Name and Manufacturer
					\$	\$	
	GPO Box 9826 HOBART TAS 7001						

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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 anti-rheumatic 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) and the T-cell co-stimulation modulator (abatacept).

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

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

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 Medicare Australia 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 and tocilizumab, 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 Medicare Australia 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 Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia 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 Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty	Maximum Recordable Value for Safety Net	Brand Name and Manufacturer
					\$	\$	

Rituximab patients:

A further application may be submitted to Medicare Australia 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 Medicare Australia 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 Medicare Australia 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.

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.

Note

(3) Baseline measurements to determine response.

Medicare Australia 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 Medicare Australia 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

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty	Maximum Recordable Value for Safety Net	Brand Name and Manufacturer
					\$	\$	
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.							

(4) Patients 'grandfathered' onto PBS-subsidised treatment with certolizumab pegol, golimumab or tocilizumab.

From 1 August 2010, a patient who commenced treatment with certolizumab pegol or golimumab for severe rheumatoid arthritis prior to 1 March 2010 or tocilizumab for severe rheumatoid arthritis prior to 1 July 2009 and who was 'grandfathered' on to PBS-subsidised therapy, and who continues to receive treatment will have further applications for treatment with certolizumab pegol, golimumab or tocilizumab assessed under the continuing treatment restriction.

A patient may only qualify for PBS-subsidised treatment under the grandfather restriction (Initial 3 ('grandfather patients')) once. A maximum of 24 weeks of treatment with certolizumab pegol, golimumab or tocilizumab will be authorised under this restriction.

Authority required

Initial 1 (new patient or patient re-commencing after a break of more than 24 months)

Initial PBS-subsidised treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

- (a) have severe active rheumatoid arthritis; and
- (b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and
- (c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to 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:
 - hydroxychloroquine at a dose of at least 200 mg daily; or
 - leflunomide at a dose of at least 10 mg daily; or
 - sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:

- hydroxychloroquine at a dose of at least 200 mg daily; and/or
- leflunomide at a dose of at least 10 mg daily; and/or
- sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

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, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:

- azathioprine at a dose of at least 1 mg/kg per day; and/or
- cyclosporin at a dose of at least 2 mg/kg/day; and/or
- sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

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. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

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

- (i) a total active joint count of at least 20 active (swollen and tender) joints; or
- (ii) at least 4 active joints from the following list of major joints:
 - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - 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.

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty	Maximum Recordable Value for Safety Net	Brand Name and Manufacturer
					\$	\$	

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

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 [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
- (3) a signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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 Medicare Australia 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 to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Authority required

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

Initial course of PBS-subsidised treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

- (a) have a documented history of severe active rheumatoid arthritis; and
- (b) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

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 [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with etanercept and who wish 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 etanercept treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised etanercept treatment was approved under either of the initial 1 or 2 treatment restrictions, patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

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

Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

Note

Special Pricing Arrangements apply.

8637N	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes	2	3	..	*1829.00	34.20	Enbrel	WX
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GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty	Maximum Recordable Value for Safety Net	Brand Name and Manufacturer
					\$	\$	
9089J	solvent 1 mL Injections 50 mg in 1 mL single use pre-filled syringes, 4	1	3	..	1774.37	34.20	Enbrel WX
9459W	Injection 50 mg in 1 mL single use auto-injector, 4	1	3	..	1774.37	34.20	Enbrel WX

ETANERCEPT

Note

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 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 anti-rheumatic 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) and the T-cell co-stimulation modulator (abatacept).

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

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

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 Medicare Australia 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).

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty	Maximum Recordable Value for Safety Net	Brand Name and Manufacturer
					\$	\$	

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 and tocilizumab, 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 Medicare Australia 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 Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia 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 Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Rituximab patients:

A further application may be submitted to Medicare Australia 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 Medicare Australia 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 Medicare Australia 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.

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

GENERAL PHARMACEUTICAL BENEFITS

							Maximum Recordable Value for Safety Net
	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	\$	Brand Name and Manufacturer
Code	prescription or remaining repeats for the bDMARD the patient is ceasing.						

Note

(3) Baseline measurements to determine response.

Medicare Australia 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 Medicare Australia 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.

(4) Patients 'grandfathered' onto PBS-subsidised treatment with certolizumab pegol, golimumab or tocilizumab.

From 1 August 2010, a patient who commenced treatment with certolizumab pegol or golimumab for severe rheumatoid arthritis prior to 1 March 2010 or tocilizumab for severe rheumatoid arthritis prior to 1 July 2009 and who was 'grandfathered' on to PBS-subsidised therapy, and who continues to receive treatment will have further applications for treatment with certolizumab pegol, golimumab or tocilizumab assessed under the continuing treatment restriction.

A patient may only qualify for PBS-subsidised treatment under the grandfather restriction (Initial 3 ('grandfather patients')) once. A maximum of 24 weeks of treatment with certolizumab pegol, golimumab or tocilizumab will be authorised under this restriction.

Authority required

Continuing treatment

Continuing PBS-subsidised treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:

- (a) who have a documented history of severe active rheumatoid arthritis; and
- (b) who have demonstrated an adequate response to treatment with etanercept; and
- (c) whose most recent course of PBS-subsidised bDMARD treatment was with etanercept.

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:

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

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

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
<u>Note</u> No applications for increased maximum quantities and/or repeats will be authorised.								
<u>Note</u> Special Pricing Arrangements apply.								
8638P	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	2	5	..	*1829.00	34.20	Enbrel	WX
9090K	Injections 50 mg in 1 mL single use pre-filled syringes, 4	1	5	..	1774.37	34.20	Enbrel	WX
9460X	Injection 50 mg in 1 mL single use auto-injector, 4	1	5	..	1774.37	34.20	Enbrel	WX
ETONOGESTREL								
8487Q NP	Subcutaneous implant 68 mg	1	..	..	215.92	34.20	^a Implanon	SH
							^a Implanon NXT	MK

GOLIMUMAB

Note

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe golimumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 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 anti-rheumatic 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) and the T-cell co-stimulation modulator (abatacept).

