



Australian Government

Department of Health and Ageing

SCHEDULE OF PHARMACEUTICAL BENEFITS

SUMMARY OF CHANGES

EFFECTIVE 1 MARCH 2008

PHARMACEUTICAL BENEFITS

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 March 2008. 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 March 2008 and are included, where applicable, in prices published in the Schedule—

Dispensing Fees:	Ready-prepared	\$5.44
	Dangerous drug fee	\$2.71
	Extemporaneously-prepared	\$7.48
	Allowable additional patient charge*	\$3.63
Additional Fees (for safety net prices):	Ready-prepared	\$1.01
	Extemporaneously-prepared	\$1.40
Patient Co-payments:	General	\$31.30
	Concessional	\$5.00
Safety Net Thresholds:	General	\$1141.80
	Concessional	\$290.00
Safety Net Card Issue Fee:		\$7.86

*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

(see under 'RESTRICTIONS' below for full details)

9133Q	Amino acid formula with vitamins and minerals without methionine , Oral liquid 130 mL, 30 (<i>HCU Cooler</i>)
9132P	Amino acid formula with vitamins and minerals without phenylalanine and tyrosine , Oral liquid 130 mL, 30 (<i>TYR Cooler</i>)
9134R	Isoleucine with carbohydrate , Sachets 4 g containing 50 mg isoleucine, 30 (<i>Isoleucine Amino Acid Supplement</i>)
9131N	Pemetrexed disodium , Powder for I.V. infusion 100 mg (base) (<i>Alimta</i>)
9135T	Valine with carbohydrate , Sachets 4 g containing 50 mg valine, 30 (<i>Valine Amino Acid Supplement</i>)

Additions - Brands

1891M	GA-Amclav 500/125, GM — Amoxycillin with clavulanic acid , Tablet 500 mg-125 mg
5008N	GA-Amclav 500/125, GM — Amoxycillin with clavulanic acid , Tablet 500 mg-125 mg (Dental)
8254K	GA-Amclav Forte 875/125, GM — Amoxycillin with clavulanic acid , Tablet 875 mg-125 mg
5006L	GA-Amclav Forte 875/125, GM — Amoxycillin with clavulanic acid , Tablet 875 mg-125 mg (Dental)
8220P	Citalobell, BF — Citalopram hydrobromide , Tablet 20 mg (base)
8539K	Oxaliplan 50, WQ — Oxaliplatin , Powder for I.V. infusion 50 mg
8540L	Oxaliplan 100, WQ — Oxaliplatin , Powder for I.V. infusion 100 mg
2791X	Dolapril 0.5, AW — Trandolapril , Capsule 500 micrograms
2792Y	Dolapril 1, AW — Trandolapril , Capsule 1 mg
2793B	Dolapril 2, AW — Trandolapril , Capsule 2 mg
8758Y	Dolapril 4, AW — Trandolapril , Capsule 4 mg

DELETIONS

Deletions - Items

1541D	Ipratropium bromide , Nebuliser solution 250 micrograms (anhydrous) per mL (0.025%), 20 mL (<i>Atrovent</i>)
1371E	Ranibizumab , Solution for intravitreal injection 3 mg in 0.3 mL (<i>Lucentis</i>) (deletion due to consolidation with 1382R)

Deletions - Brand

8513C	Remeron, OR — Mirtazapine , Tablet 30 mg
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ALTERATIONS

Alterations — Manufacturer's Code

		From	To
1153Q	Carbimazole , Tablet 5 mg (<i>Neo-Mercazole</i>)	RO	LM

Alterations — Maximum Quantity

		From	To
8560M	Calcium , Tablet 250 mg (as citrate) (<i>Citracal</i>)	120	240
3116B	Calcium , Tablet (chewable) 500 mg (as carbonate) (<i>Cal-Sup</i>)	120	240

Alterations — Number of Repeats

		<i>From</i>	<i>To</i>
8599N	Mesalazine , Sachet containing granules, 1 g per sachet (<i>Salofalk</i>)	2	5
1382R	Ranibizumab , Solution for intravitreal injection 3 mg in 0.3 mL (<i>Lucentis</i>)	1	2

Alterations — Restrictions

(see under 'RESTRICTIONS' below for full details)

Restrictions have been amended in respect of the following:

8574G	Amino acids—synthetic, formula , Compound powder 400 g (<i>EleCare</i>)
8443J	Amino acids—synthetic, formula , Compound powder 400 g (<i>Neocate</i>)
8754R	Amino acids—synthetic, formula , Compound powder 400 g (<i>Neocate Advance</i>)
2244D	Amino acids—synthetic, formula , Compound powder 400 g (<i>Neocate Advance Tropical Flavour</i>)
8575H	Amino acids—synthetic, formula , Compound powder 400 g (<i>EleCare</i>) (Diff. Restriction)
3066J	Amino acids—synthetic, formula , Compound powder 400 g (<i>Neocate</i>) (Diff. Restriction)
8755T	Amino acids—synthetic, formula , Compound powder 400 g (<i>Neocate Advance</i>) (Diff. Restriction)
2553J	Amino acids—synthetic, formula , Compound powder 400 g (<i>Neocate Advance Tropical Flavour</i>) (Diff. Restriction)
2246F	Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids , Compound powder 400 g (<i>Neocate LCP</i>)
2560R	Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids , Compound powder 400 g (<i>Neocate LCP</i>) (Diff. Restriction)
2546B	Imiquimod , Cream 50 mg per g (5%), 250 mg single use sachets, 12 (<i>Aldara</i>)
8039D	Oxybutynin hydrochloride , Tablet 5 mg (<i>Ditropan</i> , <i>Oxybutynin Sandoz</i> , <i>Oxybutynin Winthrop</i>)
2676W	Protein hydrolysate formula with medium chain triglycerides , Compound powder 400 g (<i>Alfaré</i>)
8259Q	Protein hydrolysate formula with medium chain triglycerides , Compound powder 450 g (<i>Pepti-Junior</i>)
2142R	Sevelamer hydrochloride , Tablet 800 mg (<i>Renagel</i>)
1382R	Ranibizumab , Solution for intravitreal injection 3 mg in 0.3 mL (<i>Lucentis</i>)

Alterations - Notes

(see under 'NOTES' below for full details)

Notes have been amended in respect of the following:

9034L	Adalimumab , Injection 40 mg in 0.8 mL pre-filled syringe (<i>Humira</i>)
9102C	Adalimumab , Injection 40 mg in 0.8 mL pre-filled pen (<i>Humira</i>)
9036N	Etanercept , Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL (<i>Enbrel</i>)
9084D	Etanercept , Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (<i>Enbrel</i>)
9088H	Etanercept , Injections 50 mg in 1 mL single use pre-filled syringes, 4 (<i>Enbrel</i>)
9128K	Varenicline , Box containing 11 tablets 0.5 mg (as tartrate) and 14 tablets 1 mg (as tartrate) in the first pack and 28 tablets 1 mg (as tartrate) in the second pack (<i>Champix</i>)
9129L	Varenicline , Tablet 1 mg (as tartrate) (<i>Champix</i>)