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

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

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 Medicare Australia 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.

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty	Maximum Recordable Value for Safety Net	Brand Name and Manufacturer
					\$	\$	

(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 and tocilizumab, 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 Medicare Australia 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 Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia 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 Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Rituximab patients:

A further application may be submitted to Medicare Australia 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 Medicare Australia 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 Medicare Australia 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.

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.

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty	Maximum Recordable Value for Safety Net	Brand Name and Manufacturer
					\$	\$	

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.

Note

(3) Baseline measurements to determine response.

Medicare Australia 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 Medicare Australia 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.

(4) Patients 'grandfathered' onto PBS-subsidised treatment with certolizumab pegol, golimumab or tocilizumab.

From 1 August 2010, a patient who commenced treatment with certolizumab pegol or golimumab for severe rheumatoid arthritis prior to 1 March 2010 or tocilizumab for severe rheumatoid arthritis prior to 1 July 2009 and who was 'grandfathered' on to PBS-subsidised therapy, and who continues to receive treatment will have further applications for treatment with certolizumab pegol, golimumab or tocilizumab assessed under the continuing treatment restriction.

A patient may only qualify for PBS-subsidised treatment under the grandfather restriction (Initial 3 ('grandfather patients')) once. A maximum of 24 weeks of treatment with certolizumab pegol, golimumab or tocilizumab will be authorised under this restriction.

Authority required

Initial 1 (new patient or patient re-commencing after a break of more than 24 months)

Initial PBS-subsidised treatment with golimumab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

- (a) have severe active rheumatoid arthritis; and
- (b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and
- (c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to 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:
 - hydroxychloroquine at a dose of at least 200 mg daily; or
 - leflunomide at a dose of at least 10 mg daily; or
 - sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:

- hydroxychloroquine at a dose of at least 200 mg daily; and/or
- leflunomide at a dose of at least 10 mg daily; and/or
- sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

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, then one or more of the following DMARDs may be used in place of these

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty	Maximum Recordable Value for Safety Net	Brand Name and Manufacturer
					\$	\$	

agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:

- azathioprine at a dose of at least 1 mg/kg per day; and/or
- cyclosporin at a dose of at least 2 mg/kg/day; and/or
- sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

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. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

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

- (i) a total active joint count of at least 20 active (swollen and tender) joints; or
- (ii) at least 4 active joints from the following list of major joints:
 - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - 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 reason this criterion cannot be satisfied.

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

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

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
- (3) a signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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 Medicare Australia 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 to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with golimumab.

Patients who fail to demonstrate a response to treatment with golimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Authority required

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

Initial course of PBS-subsidised treatment with golimumab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

- (a) have a documented history of severe active rheumatoid arthritis; and
- (b) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

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

- (1) a completed authority prescription form; and

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty	Maximum Recordable Value for Safety Net	Brand Name and Manufacturer
					\$	\$	
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].							

Applications for patients who have received PBS-subsidised treatment with golimumab and who wish 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 golimumab treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised golimumab treatment was approved under either of the initial 1 or 2 treatment restrictions, patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

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

Patients who fail to demonstrate a response to treatment with golimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note

Special Pricing Arrangements apply.

3426H	Injection 50 mg in 0.5 mL single use pre-filled syringe	1	3	..	1777.29	34.20	Simponi	SH
3427J	Injection 50 mg in 0.5 mL single use pre-filled pen	1	3	..	1777.29	34.20	Simponi	SH

GOLIMUMAB

Note

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe golimumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 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 anti-rheumatic 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) and the T-cell co-stimulation modulator (abatacept).

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

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

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.

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty	Maximum Recordable Value for Safety Net	Brand Name and Manufacturer
					\$	\$	

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia 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 and tocilizumab, 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 Medicare Australia 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 Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia 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 Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Rituximab patients:

A further application may be submitted to Medicare Australia 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 Medicare Australia 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 Medicare Australia 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

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					\$	\$	

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.

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.

Note

(3) Baseline measurements to determine response.

Medicare Australia 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 Medicare Australia 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.

(4) Patients 'grandfathered' onto PBS-subsidised treatment with certolizumab pegol, golimumab or tocilizumab.

From 1 August 2010, a patient who commenced treatment with certolizumab pegol or golimumab for severe rheumatoid arthritis prior to 1 March 2010 or tocilizumab for severe rheumatoid arthritis prior to 1 July 2009 and who was 'grandfathered' on to PBS-subsidised therapy, and who continues to receive treatment will have further applications for treatment with certolizumab pegol, golimumab or tocilizumab assessed under the continuing treatment restriction.

A patient may only qualify for PBS-subsidised treatment under the grandfather restriction (Initial 3 ('grandfather patients')) once. A maximum of 24 weeks of treatment with certolizumab pegol, golimumab or tocilizumab will be authorised under this restriction.

Authority required

Initial 3 ('grandfather' patients)

Initial PBS-subsidised supply for continuing treatment with golimumab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of an adult who:

- (a) has a documented history of severe active rheumatoid arthritis; and
- (b) was receiving treatment with golimumab prior to 1 March 2010; and
- (c) has demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with golimumab; and
- (d) is receiving treatment with golimumab at the time of application.

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

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

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					\$	\$	

The same indices of disease severity used to establish baseline at the commencement of treatment with a bDMARD must be used for assessment of all continuing applications.

The assessment of the patient's response to a continuing course of therapy must be made within 4 weeks prior to completion of that course and posted to Medicare Australia 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 criterion.

A maximum of 24 weeks of treatment with golimumab will be approved under this criterion.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only.

Patients who fail to demonstrate a response to treatment with golimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Authority required

Continuing treatment

Continuing PBS-subsidised treatment with golimumab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:

- (a) who have a documented history of severe active rheumatoid arthritis; and
- (b) who have demonstrated an adequate response to treatment with golimumab; and
- (c) whose most recent course of PBS-subsidised bDMARD treatment was with golimumab.

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:

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

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

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with golimumab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia 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.

Patients who fail to demonstrate a response to treatment with golimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note

Special Pricing Arrangements apply.

3428K	Injection 50 mg in 0.5 mL single use pre-filled syringe	1	5	..	1777.29	34.20	Simponi	SH
3429L	Injection 50 mg in 0.5 mL single use pre-filled pen	1	5	..	1777.29	34.20	Simponi	SH

MILK POWDER—LACTOSE FREE FORMULA

Authority required

Acute lactose intolerance in infants up to the age of 12 months. The date of birth of the patient must be included in the authority application.

Note

No applications for increased maximum quantities and/or repeats will be authorised. No more than 1 application per patient will be authorised.

8282X	Infant formula powder 900 g	5	..	..	*112.87	34.20	S-26 LF	PF
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GENERAL PHARMACEUTICAL BENEFITS

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					\$	\$	

NP

MILK POWDER—LACTOSE FREE FORMULA

Authority required

Proven chronic lactose intolerance in infants up to the age of 12 months. The date of birth of the patient must be included in the authority application. Lactose intolerance must have been proven by either:

- (a) relief of symptoms on supervised withdrawal of lactose from the diet for 3 or 4 days and subsequent re-emergence of symptoms on rechallenge with lactose containing formulae or milk or food; or
- (b) not less than 0.5% reducing substance in stool exudate tested with copper sulfate diagnostic compound tablet; or
- (c) hydrogen breath test.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

8283Y NP	Infant formula powder 900 g	5	5	..	*112.87	34.20	S-26 LF	PF
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PHENOBARBITONE

Restricted benefit

Epilepsy.

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.

1850J NP	Tablet 30 mg	200	4	..	16.60	17.67	Aspen Pharma Pty Ltd	QA
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PHENOXYMETHYLPENICILLIN

8976K NP	Powder for oral liquid 125 mg (as potassium) per 5 mL, 100 mL	2	1	..	*#16.71	18.12	Phenoxyethyl-penicillin-AFT	AE
5024K	Powder for oral liquid 125 mg (as potassium) per 5 mL, 100 mL (Dental)	2	..	..	*#16.71	18.12	Phenoxyethyl-penicillin-AFT	AE
8977L NP	Powder for oral liquid 250 mg (as potassium) per 5 mL, 100 mL	2	1	..	*#19.27	20.68	Phenoxyethyl-penicillin-AFT	AE
5029Q	Powder for oral liquid 250 mg (as potassium) per 5 mL, 100 mL (Dental)	2	..	..	*#19.27	20.68	Phenoxyethyl-penicillin-AFT	AE

PIOGLITAZONE

Note

Pioglitazone hydrochloride is not PBS-subsidised as monotherapy or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

Authority required (STREAMLINED)

3540

Dual oral combination therapy with metformin or a sulfonylurea

Type 2 diabetes, in combination with either metformin or a sulfonylurea, in a patient whose HbA1c is greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 despite treatment with either metformin or a sulfonylurea and where a combination of metformin and a sulfonylurea is contraindicated or not tolerated.

The date and level of the qualifying HbA1c must be documented in the patient's medical records at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) red cell transfusion within the previous 3 months.

A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone or a glucagon-like peptide-1, must be documented in the patient's medical records.

Authority required (STREAMLINED)

3541

Combination therapy with insulin

Type 2 diabetes, in combination with insulin, in a patient whose HbA1c is greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor

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					Max. Qty \$	Value for Safety Net \$	
	(gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 despite treatment with insulin and oral anti-diabetic agents, or insulin alone where metformin is contraindicated.						

The date and level of the qualifying HbA1c must be documented in the patient's medical records at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) red cell transfusion within the previous 3 months.

A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone or a glucagon-like peptide-1, must be documented in the patient's medical records.

Authority required (STREAMLINED)

3542

Triple oral combination therapy with metformin and a sulfonylurea

Type 2 diabetes, in combination with metformin and a sulfonylurea, in a patient whose HbA1c is greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 despite treatment with maximally tolerated doses of metformin and a sulfonylurea.

The date and level of the qualifying HbA1c must be documented in the patient's medical records at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) red cell transfusion within the previous 3 months.

A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone or a glucagon-like peptide-1, must be documented in the patient's medical records.

8694N NP	Tablet 15 mg (as hydrochloride)	28	5	..	53.00	34.20	^a Acpio 15	QA
							^a Actos	LY
							^a APOTEX- Pioglitazone	TX
							^a Chem mart Pioglitazone	CH
							^a Pharmacor Pioglitazone 15	CR
							^a Pioglitazone generichealth 15	GQ
							^a Pioglitazone Sandoz	SZ
							^a Pizaccord	MI
							^a Terry White Chemists Pioglitazone	TW
							^a Vexazone	AF
8695P NP	Tablet 30 mg (as hydrochloride)	28	5	..	77.62	34.20	^a Acpio 30	QA
							^a Actos	LY
							^a APOTEX- Pioglitazone	TX
							^a Chem mart Pioglitazone	CH
							^a Pharmacor Pioglitazone 30	CR
							^a Pioglitazone generichealth 30	GQ
							^a Pioglitazone Sandoz	SZ
							^a Pizaccord	MI
							^a Terry White Chemists Pioglitazone	TW
							^a Vexazone	AF
8696Q	Tablet 45 mg (as hydrochloride)	28	5	..	99.01	34.20	^a Acpio 45	QA

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty	Maximum Recordable Value for Safety Net	Brand Name and Manufacturer
					\$	\$	
NP							^a Actos LY
							^a APOTEX- Pioglitazone TX
							^a Chem mart Pioglitazone CH
							^a Pharmacor Pioglitazone 45 CR
							^a Pioglitazone generichealth 45 GQ
							^a Pioglitazone Sandoz SZ
							^a Pizaccord MI
							^a Terry White Chemists TW
							^a Pioglitazone
							^a Vexazone AF

RISEDRONATE SODIUM

Authority required (STREAMLINED)

3070

Treatment as the sole PBS-subsidised anti-resorptive agent for corticosteroid-induced osteoporosis in a patient currently on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy with a Bone Mineral Density (BMD) T-score of -1.5 or less.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