Alterations - Restrictions and Notes

(see under 'RESTRICTIONS' and 'NOTES' below for full details)

Both restrictions and notes have been amended in respect of the following:

8737W	Adalimumab , Injection 40 mg in 0.8 mL pre-filled syringe (<i>Humira</i>)
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9099X	Adalimumab , Injection 40 mg in 0.8 mL pre-filled pen (<i>Humira</i>)
8741C	Adalimumab , Injection 40 mg in 0.8 mL pre-filled syringe (<i>Humira</i>) (Diff. Max. Rpts)
9100Y	Adalimumab , Injection 40 mg in 0.8 mL pre-filled pen (<i>Humira</i>) (Diff. Max. Rpts)
9033K	Adalimumab , Injection 40 mg in 0.8 mL pre-filled syringe (<i>Humira</i>) (Diff. Restriction)
9101B	Adalimumab , Injection 40 mg in 0.8 mL pre-filled pen (<i>Humira</i>) (Diff. Restriction)
8773R	Anakinra , Injection 100 mg in 0.67 mL single use pre-filled syringe (<i>Kineret</i>)
8774T	Anakinra , Injection 100 mg in 0.67 mL single use pre-filled syringe (<i>Kineret</i>) (Diff. Max. Rpts.)
8465M	Bupropion hydrochloride , Tablet 150 mg (sustained release) (<i>Bupropion-RL, Clorprax, Prexaton, Zyban</i>)
8710K	Bupropion hydrochloride , Tablet 150 mg (sustained release) (<i>Bupropion-RL, Clorprax, Prexaton, Zyban</i>) (Diff. Max. Qty)
8637N	Etanercept , Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL (<i>Enbrel</i>)
8861J	Etanercept , Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (<i>Enbrel</i>)
9089J	Etanercept , Injections 50 mg in 1 mL single use pre-filled syringes, 4 (<i>Enbrel</i>)
8638P	Etanercept , Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL (<i>Enbrel</i>) (Diff. Max. Rpts)
8862K	Etanercept , Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (<i>Enbrel</i>) (Diff. Max. Rpts)
9090K	Etanercept , Injections 50 mg in 1 mL single use pre-filled syringes, 4 (<i>Enbrel</i>) (Diff. Max. Rpts)
9035M	Etanercept , Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL (<i>Enbrel</i>) (Diff. Restriction)
9083C	Etanercept , Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (<i>Enbrel</i>) (Diff. Restriction)
9087G	Etanercept , Injections 50 mg in 1 mL single use pre-filled syringes, 4 (<i>Enbrel</i>) (Diff. Restriction)

SECTION 100 - HIGHLY SPECIALISED DRUGS PROGRAM

ADDITIONS

Additions - Items

(see under 'RESTRICTIONS' and 'NOTES' below for full details of items where a restriction and/or note applies)

9621J	Abatacept , Powder for I.V. infusion 250 mg (<i>Orencia</i>)
9619G	Ibandronate sodium , Concentrated injection for I.V. infusion equivalent to 6 mg ibandronic acid in 6 mL (<i>Bondronat</i>)
9620H	Sevelamer hydrochloride , Tablet 800 mg (<i>Renagel</i>)

DELETIONS

Deletions - Item

6283Q	Efavirenz , Capsule 200 mg (<i>Stocrin</i>)
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ALTERATIONS

Alterations - Restrictions

(see under 'RESTRICTIONS' below for full details)

Restrictions have been amended in respect of the following:

6126K	Filgrastim , Injection 300 micrograms in 1 mL (<i>Neupogen</i>)
6291D	Filgrastim , Injection 300 micrograms in 0.5 mL single use pre-filled syringe (<i>Neupogen</i>)

6127L	Filgrastim , Injection 480 micrograms in 1.6 mL (<i>Neupogen</i>)
6292E	Filgrastim , Injection 480 micrograms in 0.5 mL single use pre-filled syringe (<i>Neupogen</i>)
9602J	Entecavir monohydrate , Tablet 0.5 mg (<i>Baraclude</i>)
9603K	Entecavir monohydrate , Tablet 1 mg (<i>Baraclude</i>)
6210W	Interferon alfa-2a , Injection 3,000,000 i.u. in 0.5 mL single dose pre-filled syringe (<i>Roferon-A</i>)
6211X	Interferon alfa-2a , Injection 4,500,000 i.u. in 0.5 mL single dose pre-filled syringe (<i>Roferon-A</i>)
6212Y	Interferon alfa-2a , Injection 6,000,000 i.u. in 0.5 mL single dose pre-filled syringe (<i>Roferon-A</i>)
6213B	Interferon alfa-2a , Injection 9,000,000 i.u. in 0.5 mL single dose pre-filled syringe (<i>Roferon-A</i>)
6246R	Interferon alfa-2b , Solution for injection 10,000,000 i.u. in 1 mL single dose vial (<i>Intron A</i>)
6253D	Interferon alfa-2b , Solution for injection 18,000,000 i.u. in 1.2 mL multi-dose injection pen (<i>Intron A Redipen</i>)
6218G	Interferon alfa-2b , Solution for injection 18,000,000 i.u. in 3 mL single dose vial (<i>Intron A</i>)
6219H	Interferon alfa-2b , Solution for injection 25,000,000 i.u. in 2.5 mL single dose vial (<i>Intron A</i>)
6254E	Interferon alfa-2b , Solution for injection 30,000,000 i.u. in 1.2 mL multi-dose injection pen (<i>Intron A Redipen</i>)
6255F	Interferon alfa-2b , Solution for injection 60,000,000 i.u. in 1.2 mL multi-dose injection pen (<i>Intron A Redipen</i>)
6257H	Lamivudine , Tablet 100 mg (<i>Zeffix</i>)
6271C	Lamivudine , Oral solution 5 mg per mL, 240 mL (<i>Zeffix</i>)
6363X	Pegfilgrastim , Injection 6 mg in 0.6 mL single use pre-filled syringe (<i>Neulasta</i>)
6439X	Peginterferon alfa-2a , Injection 135 micrograms in 0.5 mL single use pre-filled syringe (<i>Pegasys</i>)
6449K	Peginterferon alfa-2a , Injection 180 micrograms in 0.5 mL single use pre-filled syringe (<i>Pegasys</i>)

Alterations - Restrictions and Notes

(see under 'RESTRICTIONS' and 'NOTES' below for full details)

Both restrictions and notes have been amended in respect of the following:

6450L	Adefovir dipivoxil , Tablet 10 mg (<i>Hepsera</i>)
6397Q	Infliximab , Powder for I.V. infusion 100 mg (<i>Remicade</i>)
6496X	Infliximab , Powder for I.V. infusion 100 mg (<i>Remicade</i>) (Diff. Restriction)
9611W	Rituximab , Solution for I.V. infusion 500 mg in 50 mL (<i>Mabthera</i>)

ADVANCE NOTICES*Advance Notices - Deletion of Items*

The following item will be deleted from the Schedule of Pharmaceutical Benefits on 1 **April** 2008:

Item discontinued by the manufacturer -

8645B **Oestradiol hemihydrate**, Nasal spray 150 micrograms per actuation, 60 actuations, 4.2 mL (*Aerodiol*)

The following item will be deleted from the Schedule of Pharmaceutical Benefits on 1 **May** 2008:

Item discontinued by the manufacturer -

3027H **Salmeterol xinafoate**, Oral pressurised inhalation 25 micrograms (base) per dose (120 doses) (*Serevent*)

RESTRICTIONS

The text of restrictions mentioned above:

9621J **Abatacept**, Powder for I.V. infusion 250 mg (*Orencia*)

Public and private hospital authority required

Initial 1 (new patients)

Application for 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 prior PBS-subsidised treatment with a bDMARD for this condition in this treatment cycle; and
- (c) have failed to achieve an adequate response to the following treatments:
 - (i) methotrexate at a dose of at least 20 mg weekly; and
 - (ii) methotrexate (at a minimum dose of 7.5 mg weekly), in combination with 2 other non-biological disease modifying anti-rheumatic drugs (DMARDs), for a minimum of 3 months; and
 - (iii) a minimum of 3 months' treatment with:
 - leflunomide alone; or
 - leflunomide in combination with methotrexate; or
 - cyclosporin.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities, including severity, can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

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

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

AND either

- (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).

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

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

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

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes details of the patient's ESR and CRP measurements and the patient's active joint count which must have been assessed no earlier than 1 month prior to the date of application; 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, in this treatment cycle. Patients may re-trial abatacept after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle.

Public and private hospital authority required

Initial 2 (change or re-commencement)

Application for an 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 in this treatment cycle 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 within this treatment cycle and who wish to re-commence therapy with this drug within this same cycle, 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.

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 treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy), 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, in this treatment cycle. Patients may re-trial abatacept after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle

Public and private hospital authority required

Initial 3 ('grandfather' patients)

Initial PBS-subsidised supply for continuing 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 an adult who:

- (a) has a documented history of severe active rheumatoid arthritis; and
- (b) was receiving treatment with abatacept prior to 1 November 2007; and
- (c) has demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with abatacept.

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] which includes the 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 abatacept will be approved under this criterion.

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 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 3 bDMARDs are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new bDMARD Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this Cycle and the date of the first application under the new Cycle

Public and private hospital 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 in this treatment cycle 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, in this treatment cycle. Patients may re-trial abatacept after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle

9099X
8737W

Adalimumab, Injection 40 mg in 0.8 mL pre-filled pen (*Humira*)

Adalimumab, Injection 40 mg in 0.8 mL pre-filled syringe (*Humira*)

Authority required

Initial 1 (new patients)

Application for 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 prior PBS-subsidised treatment with a bDMARD for this condition in this treatment cycle; and
- (c) have failed to achieve an adequate response to the following treatments:
 - (i) methotrexate at a dose of at least 20 mg weekly; and
 - (ii) methotrexate (at a minimum dose of 7.5 mg weekly), in combination with 2 other non-biological disease modifying anti-rheumatic drugs (DMARDs), for a minimum of 3 months; and
 - (iii) a minimum of 3 months' treatment with:
 - leflunomide alone; or
 - leflunomide in combination with methotrexate; or
 - cyclosporin.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of

application. Details of the accepted toxicities, including severity, can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

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

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

AND either

(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).

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

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

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

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes details of the patient's ESR and CRP measurements and the patient's active joint count which must have been assessed no earlier than 1 month prior to the date of application; 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, in this treatment cycle. Patients may re-trial adalimumab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle.

Authority required

Initial 2 (change or re-commencement)

Application for an 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 in this treatment cycle 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 within this treatment cycle and who wish to re-commence therapy with this drug within this same cycle, 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 treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy), 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 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, in this treatment cycle. Patients may re-trial adalimumab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle

9100Y **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen (*Humira*)
8741C **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled syringe (*Humira*)

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 in this treatment cycle 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 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, in this treatment cycle. Patients may re-trial adalimumab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle

9101B **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen (*Humira*)
 9033K **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled syringe (*Humira*)

Authority required

Initial 1

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

- (1) have severe active psoriatic arthritis with a record of rheumatoid factor negative status within the last 12 months; and
- (2) have received no prior PBS-subsidised biological treatment for this condition in this Treatment Cycle; and
- (3) have failed to achieve an adequate response to:
 - (a) methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; and
 - (b) sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or
 - (c) leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months.

Patients must have had the psoriatic component of their disease confirmed by a dermatologist or by biopsy at any time.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities, including severity, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

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

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

- (i) an 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).

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

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

- (1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes details of the patient's ESR and CRP measurements and the patient's active joint count which must have been assessed no earlier than 1 month prior to the date of application; and

(3) a copy of the signed patient acknowledgement form which is included in the Supporting Information Form. Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated.

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).

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, in this Treatment Cycle

Authority required

Initial 2

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

- (1) have a documented history of severe active psoriatic arthritis with a record of rheumatoid factor negative status within the last 12 months; and
- (2) have received prior PBS-subsidised biological treatment for this condition in this Treatment Cycle and are eligible to receive further biological therapy; and
- (3) have not failed treatment with adalimumab during the current Treatment Cycle.

Applications for patients who have demonstrated a response to PBS-subsidised adalimumab treatment within this Treatment Cycle and who wish to re-commence adalimumab treatment within the same Cycle following a break in therapy, will only be approved where evidence of a response to the patient's most recent course of PBS-subsidised adalimumab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), 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 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.

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

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

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).

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, in this Treatment Cycle.

Once patients fail to respond to treatment with 3 biological agents, they are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription

for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

- 6450L **Adefovir dipivoxil**, Tablet 10 mg (*Hepsera*)
Private hospital authority required
 Chronic hepatitis B in a patient who has failed antihepadnaviral therapy and who satisfies all of the following criteria: (1)(a) Repeatedly elevated (greater than 1.2 times the upper limit of normal) serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection (HBe antigen positive and/or serum HBV DNA positive); or
 (b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance;
 (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.
 Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy
- 9133Q **Amino acid formula with vitamins and minerals without methionine**, Oral liquid 130 mL, 30 (*HCU Cooler*)
Restricted benefit
 Pyridoxine non-responsive homocystinuria
- 9132P **Amino acid formula with vitamins and minerals without phenylalanine and tyrosine**, Oral liquid 130 mL, 30 (*TYR Cooler*)
Restricted benefit
 Tyrosinaemia
- 8574G **Amino acids—synthetic, formula**, Compound powder 400 g (*EleCare*)
 8443J **Amino acids—synthetic, formula**, Compound powder 400 g (*Neocate*)
 8754R **Amino acids—synthetic, formula**, Compound powder 400 g (*Neocate Advance*)
 2244D **Amino acids—synthetic, formula**, Compound powder 400 g (*Neocate Advance Tropical Flavour*)
 2246F **Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids**, Compound powder 400 g (*Neocate LCP*)
Authority required
 Initial treatment, for up to 3 months, for combined intolerance (not infant colic) to cows' milk protein, soy protein and protein hydrolysate formulae in a child up to the age of 2 years. Combined intolerance is demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula. The date of birth of the patient must be included in the authority application
Authority required
 Initial treatment, in consultation with a paediatric gastroenterologist or specialist allergist, for up to 3 months, of a child up to the age of 2 years with severe intolerance (not infant colic) to cows' milk protein. The date of birth of the patient must be included in the authority application
- 8575H **Amino acids—synthetic, formula**, Compound powder 400 g (*EleCare*)
 3066J **Amino acids—synthetic, formula**, Compound powder 400 g (*Neocate*)
 8755T **Amino acids—synthetic, formula**, Compound powder 400 g (*Neocate Advance*)
 2553J **Amino acids—synthetic, formula**, Compound powder 400 g (*Neocate Advance Tropical Flavour*)