2645

Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a patient aged 70 years of age or older with a Bone Mineral Density (BMD) T-score of -3.0 or less.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

2646

Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Note

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

8972F	Tablet 35 mg (enteric coated)	4	5	..	46.55	34.20	Actonel EC	SW
NP								
8621R	Tablet 35 mg	4	5	..	46.55	34.20	^a Acris Once-a-Week	AF
NP								
							^a Actonel Once-a-Week	SW
							^a APO-Risedronate	TX
							^a Chem mart Risedronate	CH
							^a Risedro once a week	QA
							^a Terry White Chemists Risedronate	TW

RISEDRONATE SODIUM and CALCIUM CARBONATE

Authority required (STREAMLINED)

3070

Treatment as the sole PBS-subsidised anti-resorptive agent for corticosteroid-induced osteoporosis in a patient currently on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy with a Bone Mineral Density (BMD) T-score of -1.5 or less.

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					\$	\$	
	The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.						
	<u>Authority required (STREAMLINED)</u>						
	2645						
	Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a patient aged 70 years of age or older with a Bone Mineral Density (BMD) T-score of -3.0 or less.						
	The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.						
	<u>Authority required (STREAMLINED)</u>						
	2646						
	Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.						
	A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.						
	<u>Note</u>						
	Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.						
8973G NP	Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium)	1	5	..	46.55	34.20	Actonel EC Combi SW
RISEDRONATE SODIUM and CALCIUM CARBONATE with COLECALCIFEROL							
	<u>Authority required (STREAMLINED)</u>						
	3070						
	Treatment as the sole PBS-subsidised anti-resorptive agent for corticosteroid-induced osteoporosis in a patient currently on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy with a Bone Mineral Density (BMD) T-score of -1.5 or less.						
	The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.						
	<u>Authority required (STREAMLINED)</u>						
	2645						
	Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a patient aged 70 years of age or older with a Bone Mineral Density (BMD) T-score of -3.0 or less.						
	The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.						
	<u>Authority required (STREAMLINED)</u>						
	2646						
	Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.						
	A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.						
	<u>Note</u>						
	Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid.						
8974H NP	Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms	1	5	..	46.55	34.20	Actonel EC Combi D SW
SALBUTAMOL SULFATE							
8288F NP	Oral pressurised inhalation 100 micrograms (base) per dose (200 doses), CFC-free formulation	2	5	..	*15.22	16.29	^a Airomir IA
						^a	APO-Salbutamol TX
						^a	Asmol CFC-free AL
				^B 1.56	*16.78	16.29	^a Ventolin CFC-free GK
3495Y	Oral pressurised inhalation 100 micrograms	1	..	..	10.82	11.89	^a Airomir IA

2011W NP	Tablet 10 mg	30	5	..	24.11	25.18	^a	APO-Simvastatin	TX
							^a	Chem mart Simvastatin	CH
							^a	GenRx Simvastatin	GX
							^a	Pharmacor Simvastatin 10	MI
							^a	Ransim	RA
							^a	Simvahexal	SZ
							^a	Simvar 10	QA
							^a	Simvastatin-DP	GM
							^a	Simvastatin-GA 10	GN
							^a	Simvastatin generichealth	GQ
							^a	Simvastatin Pfizer	FZ
							^a	Simvastatin-Spirit 10	ZP
							^a	Simvastatin Winthrop	WA
							^a	Simvasyn	CR
							^a	Terry White Chemists Simvastatin	TW
							^a	Zimstat	AF
				^B 3.33	27.44	25.18	^a	Lipex 10	FR
							^a	Zocor	MK
2012X NP	Tablet 20 mg	30	5	..	31.87	32.94	^a	APO-Simvastatin	TX

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
8173E NP	Tablet 40 mg	30	5	..	42.77	34.20	^a Chem mart CH
							^a Simvastatin GX
							^a GenRx Simvastatin MI
							^a Pharmacor Simvastatin 20 RA
							^a Ransim SZ
							^a Simvahexal QA
							^a Simvar 20 GM
							^a Simvastatin-DP GN
							^a Simvastatin-GA 20 GQ
							^a Simvastatin generichealth FZ
							^a Simvastatin Pfizer ZP
							^a Simvastatin-Spirit 20 WA
							^a Simvastatin Winthrop CR
							^a Simvasyn TW
							^a Terry White Chemists Simvastatin AF
							^a Zimstat FR
							^a Lipex 20 MK
							^a Zocor TX
							^a APO-Simvastatin
8313M NP	Tablet 80 mg	30	5	..	56.77	34.20	^a Chem mart CH
							^a Simvastatin GX
							^a GenRx Simvastatin MI
							^a Pharmacor Simvastatin 40 RA
							^a Ransim SZ
							^a Simvahexal QA
							^a Simvar 40 GM
							^a Simvastatin-DP GN
							^a Simvastatin-GA 40 GQ
							^a Simvastatin generichealth FZ
							^a Simvastatin Pfizer ZP
							^a Simvastatin-Spirit 40 WA
							^a Simvastatin Winthrop CR
							^a Simvasyn TW
							^a Terry White Chemists Simvastatin AF
							^a Zimstat FR
							^a Lipex 40 MK
							^a Zocor TX
							^a APO-Simvastatin
8313M NP	Tablet 80 mg	30	5	..	56.77	34.20	^a Chem mart CH
							^a Simvastatin GX
							^a GenRx Simvastatin MI
							^a Pharmacor Simvastatin 80 RA
							^a Ransim SZ
							^a Simvahexal QA
							^a Simvar 80

SIMVASTATIN

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

No applications for increased maximum quantities and/or repeats will be authorised.