2560R **Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids**, Compound powder 400 g (*Neocate LCP*)

Authority required

Continuing treatment for combined intolerance (not infant colic) to cows' milk protein, soy protein and protein hydrolysate formulae in a child up to the age of 2 years, where the child has been assessed by a suitably qualified allergist or paediatrician. The date of birth of the patient must be included in the authority application

Authority required

Treatment for combined intolerance (not infant colic) to cows' milk protein, soy protein and protein hydrolysate formulae in a child aged 2 years and over, where the child is assessed by a suitably qualified allergist or paediatrician at intervals not greater than 6 months. The date of birth of the patient must be included in the authority application

Authority required

Continuing treatment for severe intolerance (not infant colic) to cows' milk protein in a child up to the age of 2 years, where the child has been assessed by a paediatric gastroenterologist or specialist allergist and soy protein and protein hydrolysate formulae are not tolerated or not likely to be tolerated. The date of birth of the patient must be included in the authority application

Authority required

Treatment for severe intolerance (not infant colic) to cows' milk protein in a child aged 2 years and over, where the child is assessed by a paediatric gastroenterologist or specialist allergist at intervals not greater than 6 months. The date of birth of the patient must be included in the authority application

Authority required

Severe intestinal malabsorption including short bowel syndrome where protein hydrolysate formulae have failed

Authority required

Severe intestinal malabsorption including short bowel syndrome where the patient has been receiving parenteral nutrition

8773R **Anakinra**, Injection 100 mg in 0.67 mL single use pre-filled syringe (*Kineret*)

Authority required

Initial 1 (new patients)

Application for initial PBS-subsidised treatment with anakinra, 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 prior PBS-subsidised treatment with a bDMARD for this condition in this treatment cycle; and
- (c) have failed to achieve an adequate response to the following treatments:
 - (i) methotrexate at a dose of at least 20 mg weekly; and
 - (ii) methotrexate (at a minimum dose of 7.5 mg weekly), in combination with 2 other non-biological disease modifying anti-rheumatic drugs (DMARDs), for a minimum of 3 months; and
 - (iii) a minimum of 3 months' treatment with:
 - leflunomide alone; or
 - leflunomide in combination with methotrexate; or
 - cyclosporin.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of

application. Details of the accepted toxicities, including severity, can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

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

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

AND either

(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).

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

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

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

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes details of the patient's ESR and CRP measurements and the patient's active joint count which must have been assessed no earlier than 1 month prior to the date of application; 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 anakinra.

Patients who fail to demonstrate a response to treatment with anakinra under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this treatment cycle. Patients may re-trial anakinra after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle.

Authority required

Initial 2 (change or re-commencement)

Application for an initial course of PBS-subsidised treatment with anakinra, 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 in this treatment cycle 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 anakinra within this treatment cycle and who wish to re-commence therapy with this drug within this same cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised anakinra 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 anakinra treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy), 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 anakinra 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 anakinra under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this treatment cycle. Patients may re-trial anakinra after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle

8774T **Anakinra**, Injection 100 mg in 0.67 mL single use pre-filled syringe (*Kineret*)

Authority required

Continuing treatment

Continuing PBS-subsidised treatment with anakinra, 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 anakinra; and
- (c) whose most recent course of PBS-subsidised bDMARD treatment in this treatment cycle was with anakinra.

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 anakinra 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 anakinra, 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 anakinra under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this treatment cycle. Patients may re-trial anakinra after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle

8465M **Bupropion hydrochloride**, Tablet 150 mg (sustained release) (*Bupropion-RL, Clorprax, Prexaton, Zyban*)

Authority required

Commencement of short-term, sole PBS-subsidised, therapy as an aid to achieving abstinence in a patient who has indicated they are ready to cease smoking and:

- (a) who has entered a comprehensive support and counselling program; or
- (b) who is entering a comprehensive support and counselling program during the consultation at which this authority is requested.

Details of the program must be specified in the authority application.

8710K **Bupropion hydrochloride**, Tablet 150 mg (sustained release) (*Bupropion-RL, Clorprax, Prexaton, Zyban*)

Authority required

Completion of short-term, sole PBS-subsidised, therapy as an aid to achieving abstinence in a patient who has previously been issued with an authority prescription for this drug and who is enrolled in a comprehensive support and counselling program

9602J **Entecavir monohydrate**, Tablet 0.5 mg (*Baraclude*)

Private hospital authority required

Patients aged 16 years or older with chronic hepatitis B who satisfy all of the following criteria:

- (1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy);
- (2)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection (HBe antigen positive and/or HBV DNA positive); or
- (b) Elevated HBV DNA levels;
- (3) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy

9603K **Entecavir monohydrate**, Tablet 1 mg (*Baraclude*)

Private hospital authority required

Patients aged 16 years or older with chronic hepatitis B who have failed lamivudine therapy and who satisfy all of the following criteria:

(1)(a) Repeatedly elevated (greater than 1.2 times the upper limit of normal) serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection (HBe antigen positive and/or serum HBV DNA positive); or
 (b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance;

(2) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy

9089J **Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*)

8637N **Etanercept**, Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*)

8861J **Etanercept**, Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*)

Authority required

Initial 1 (new patients)

Application for 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 prior PBS-subsidised treatment with a bDMARD for this condition in this treatment cycle; and
- (c) have failed to achieve an adequate response to the following treatments:
 - (i) methotrexate at a dose of at least 20 mg weekly; and
 - (ii) methotrexate (at a minimum dose of 7.5 mg weekly), in combination with 2 other non-biological disease modifying anti-rheumatic drugs (DMARDs), for a minimum of 3 months; and
 - (iii) a minimum of 3 months' treatment with:
 - leflunomide alone; or
 - leflunomide in combination with methotrexate; or
 - cyclosporin.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities, including severity, can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

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

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

AND either

- (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).