9242K	Tablet 10 mg	30	11	..	24.11	25.18	^a APO-Simvastatin	TX
							^a Chem mart	CH
							Simvastatin	
							^a GenRx Simvastatin	GX
							^a Pharmacor	MI
							Simvastatin 10	
							^a Ransim	RA
							^a Simvahexal	SZ
							^a Simvar 10	QA
							^a Simvastatin-DP	GM
							^a Simvastatin-GA 10	GN
							^a Simvastatin	GQ
							generichealth	
							^a Simvastatin Pfizer	FZ
							^a Simvastatin-Spirit	ZP
10								
^a Simvastatin	WA							
Winthrop								
^a Simvasyn	CR							
^a Terry White	TW							
Chemists								
Simvastatin								
^a Zimstat	AF							
9243L	Tablet 20 mg	30	11	..	31.87	32.94	^a Lipex 10	FR
							^a Zocor	MK
							^a APO-Simvastatin	TX
							^a Chem mart	CH
							Simvastatin	
^a GenRx Simvastatin	GX							
^a Pharmacor	MI							
Simvastatin 20								
^a Ransim	RA							
^a Simvahexal	SZ							
^a Simvar 20	QA							

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty	Maximum Recordable Value for Safety Net	Brand Name and Manufacturer
					\$	\$	
9244M	Tablet 40 mg	30	11	..	42.77	34.20	^a Simvastatin-DP GM
							^a Simvastatin-GA 20 GN
							^a Simvastatin generichealth GQ
							^a Simvastatin Pfizer FZ
							^a Simvastatin-Spirit 20 ZP
							^a Simvastatin Winthrop WA
							^a Simvasyn CR
							^a Terry White Chemists Simvastatin TW
							^a Zimstat AF
							^a Lipex 20 FR
							^a Zocor MK
							^a APO-Simvastatin TX
							^a Chem mart Simvastatin CH
							^a GenRx Simvastatin GX
							^a Pharmacor Simvastatin 40 MI
							^a Ransim RA
							^a Simvahexal SZ
							^a Simvar 40 QA
							^a Simvastatin-DP GM
							^a Simvastatin-GA 40 GN
							^a Simvastatin generichealth GQ
							^a Simvastatin Pfizer FZ
							^a Simvastatin-Spirit 40 ZP
							^a Simvastatin Winthrop WA
							^a Simvasyn CR
							^a Terry White Chemists Simvastatin TW
							^a Zimstat AF
							^a Lipex 40 FR
							^a Zocor MK
9245N	Tablet 80 mg	30	11	..	56.77	34.20	^a APO-Simvastatin TX
							^a Chem mart Simvastatin CH
							^a GenRx Simvastatin GX
							^a Pharmacor Simvastatin 80 MI
							^a Ransim RA
							^a Simvahexal SZ
							^a Simvar 80 QA
							^a Simvastatin-DP GM
							^a Simvastatin-GA 80 GN
							^a Simvastatin generichealth GQ
							^a Simvastatin Pfizer FZ
							^a Simvastatin-Spirit 80 ZP
							^a Simvastatin Winthrop WA
							^a Simvasyn CR

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty	Maximum Recordable Value for Safety Net	Brand Name and Manufacturer
					\$	\$	
						^a	Terry White Chemists Simvastatin
				^B 3.32	60.09	34.20	Zimstat
						^a	Lipex 80
						^a	Zocor
							TW AF FR MK

SIROLIMUS

Caution

Careful monitoring of patients is mandatory.

Authority required

Maintenance therapy, following initiation and stabilisation of treatment with sirolimus and where therapy remains under the supervision and direction of the transplant unit reviewing that patient, of patients with renal transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application.

8984W	Tablet 0.5 mg	100	3	..	413.29	34.20	Rapamune	PF
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TELMISARTAN with AMLODIPINE

Restricted benefit

Hypertension in a patient who is not adequately controlled with either of the drugs in the combination.

8978M NP	Tablet 40 mg-5 mg (as besylate)	28	5	..	30.75	31.82	Twynsta	BY
8979N NP	Tablet 40 mg-10 mg (as besylate)	28	5	..	37.60	34.20	Twynsta	BY
8980P NP	Tablet 80 mg-5 mg (as besylate)	28	5	..	38.01	34.20	Twynsta	BY
8981Q NP	Tablet 80 mg-10 mg (as besylate)	28	5	..	44.34	34.20	Twynsta	BY

THIOTEPA

2345K	Powder for injection 15 mg	2	1	..	*155.66	34.20	Aspen Pharma Pty Ltd	QA
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**PREPARATIONS WHICH MAY BE PRESCRIBED BY PARTICIPATING
DENTAL PRACTITIONERS FOR DENTAL TREATMENT ONLY**

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for	Maximum Recordable Value for	Brand Name and Manufacturer	
					Max. Qty	Safety Net		
					\$	\$		
ADRENALINE								
5004J	Injection 1 mg in 1 mL (1 in 1,000) (Dental)	5	..	..	20.34	21.41	Link Medical Products Pty Ltd	LM
AMOXYCILLIN								
3300Q	Capsule 500 mg (Dental)	20	..	..	10.45	11.52	^a Alphamox 500	AF
							^a Amoxycillin-GA	GM
							^a Amoxycillin generichealth 500	GQ
							^a Amoxycillin Ranbaxy	RA
							^a Amoxycillin Sandoz	SZ
							^a APO-Amoxycillin	TX
							^a Chem mart Amoxycillin	CH
							^a Cilamox	QA
							^a GenRx Amoxycillin	GX
							^a Terry White Chemists Amoxycillin	TW
				^B 1.35	11.80	11.52	^a Amoxil	GK
PHENOXYMETHYLPENICILLIN								
5024K	Powder for oral liquid 125 mg (as potassium) per 5 mL, 100 mL (Dental)	2	..	..	*#16.71	18.12	Phenoxyethyl- penicillin-AFT	AE
5029Q	Powder for oral liquid 250 mg (as potassium) per 5 mL, 100 mL (Dental)	2	..	..	*#19.27	20.68	Phenoxyethyl- penicillin-AFT	AE

HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max. Qty	\$	

ABATACEPT

Note

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

Further prescribing information (including Authority Application Forms) is on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe abatacept should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 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 anti-rheumatic 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) and the T-cell co-stimulation modulator (abatacept).

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

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

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 Medicare Australia 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 and tocilizumab, 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.

HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for	Brand Name and Manufacturer
					Max. Qty \$	

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 Medicare Australia 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 Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia 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 Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Rituximab patients:

A further application may be submitted to Medicare Australia 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 Medicare Australia 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 Medicare Australia 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.

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.

HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for		Brand Name and Manufacturer
					Max. Qty	\$	

Note

(3) Baseline measurements to determine response.

Medicare Australia 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 Medicare Australia 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.

(4) Patients 'grandfathered' onto PBS-subsidised treatment with certolizumab pegol, golimumab or tocilizumab.

From 1 August 2010, a patient who commenced treatment with certolizumab pegol or golimumab for severe rheumatoid arthritis prior to 1 March 2010 or tocilizumab for severe rheumatoid arthritis prior to 1 July 2009 and who was 'grandfathered' on to PBS-subsidised therapy, and who continues to receive treatment will have further applications for treatment with certolizumab pegol, golimumab or tocilizumab assessed under the continuing treatment restriction.

A patient may only qualify for PBS-subsidised treatment under the grandfather restriction (Initial 3 ('grandfather patients')) once. A maximum of 24 weeks of treatment with certolizumab pegol, golimumab or tocilizumab will be authorised under this restriction.

Authority required

Initial 1 (new patient or patient re-commencing after a break of more than 24 months)

Initial PBS-subsidised treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

- (a) have severe active rheumatoid arthritis; and
- (b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and
- (c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to 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:
 - hydroxychloroquine at a dose of at least 200 mg daily; or
 - leflunomide at a dose of at least 10 mg daily; or
 - sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:

- hydroxychloroquine at a dose of at least 200 mg daily; and/or
- leflunomide at a dose of at least 10 mg daily; and/or
- sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

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, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:

- azathioprine at a dose of at least 1 mg/kg per day; and/or
- cyclosporin at a dose of at least 2 mg/kg/day; and/or
- sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

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

HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	

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. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

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

- (i) a total active joint count of at least 20 active (swollen and tender) joints; or
- (ii) at least 4 active joints from the following list of major joints:
 - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - 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 reason this criterion cannot be satisfied.

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

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

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
- (3) a signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion. Up to a maximum of 4 repeats may be authorised.

Where fewer than 4 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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 Medicare Australia 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 to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with abatacept.

Patients who fail to demonstrate a response to treatment with abatacept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Authority required

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

Initial course of PBS-subsidised treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

- (a) have a documented history of severe active rheumatoid arthritis; and
- (b) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

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 [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with abatacept and who wish 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 abatacept treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for		Brand Name and Manufacturer
					Max. Qty	\$	

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion. Up to a maximum of 4 repeats may be authorised.

Where fewer than 4 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised abatacept treatment was approved under either of the initial 1 or 2 treatment restrictions, patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

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

Patients who fail to demonstrate a response to treatment with abatacept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Authority required

Continuing treatment

Continuing PBS-subsidised treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:

- (a) who have a documented history of severe active rheumatoid arthritis; and
- (b) who have demonstrated an adequate response to treatment with abatacept; and
- (c) whose most recent course of PBS-subsidised bDMARD treatment was with abatacept.

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:

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

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

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion. Up to a maximum of 5 repeats may be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Patients who fail to demonstrate a response to treatment with abatacept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note

Special Pricing Arrangements apply.

5605B	Powder for I.V. infusion 250 mg (Public)	1	..	..	504.43	Orencia	BQ
9621J	Powder for I.V. infusion 250 mg (Private)	1	..	..	531.03	Orencia	BQ

HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max. Qty	\$	

INFLIXIMAB

Note

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 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 anti-rheumatic 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) and the T-cell co-stimulation modulator (abatacept).

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

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

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 Medicare Australia 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 and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2

HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	

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 Medicare Australia 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 Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia 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 Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Rituximab patients:

A further application may be submitted to Medicare Australia 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 Medicare Australia 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 Medicare Australia 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.

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.

HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for		Brand Name and Manufacturer
					Max. Qty	\$	

Note

(3) Baseline measurements to determine response.

Medicare Australia 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 Medicare Australia 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.

(4) Patients 'grandfathered' onto PBS-subsidised treatment with certolizumab pegol, golimumab or tocilizumab.

From 1 August 2010, a patient who commenced treatment with certolizumab pegol or golimumab for severe rheumatoid arthritis prior to 1 March 2010 or tocilizumab for severe rheumatoid arthritis prior to 1 July 2009 and who was 'grandfathered' on to PBS-subsidised therapy, and who continues to receive treatment will have further applications for treatment with certolizumab pegol, golimumab or tocilizumab assessed under the continuing treatment restriction.

A patient may only qualify for PBS-subsidised treatment under the grandfather restriction (Initial 3 ('grandfather patients')) once. A maximum of 24 weeks of treatment with certolizumab pegol, golimumab or tocilizumab will be authorised under this restriction.

Authority required

Initial 1 (new patient or patient re-commencing after a break of more than 24 months)

Initial PBS-subsidised treatment with infliximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

- (a) have severe active rheumatoid arthritis; and
- (b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and
- (c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to 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:
 - hydroxychloroquine at a dose of at least 200 mg daily; or
 - leflunomide at a dose of at least 10 mg daily; or
 - sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:

- hydroxychloroquine at a dose of at least 200 mg daily; and/or
- leflunomide at a dose of at least 10 mg daily; and/or
- sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

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, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:

- azathioprine at a dose of at least 1 mg/kg per day; and/or
- cyclosporin at a dose of at least 2 mg/kg/day; and/or
- sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

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

HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	

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. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

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

- (i) a total active joint count of at least 20 active (swollen and tender) joints; or
- (ii) at least 4 active joints from the following list of major joints:
 - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - 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 reason this criterion cannot be satisfied.

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

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

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
- (3) a signed patient acknowledgement.

A maximum of 22 weeks of treatment will be authorised under this restriction.

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

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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 Medicare Australia 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 to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Authority required

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

Initial course of PBS-subsidised treatment with infliximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

- (a) have a documented history of severe active rheumatoid arthritis; and
- (b) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

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 [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with infliximab and who wish 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 infliximab treatment, within the timeframes specified below.