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

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

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

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes details of the patient's ESR and CRP measurements and the patient's active joint count which must have been assessed no earlier than 1 month prior to the date of application; 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, in this treatment cycle. Patients may re-trial etanercept after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle

Authority required

Initial 2 (change or re-commencement)

Application for an 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 in this treatment cycle 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 within this treatment cycle and who wish to re-commence therapy with this drug within this same cycle, 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 treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy), 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, in this treatment cycle. Patients may re-trial etanercept after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle

Authority required

Initial treatment, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of patients aged 18 years or older with a documented history of severe active polyarticular course juvenile chronic arthritis with onset prior to the age of 18 years; AND
 (a) who have signed a patient agreement form indicating that they understand and acknowledge that PBS-subsidised treatment will cease if the predetermined response criteria do not support continuation of PBS-subsidised treatment; AND
 (b) who have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly; AND
 (c) who have failed to achieve an adequate response to methotrexate, in combination with 2 other disease modifying anti-rheumatic drugs (DMARDs), for a minimum of 3 months; AND
 (d) who have subsequently failed to achieve an adequate response following a minimum of 3 months' treatment with:
 (i) leflunomide alone; or
 (ii) leflunomide in combination with methotrexate; or
 (iii) cyclosporin.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use, the patient is exempted from demonstrating an inadequate response to the above treatment regimens. Details of the contraindication or intolerance, including the degree of toxicity, must be provided at the time of application.

The following criteria must be met in order to demonstrate failure to achieve an adequate response: 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) an active joint count of at least 20 active (swollen and tender) joints; or
- (ii) at least 4 active joints from the following list:
 - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

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

The authority application must be in writing and must include sufficient information to determine the patient's eligibility according to the above criteria. The date of joint assessment must be provided.

Where fewer than 3 repeats are requested at the time of the initial authority application, authority approvals for sufficient repeats to complete a maximum of 4 months of treatment may be requested by telephone. Under no circumstances will telephone approvals be granted for initial or continuing authority applications, or for treatment that would otherwise extend the initial treatment period beyond 4 months.

The assessment of the patient's response to the initial course of treatment should be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. Applications for continuing treatment with etanercept should be made prior to the completion of 16 weeks of treatment to ensure continuity for those patients who meet the criteria

- 9090K **Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*)
- 8638P **Etanercept**, Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*)
- 8862K **Etanercept**, Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*)

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 in this treatment cycle 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, in this treatment cycle. Patients may re-trial etanercept after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle

Authority required

Initial PBS-subsidised supply for continuing treatment, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of patients aged 18 years or older with a documented history of severe active polyarticular course juvenile chronic arthritis with onset prior to the age of 18 years, and who were receiving treatment with etanercept prior to 1 December 2002; AND

- (a) who have signed a patient agreement form indicating that they understand and acknowledge that PBS-subsidised treatment will cease if the predetermined response criteria do not support continuation of PBS-subsidised treatment; AND

(b) who have demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with etanercept.

The authority application must be in writing and must include sufficient information to determine the patient's eligibility. The date of assessment of the patient must be provided

Authority required

Continuing PBS-subsidised treatment, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of patients aged 18 years or older with a documented history of severe active polyarticular course juvenile chronic arthritis with onset prior to the age of 18 years, who, at the time of application, demonstrate an adequate response to treatment with etanercept as manifested by: 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 1 or more of the following:

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

All authority applications for continuing treatment with etanercept must be in writing and must include sufficient information to determine the patient's response according to the above criteria. The date of assessment of the patient must be provided.

Patients who fail to demonstrate an adequate response, as specified in the criteria for continuing treatment with etanercept, will not be eligible to recommence treatment with etanercept within 12 months of the date on which treatment was ceased.

Where re-treatment with etanercept after a break in PBS-subsidised treatment with the drug is being sought, the reason for and date of cessation of the previous treatment course with etanercept must be included in the application

9087G **Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*)

9035M **Etanercept**, Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*)

9083C **Etanercept**, Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*)

Authority required

Initial 1

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

- (1) have severe active psoriatic arthritis with a record of rheumatoid factor negative status within the last 12 months; and
- (2) have received no prior PBS-subsidised biological treatment for this condition in this Treatment Cycle; and
- (3) have failed to achieve an adequate response to:
 - (a) methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; and
 - (b) sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or
 - (c) leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months.

Patients must have had the psoriatic component of their disease confirmed by a dermatologist or by biopsy at any time.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of

application. Details of acceptable toxicities, including severity, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

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

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

(i) an 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).

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

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

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes details of the patient's ESR and CRP measurements and the patient's active joint count which must have been assessed no earlier than 1 month prior to the date of application; and

(3) a copy of the signed patient acknowledgement form which is included in the Supporting Information Form. Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated.

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).

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, in this Treatment Cycle

Authority required

Initial 2

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

(1) have a documented history of severe active psoriatic arthritis with a record of rheumatoid factor negative status within the last 12 months; and

(2) have received prior PBS-subsidised biological treatment for this condition in this Treatment Cycle and are eligible to receive further biological therapy; and

(3) have not failed treatment with etanercept during the current Treatment Cycle.

Applications for patients who have demonstrated a response to PBS-subsidised etanercept treatment within this Treatment Cycle and who wish to re-commence etanercept treatment within the same Cycle following a break in therapy, will only be approved where evidence of a response to the patient's most recent course of PBS-subsidised etanercept treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

Where the most recent course of PBS-subsidised etanercept treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), 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.

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

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

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).

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, in this Treatment Cycle.

Once patients fail to respond to treatment with 3 biological agents, they are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

- 6291D **Filgrastim**, Injection 300 micrograms in 0.5 mL single use pre-filled syringe (*Neupogen*)
 6126K **Filgrastim**, Injection 300 micrograms in 1 mL (*Neupogen*)
 6292E **Filgrastim**, Injection 480 micrograms in 0.5 mL single use pre-filled syringe (*Neupogen*)
 6127L **Filgrastim**, Injection 480 micrograms in 1.6 mL (*Neupogen*)

Private hospital authority required

For use in patients undergoing induction and consolidation therapy for acute myeloid leukaemia

Private hospital authority required

Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for autologous transplantation into patients with non-myeloid malignancies who have had myeloablative or myelosuppressive therapy

Private hospital authority required

Mobilisation of peripheral blood progenitor cells, in normal volunteers, for use in allogeneic transplantation

Private hospital authority required

Patients receiving marrow-ablative chemotherapy and subsequent bone marrow transplantation

Private hospital authority required

Patients with non-myeloid malignancies receiving marrow-ablative chemotherapy and subsequent autologous peripheral blood progenitor cell transplantation

Private hospital authority required

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in

acute lymphoblastic leukaemia

Private hospital authority required

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in

breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide)

Private hospital authority required

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in

Ewing's sarcoma

Private hospital authority required

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in

germ cell tumours

Private hospital authority required

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in

infants and children with CNS tumours

Private hospital authority required

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in

neuroblastoma

Private hospital authority required

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in

non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen)

Private hospital authority required

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in

osteosarcoma

Private hospital authority required

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in

relapsed Hodgkin's disease

Private hospital authority required

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in

rhabdomyosarcoma

Private hospital authority required

Patients with breast cancer receiving standard dose adjuvant chemotherapy who have had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Private hospital authority required

Patients receiving first-line chemotherapy for Hodgkin's disease who have had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Private hospital authority required

Patients receiving chemotherapy for myeloma who have had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination,

dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Private hospital authority required

Patients with severe congenital neutropenia (absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, and in whom a bone marrow examination has shown evidence of maturational arrest of the neutrophil lineage)

Private hospital authority required

Patients with severe chronic neutropenia (absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, or evidence of neutrophil dysfunction, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months))

Private hospital authority required

Patients with chronic cyclic neutropenia (absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months))

9619G **Ibandronate sodium**, Concentrated injection for I.V. infusion equivalent to 6 mg ibandronic acid in 6 mL (*Bondronat*)

Private hospital authority required

Bone metastases from breast cancer

2546B **Imiquimod**, Cream 50 mg per g (5%), 250 mg single use sachets, 12 (*Aldara*)

Authority required

Treatment of biopsy confirmed primary (previously untreated) superficial basal cell carcinoma (sBCC) in patients with normal immune function for whom surgical excision, cryotherapy, or curettage with diathermy are inappropriate and topical drug therapy is required.