A maximum of 22 weeks of treatment will be authorised under this restriction.

HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for		Brand Name and Manufacturer
					Max. Qty	\$	

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

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial 1 or 2 treatment restrictions, patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

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

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Authority required

Continuing treatment

Continuing PBS-subsidised treatment with infliximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:

- (a) who have a documented history of severe active rheumatoid arthritis; and
- (b) who have demonstrated an adequate response to treatment with infliximab; and
- (c) whose most recent course of PBS-subsidised bDMARD treatment was with infliximab.

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:

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

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

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 3 mg per kg. Up to a maximum of 2 repeats may be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note

Special Pricing Arrangements apply.

5757B	Powder for I.V. infusion 100 mg (Public)	1	..	..	751.70	Remicade	SH
6397Q	Powder for I.V. infusion 100 mg (Private)	1	..	..	788.19	Remicade	SH

HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max. Qty	Max. Qty	

RITUXIMAB

Note

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

Further prescribing information (including Authority Application Forms) is on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe rituximab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 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 anti-rheumatic 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) and the T-cell co-stimulation modulator (abatacept).

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

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

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 Medicare Australia 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 and tocilizumab, 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.

HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for Max. Qty	Brand Name and Manufacturer
					\$	

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 Medicare Australia 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 Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia 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 Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Rituximab patients:

A further application may be submitted to Medicare Australia 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 Medicare Australia 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 Medicare Australia 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.

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.

Note

(3) Baseline measurements to determine response.

HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max. Qty	\$	

Medicare Australia 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 Medicare Australia 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.

(4) Patients 'grandfathered' onto PBS-subsidised treatment with certolizumab pegol, golimumab or tocilizumab.

From 1 August 2010, a patient who commenced treatment with certolizumab pegol or golimumab for severe rheumatoid arthritis prior to 1 March 2010 or tocilizumab for severe rheumatoid arthritis prior to 1 July 2009 and who was 'grandfathered' on to PBS-subsidised therapy, and who continues to receive treatment will have further applications for treatment with certolizumab pegol, golimumab or tocilizumab assessed under the continuing treatment restriction.

A patient may only qualify for PBS-subsidised treatment under the grandfather restriction (Initial 3 ('grandfather patients')) once. A maximum of 24 weeks of treatment with certolizumab pegol, golimumab or tocilizumab will be authorised under this restriction.

Authority required

Initial 1 (patient re-commencing after a break of more than 24 months)

Initial PBS-subsidised treatment with rituximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

- (a) have severe active rheumatoid arthritis; and
- (b) have failed to respond to at least 1 PBS-subsidised TNF- α antagonist; and
- (c) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and
- (d) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to 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:
 - hydroxychloroquine at a dose of at least 200 mg daily; or
 - leflunomide at a dose of at least 10 mg daily; or
 - sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:

- hydroxychloroquine at a dose of at least 200 mg daily; and/or
- leflunomide at a dose of at least 10 mg daily; and/or
- sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

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, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:

- azathioprine at a dose of at least 1 mg/kg per day; and/or
- cyclosporin at a dose of at least 2 mg/kg/day; and/or
- sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

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.

HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max. Qty	\$	

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. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

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

- (i) a total active joint count of at least 20 active (swollen and tender) joints; or
- (ii) at least 4 active joints from the following list of major joints:
 - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - 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 reason this criterion cannot be satisfied.

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

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

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
- (3) a signed patient acknowledgement.

A maximum of two infusions will be authorised under this restriction.

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 Medicare Australia within 4 weeks of the date it was conducted.

Where a response assessment is not undertaken and submitted to Medicare Australia 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.

Patients who fail 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.

Patients who fail to demonstrate a response to rituximab treatment 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.

Authority required

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

Initial course of PBS-subsidised treatment with rituximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

- (a) have a documented history of severe active rheumatoid arthritis; and
- (b) have failed to respond to at least 1 PBS-subsidised TNF-alfa antagonist; and
- (c) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

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 [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with rituximab and who wish 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.

A maximum of two infusions will be authorised under this restriction.

HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	

Where the most recent course of PBS-subsidised rituximab treatment was approved under either of the initial 1 or 2 treatment restrictions patients must be assessed for response at least 12 weeks after the first infusion. This assessment must be provided to Medicare Australia no later than 4 weeks from the date of 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 to Medicare Australia within 4 weeks of assessment.

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.

Patients who fail 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.

Patients who fail to demonstrate a response to rituximab treatment 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.

Authority required

Continuing treatment

Continuing PBS-subsidised treatment with rituximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:

- (a) who have a documented history of severe active rheumatoid arthritis; and
- (b) who have demonstrated an adequate response to treatment with rituximab; and
- (c) whose most recent course of PBS-subsidised bDMARD treatment was with rituximab.

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:

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

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

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of two infusions will be authorised under this restriction.

Patients 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 demonstration of response must be submitted to Medicare Australia within 4 weeks of assessment.

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.

Patients who fail 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.

Note

Special Pricing Arrangements apply.

9544H	Solution for I.V. infusion 500 mg in 50 mL (Public)	1	..	..	2263.57	Mabthera	RO
9611W	Solution for I.V. infusion 500 mg in 50 mL (Private)	1	..	..	2309.99	Mabthera	RO

SIROLIMUS

Caution

Careful monitoring of patients is mandatory.

Authority required (STREAMLINED)

3355

Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required.

HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer	
9747B	Tablet 0.5 mg (Public)	200	5	..	*723.34	Rapamune	PF
SIROLIMUS							
<u>Caution</u>							
Careful monitoring of patients is mandatory.							
<u>Authority required</u>							
Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required.							
9748C	Tablet 0.5 mg (Private)	200	5	..	*758.70	Rapamune	PF

TOCILIZUMAB

Note

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

Further prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe tocilizumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 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 anti-rheumatic 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) and the T-cell co-stimulation modulator (abatacept).

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

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

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 Medicare Australia 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.

HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max. Qty	Max. Qty	
					\$	\$	

(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 and tocilizumab, 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 Medicare Australia 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 Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia 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 Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Rituximab patients:

A further application may be submitted to Medicare Australia 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 Medicare Australia 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 Medicare Australia 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.

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.

HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for		Brand Name and Manufacturer
					Max. Qty	\$	

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.

Note

(3) Baseline measurements to determine response.

Medicare Australia 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 Medicare Australia 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.

(4) Patients 'grandfathered' onto PBS-subsidised treatment with certolizumab pegol, golimumab or tocilizumab.

From 1 August 2010, a patient who commenced treatment with certolizumab pegol or golimumab for severe rheumatoid arthritis prior to 1 March 2010 or tocilizumab for severe rheumatoid arthritis prior to 1 July 2009 and who was 'grandfathered' on to PBS-subsidised therapy, and who continues to receive treatment will have further applications for treatment with certolizumab pegol, golimumab or tocilizumab assessed under the continuing treatment restriction.

A patient may only qualify for PBS-subsidised treatment under the grandfather restriction (Initial 3 ('grandfather patients')) once. A maximum of 24 weeks of treatment with certolizumab pegol, golimumab or tocilizumab will be authorised under this restriction.

Authority required

Initial 1 (new patient or patient re-commencing after a break of more than 24 months)

Initial PBS-subsidised treatment with tocilizumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

- (a) have severe active rheumatoid arthritis; and
- (b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and
- (c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to 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:
 - hydroxychloroquine at a dose of at least 200 mg daily; or
 - leflunomide at a dose of at least 10 mg daily; or
 - sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:

- hydroxychloroquine at a dose of at least 200 mg daily; and/or
- leflunomide at a dose of at least 10 mg daily; and/or
- sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max. Qty	\$	

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, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:

- azathioprine at a dose of at least 1 mg/kg per day; and/or
- cyclosporin at a dose of at least 2 mg/kg/day; and/or
- sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

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. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

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

- (i) a total active joint count of at least 20 active (swollen and tender) joints; or
- (ii) at least 4 active joints from the following list of major joints:
 - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - 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 reason this criterion cannot be satisfied.

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

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

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
- (3) a signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength, based on the weight of the patient, to provide sufficient 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 of each strength may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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 Medicare Australia 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 to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

Patients who fail to demonstrate a response to treatment with tocilizumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	

Authority required

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

Initial course of PBS-subsidised treatment with tocilizumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

- (a) have a documented history of severe active rheumatoid arthritis; and
- (b) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

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

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with tocilizumab and who wish 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.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength, based on the weight of the patient, to provide sufficient 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 of each strength may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the initial 1 or 2 treatment restrictions, patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia 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, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients who fail to demonstrate a response to treatment with tocilizumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Authority required

Initial 3 ('grandfather' patients)

Initial PBS-subsidised supply for continuing treatment with tocilizumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of an adult who:

- (a) has a documented history of severe active rheumatoid arthritis; and
- (b) was receiving treatment with tocilizumab prior to 1 July 2009; and
- (c) has demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with tocilizumab; and
- (d) is receiving treatment with tocilizumab at the time of application.

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

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

The same indices of disease severity used to establish baseline at the commencement of treatment with a bDMARD must be used for assessment of all continuing applications.

The assessment of the patient's response to a continuing course of therapy must be made within 4 weeks prior to completion of that course and posted to Medicare Australia 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 criterion.

A maximum of 24 weeks of treatment with tocilizumab will be approved under this criterion.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength, based on the weight of the patient, to provide sufficient 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 of each strength may be authorised.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

HIGHLY SPECIALISED DRUGS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium \$	Dispensed Price for Max. Qty	Brand Name and Manufacturer
					\$	

Patients may qualify for PBS-subsidised treatment under this restriction once only.

Patients who fail to demonstrate a response to treatment with tocilizumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Authority required

Continuing treatment

Continuing PBS-subsidised treatment with tocilizumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:

- (a) who have a documented history of severe active rheumatoid arthritis; and
- (b) who have demonstrated an adequate response to treatment with tocilizumab; and
- (c) whose most recent course of PBS-subsidised bDMARD treatment was with tocilizumab.

An adequate response to treatment is defined as:

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

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

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

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength, based on the weight of the patient, to provide sufficient 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 of each strength may be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia 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.

Patients who fail to demonstrate a response to treatment with tocilizumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note

Special Pricing Arrangements apply.

9657G	Concentrate for injection 80 mg in 4 mL (Public)	1	..	..	186.88	Actemra	RO
9671B	Concentrate for injection 80 mg in 4 mL (Private)	1	..	..	200.78	Actemra	RO
9658H	Concentrate for injection 200 mg in 10 mL (Public)	1	..	..	467.20	Actemra	RO
9672C	Concentrate for injection 200 mg in 10 mL (Private)	1	..	..	492.31	Actemra	RO
9659J	Concentrate for injection 400 mg in 20 mL (Public)	1	..	..	934.40	Actemra	RO
9673D	Concentrate for injection 400 mg in 20 mL (Private)	1	..	..	978.20	Actemra	RO

REPATRIATION PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
RISEDRONATE SODIUM								
<u>Authority required</u>								
For preservation of bone mineral density in patients on long-term glucocorticoid therapy where patients are undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day. Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more and demonstrate that the patient is osteopenic (bone mineral density t-score of less than -1.0).								
4444X	Tablet 35 mg	4	5	..	46.55	5.60	^a Actonel Once-a-Week	SW
							^a APO-Risedronate	TX
							^a Chem mart Risedronate	CH
							^a Risedro once a week	QA
							^a Terry White Chemists Risedronate	TW
TERBINAFINE								
<u>Authority required</u>								
Onychomycosis due to dermatophyte infection proven by microscopy or culture and confirmed by an approved pathology provider.								
4011D	Tablet 250 mg (as hydrochloride)	42	1	..	98.01	5.60	^a Lamisil	NV
							^a Tamsil	QA
							^a Terbihexal	SZ
							^a Terbinafine-DP	GN
							^a Tinasil	AF