The date of the pathology report and name of the Approved Pathology Authority must be provided at the time of application

6397Q **Infliximab**, Powder for I.V. infusion 100 mg (*Remicade*)

Public and private hospital authority required

Initial 1 (new patients)

Application for 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 prior PBS-subsidised treatment with a bDMARD for this condition in this treatment cycle; and
- (c) have failed to achieve an adequate response to the following treatments:
 - (i) methotrexate at a dose of at least 20 mg weekly; and
 - (ii) methotrexate (at a minimum dose of 7.5 mg weekly), in combination with 2 other non-biological disease modifying anti-rheumatic drugs (DMARDs), for a minimum of 3 months; and
 - (iii) a minimum of 3 months' treatment with:
 - leflunomide alone; or
 - leflunomide in combination with methotrexate; or
 - cyclosporin.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities, including severity, can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

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

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

AND either

(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).

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

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

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

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes details of the patient's ESR and CRP measurements and the patient's active joint count which must have been assessed no earlier than 1 month prior to the date of application; 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, in this treatment cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle

Public and private hospital authority required

Initial 2 (change or re-commencement)

Application for an 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 in this treatment cycle 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 within this treatment cycle and who wish to re-commence therapy with this drug within this same cycle, 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.

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 treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy), 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, in this treatment cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle

Public and private hospital 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 in this treatment cycle 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, in this treatment cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle

6496X **Infliximab**, Powder for I.V. infusion 100 mg (*Remicade*)

Public and private hospital authority required

Initial 1

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

- (1) have severe active psoriatic arthritis with a record of rheumatoid factor negative status within the last 12 months; and
- (2) have received no prior PBS-subsidised biological treatment for this condition in this Treatment Cycle; and
- (3) have failed to achieve an adequate response to:
 - (a) methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; and
 - (b) sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or
 - (c) leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months.

Patients must have had the psoriatic component of their disease confirmed by a dermatologist or by biopsy at any time.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities, including severity, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

- (i) an 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).

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

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

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes details of the patient's ESR and CRP measurements and the patient's active joint count which must have been assessed no earlier than 1 month prior to the date of application; and
- (3) a copy of the signed patient acknowledgement form which is included in the Supporting Information Form. Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated.

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 5 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).

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, in this Treatment Cycle

Public and private hospital authority required

Initial 2

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

- (1) have a documented history of severe active psoriatic arthritis with a record of rheumatoid factor negative status within the last 12 months; and
- (2) have received prior PBS-subsidised biological treatment for this condition in this Treatment Cycle and are eligible to receive further biological therapy; and
- (3) have not failed treatment with infliximab during the current Treatment Cycle.

Applications for patients who have demonstrated a response to PBS-subsidised infliximab treatment within this Treatment Cycle and who wish to re-commence infliximab treatment within the same Cycle following a break in therapy, will only be approved where evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), 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.

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

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

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 5 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).

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, in this Treatment Cycle.

Once patients fail to respond to treatment with 3 biological agents, they are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

Public and private hospital authority required

Initial 3

Initial PBS-subsidised supply for continuing treatment with infliximab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

- (1) have a documented history of severe active psoriatic arthritis with a record of rheumatoid factor negative status within the last 12 months; and
- (2) were receiving treatment with infliximab prior to 16 March 2006; and
- (3) have demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with infliximab.

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

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
- (3) a copy of the signed patient acknowledgement form which is included in the Supporting Information Form. Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated.

A maximum of 24 weeks of treatment with infliximab 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 5 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).

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, in this Treatment Cycle.

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

Public and private hospital authority required

Continuing treatment

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

- (1) who have a documented history of severe active psoriatic arthritis with a record of rheumatoid factor negative status; and
- (2) whose most recent course of PBS-subsidised biological agent for this condition in the current Treatment Cycle was with infliximab; and
- (3) who, at the time of application, demonstrate an adequate response to treatment with infliximab.

An adequate response to treatment with infliximab 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 Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

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 the initial treatment course.

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 5 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).

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, in this Treatment Cycle.

Once patients fail to respond to treatment with 3 biological agents, they are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

6210W	Interferon alfa-2a , Injection 3,000,000 i.u. in 0.5 mL single dose pre-filled syringe (<i>Roferon-A</i>)
6211X	Interferon alfa-2a , Injection 4,500,000 i.u. in 0.5 mL single dose pre-filled syringe (<i>Roferon-A</i>)
6212Y	Interferon alfa-2a , Injection 6,000,000 i.u. in 0.5 mL single dose pre-filled syringe (<i>Roferon-A</i>)
6213B	Interferon alfa-2a , Injection 9,000,000 i.u. in 0.5 mL single dose pre-filled syringe (<i>Roferon-A</i>)

Private hospital authority required

Use in the treatment of Philadelphia chromosome positive myelogenous leukaemia in the chronic phase

Private hospital authority required

Patients with chronic hepatitis B who satisfy all of the following criteria:

- (1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy);
- (2)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection (HBs antigen positive and/or HBV DNA positive); or
- (b) Elevated HBV DNA levels;

(3) Are not persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L);

(4) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception

6246R **Interferon alfa-2b**, Solution for injection 10,000,000 i.u. in 1 mL single dose vial (*Intron A*)

6253D **Interferon alfa-2b**, Solution for injection 18,000,000 i.u. in 1.2 mL multi-dose injection pen (*Intron A Redipen*)

6218G **Interferon alfa-2b**, Solution for injection 18,000,000 i.u. in 3 mL single dose vial (*Intron A*)

6219H **Interferon alfa-2b**, Solution for injection 25,000,000 i.u. in 2.5 mL single dose vial (*Intron A*)

6254E **Interferon alfa-2b**, Solution for injection 30,000,000 i.u. in 1.2 mL multi-dose injection pen (*Intron A Redipen*)

6255F **Interferon alfa-2b**, Solution for injection 60,000,000 i.u. in 1.2 mL multi-dose injection pen (*Intron A Redipen*)

Private hospital authority required

Adjunctive therapy of malignant melanoma following surgery in patients with nodal involvement

Private hospital authority required

Use in the treatment of Philadelphia chromosome positive myelogenous leukaemia in the chronic phase

Private hospital authority required

Patients with chronic hepatitis B who satisfy all of the following criteria:

(1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy);

(2)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection (HBe antigen positive and/or HBV DNA positive); or

(b) Elevated HBV DNA levels;

(3) Are not persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L);

(4) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception

9134R **Isoleucine with carbohydrate**, Sachets 4 g containing 50 mg isoleucine, 30 (*Isoleucine Amino Acid Supplement*)

9135T **Valine with carbohydrate**, Sachets 4 g containing 50 mg valine, 30 (*Valine Amino Acid Supplement*)

Restricted benefit

Maple syrup urine disease

6271C **Lamivudine**, Oral solution 5 mg per mL, 240 mL (*Zeffix*)

6257H **Lamivudine**, Tablet 100 mg (*Zeffix*)

Private hospital authority required

Patients with chronic hepatitis B who satisfy all of the following criteria:

(1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy);

(2)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection (HBe antigen positive and/or HBV DNA positive); or

(b) Elevated HBV DNA levels;

(3) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy

- 8039D **Oxybutynin hydrochloride**, Tablet 5 mg (*Ditropan, Oxybutynin Sandoz, Oxybutynin Winthrop*)
Restricted benefit
 Detrusor overactivity
- 6363X **Pegfilgrastim**, Injection 6 mg in 0.6 mL single use pre-filled syringe (*Neulasta*)
Private hospital authority required
 For use in patients undergoing induction and consolidation therapy for acute myeloid leukaemia
Private hospital authority required
 Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in
 acute lymphoblastic leukaemia
Private hospital authority required
 Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in
 breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide)
Private hospital authority required
 Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in
 Ewing's sarcoma
Private hospital authority required
 Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in
 germ cell tumours
Private hospital authority required
 Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in
 infants and children with CNS tumours
Private hospital authority required
 Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in
 neuroblastoma
Private hospital authority required
 Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in
 non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen)
Private hospital authority required
 Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in
 osteosarcoma
Private hospital authority required
 Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in
 relapsed Hodgkin's disease
Private hospital authority required

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in
rhabdomyosarcoma

Private hospital authority required

Patients with breast cancer receiving standard dose adjuvant chemotherapy who have had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Private hospital authority required

Patients receiving first-line chemotherapy for Hodgkin's disease who have had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Private hospital authority required

Patients receiving chemotherapy for myeloma who have had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

6439X
6449K

Peginterferon alfa-2a, Injection 135 micrograms in 0.5 mL single use pre-filled syringe (*Pegasys*)

Peginterferon alfa-2a, Injection 180 micrograms in 0.5 mL single use pre-filled syringe (*Pegasys*)

Private hospital authority required

Monotherapy in patients with chronic hepatitis B and compensated liver disease who satisfy all of the following criteria:

- (1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy);
- (2)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection (HBe antigen positive and/or HBV DNA positive); or
- (b) Elevated HBV DNA levels;
- (3) Have received no prior peginterferon alfa therapy for the treatment of hepatitis B;
- (4) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception;
- (5) Are not persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L).

Treatment is limited to 1 course of treatment for a duration of up to 48 weeks

Private hospital authority required

Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no prior interferon alfa or peginterferon alfa treatment for hepatitis C and have a contraindication to ribavirin, who satisfy all of the following criteria:

- (1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive);
- (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.

The treatment course is limited to up to 48 weeks.

Patients may only continue treatment after the first 12 weeks if the result of an HCV RNA quantitative assay (performed at the same laboratory using the same test) shows that the plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop

9131N **Pemetrexed disodium**, Powder for I.V. infusion 100 mg (base) (*Alimta*)

Authority required

Locally advanced or metastatic non-small cell lung cancer, after prior platinum-based chemotherapy

Authority required

Mesothelioma in combination with cisplatin

2676W **Protein hydrolysate formula with medium chain triglycerides**, Compound powder 400 g (*Alfaré*)

Authority required

Initial treatment, for up to 3 months, for intolerance (not infant colic) to both cows' milk protein and soy protein in a child up to the age of 2 years. Intolerance is demonstrated when the child has failed to respond to a strict cows' milk protein free diet with a soy protein as the principal formula. The date of birth of the patient must be included in the authority application

Authority required

Continuing treatment for intolerance (not infant colic) to both cows' milk protein and soy protein in a child up to the age of 2 years, where clinical improvement has been demonstrated with the protein hydrolysate formula with medium chain triglycerides. The date of birth of the patient must be included in the authority application

Authority required

Continuing treatment for intolerance (not infant colic) to both cows' milk protein and soy protein in a child aged 2 years and over, where the child has been assessed by a suitably qualified allergist or paediatrician. The date of birth of the patient must be included in the authority application

Authority required

Initial treatment, in consultation with a paediatric gastroenterologist or specialist allergist, for up to 3 months, of a child up to the age of 2 years with severe intolerance (not infant colic) to cows' milk protein. The date of birth of the patient must be included in the authority application

Authority required

Continuing treatment for severe intolerance (not infant colic) to cows' milk protein in a child up to the age of 2 years, where clinical improvement has been demonstrated with the protein hydrolysate formula with medium chain triglycerides and soy protein is not tolerated or is likely not to be tolerated. The date of birth of the patient must be included in the authority application

Authority required

Continuing treatment for severe intolerance (not infant colic) to cows' milk protein in a child aged 2 years and over, where the child has been assessed by a paediatric gastroenterologist or specialist allergist. The date of birth of the patient must be included in the authority application

Authority required

Biliary atresia

Authority required

Chronic liver failure with fat malabsorption

Authority required

Chylous ascites

Authority required

Chylothorax

Authority required

Cystic fibrosis

Authority required

Enterokinase deficiency

Authority required

Proven fat malabsorption

Authority required

Severe diarrhoea of greater than 2 weeks' duration in an infant aged less than 4 months. The date of birth of the patient must be included in the authority application

Authority required

Severe intestinal malabsorption including short bowel syndrome

8259Q

Protein hydrolysate formula with medium chain triglycerides, Compound powder 450 g
(*Pepti-Junior*)

Authority required

Initial treatment, for up to 3 months, for intolerance (not infant colic) to both cows' milk protein and soy protein in a child up to the age of 2 years. Intolerance is demonstrated when the child has failed to respond to a strict cows' milk protein free diet with a soy protein as the principal formula. The date of birth of the patient must be included in the authority application

Authority required

Continuing treatment for intolerance (not infant colic) to both cows' milk protein and soy protein in a child up to the age of 2 years, where clinical improvement has been demonstrated with the protein hydrolysate formula with medium chain triglycerides. The date of birth of the patient must be included in the authority application

Authority required

Continuing treatment for intolerance (not infant colic) to both cows' milk protein and soy protein in a child aged 2 years and over, where the child has been assessed by a suitably qualified allergist or paediatrician. The date of birth of the patient must be included in the authority application

Authority required

Initial treatment, in consultation with a paediatric gastroenterologist or specialist allergist, for up to 3 months, of a child up to the age of 2 years with severe intolerance (not infant colic) to cows' milk protein. The date of birth of the patient must be included in the authority application

Authority required

Continuing treatment for severe intolerance (not infant colic) to cows' milk protein in a child up to the age of 2 years, where clinical improvement has been demonstrated with the protein hydrolysate formula with medium chain triglycerides and soy protein is not tolerated or is likely not to be tolerated. The date of birth of the patient must be included in the authority application

Authority required

Continuing treatment for severe intolerance (not infant colic) to cows' milk protein in a child aged 2 years and over, where the child has been assessed by a paediatric gastroenterologist or specialist allergist. The date of birth of the patient must be included in the authority application

Authority required

Biliary atresia

Authority required

Chronic liver failure with fat malabsorption

Authority required

Chylous ascites

Authority required

Cystic fibrosis

Authority required

Enterokinase deficiency

Authority required

Proven fat malabsorption

Authority required

Severe diarrhoea of greater than 2 weeks' duration in an infant aged less than 4 months. The date of birth of the patient must be included in the authority application

Authority required

Severe intestinal malabsorption including short bowel syndrome

1382R **Ranibizumab**, Solution for intravitreal injection 3 mg in 0.3 mL (*Lucentis*)

Authority required

Initial treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of subfoveal choroidal neovascularisation (CNV) due to age-related macular degeneration (AMD), as diagnosed by fluorescein angiography.

Where a fluorescein angiogram cannot be performed due to a contraindication as listed in the TGA-approved product information, details of the contraindication must be provided. A copy of the report of an alternative method of diagnosis must be included in the application, for example, optical coherence tomography (OCT) or red free photography.

Authority approvals will be administered by the PBS and Specialised Drugs Branch of Medicare Australia.

The first authority application for each eye must be made in writing, and must include:

- (a) a completed authority prescription form; and
- (b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form [www.medicareaustralia.gov.au]; and
- (c) a copy of the fluorescein angiogram or alternative method of diagnosis where applicable.

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

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Alternatively, the first authority application may be faxed to Medicare Australia on (03) 6215 5474 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Medicare Australia will then contact the prescriber by telephone. The original documentation must be posted to the above address after approval has been gained

Authority required

Continuing treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of subfoveal choroidal neovascularisation (CNV) due to age-related macular degeneration (AMD) where the patient has previously been granted an authority prescription for the same eye.

Authority approvals will be administered by the PBS and Specialised Drugs Branch of Medicare Australia. Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

9611W **Rituximab**, Solution for I.V. infusion 500 mg in 50 mL (*Mabthera*)

Public and private hospital authority required

Initial 2 (change or re-commencement)

Application for an 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 an adult who:

- (a) has a documented history of severe active rheumatoid arthritis; and
- (b) has failed to respond to at least 1 PBS-subsidised TNF-alfa antagonist in this Treatment Cycle; and
- (c) has not previously failed to respond to PBS-subsidised rituximab in the current Treatment Cycle.

Applications for patients who have demonstrated a response to PBS-subsidised rituximab treatment within this Treatment Cycle and who wish to re-commence rituximab treatment within the same Cycle following a break in therapy, will only be approved where evidence of a response to the patient's most recent course of PBS-subsidised rituximab treatment has been submitted to Medicare Australia.

A patient may qualify to receive a further course of treatment (1 infusion at week 0 and 1 infusion at week 2) 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. The demonstration of response must be submitted to Medicare Australia within 4 weeks of assessment.

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

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].

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, in this Treatment Cycle. Patients may re-trial rituximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this Cycle and the date of the first application under the new Cycle.

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.

Patients who fail to demonstrate a response to treatment with 3 bDMARDs are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new bDMARD Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this Cycle and the date of the first application under the new Cycle

Public and private hospital authority required

Initial 3 ('grandfather' patients)

Initial PBS-subsidised supply for continuing 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 an adult who:

- (a) has a documented history of severe active rheumatoid arthritis; and
- (b) was receiving treatment with rituximab prior to 7 March 2007; and
- (c) has demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with rituximab.

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] which includes the signed patient acknowledgement form.

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.

Patients who fail to demonstrate a response to treatment with 3 bDMARDs are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new bDMARD Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this Cycle and the date of the first application under the new Cycle.

Patients can qualify for PBS-subsidised treatment under this criteria once only

Public and private hospital 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 an adult:

- (a) who has a documented history of severe active rheumatoid arthritis; and
- (b) who has demonstrated an adequate response to treatment with rituximab; and
- (c) whose most recent course of PBS-subsidised bDMARD treatment in this Treatment Cycle 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 [www.medicareaustralia.gov.au].

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 patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. The demonstration of response must be submitted to Medicare Australia within 4 weeks of assessment.

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

Patients who fail to demonstrate a response to treatment with 3 bDMARDs are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new bDMARD Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this Cycle and the date of the first application under the new Cycle

2142R **Sevelamer hydrochloride**, Tablet 800 mg (*Renagel*)

Authority required

Maintenance therapy, following initiation and stabilisation of treatment with sevelamer hydrochloride, of hyperphosphataemia in an adult with chronic kidney disease on dialysis whose serum phosphate is not controlled on other products and where

serum phosphate is greater than 1.6 mmol per L

Authority required

Maintenance therapy, following initiation and stabilisation of treatment with sevelamer hydrochloride, of hyperphosphataemia in an adult with chronic kidney disease on dialysis whose serum phosphate is not controlled on other products and where

the serum calcium times phosphate product is greater than 4.0

9620H **Sevelamer hydrochloride**, Tablet 800 mg (*Renagel*)

Public and private hospital authority required

Management of hyperphosphataemia in an adult with chronic kidney disease on dialysis whose serum phosphate is not controlled on other products and where:

(a) serum phosphate is greater than 1.6 mmol per L; or

(b) the serum calcium times phosphate product is greater than 4.0.

Management includes initiation, stabilisation and review of therapy as required.

NOTES

The text of notes mentioned above:

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).

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

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

The following note applies to Abatacept, Adalimumab (8737W, 9099X, 8741C and 9100Y), Anakinra (8773R and 8774T), Etanercept (8637N, 8861J, 9089J, 8638P, 8862K and 9090K), Infliximab (6397Q) and Rituximab (9611W).

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, etanercept, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-1 inhibitor (anakinra) 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 infliximab, anakinra, rituximab and abatacept 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 only eligible to receive PBS-subsidised etanercept and adalimumab.

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.

From 1 March 2008, under the PBS, all patients will be able to commence a Treatment Cycle where they may trial PBS-subsidised bDMARD agents without having to experience a disease flare when swapping to an alternate agent.

Under these interchangeability arrangements, within a single Treatment Cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2008 is considered to be in their first Cycle as of 1 March 2008.

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

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next Cycle.

For patients who have failed PBS-subsidised treatment with 3 bDMARDs prior to 1 March 2008 please contact Medicare Australia on 1800 700 270.

The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent Cycle to the date of the first application for initial treatment with a bDMARD under the new Treatment Cycle.

A patient who has failed fewer than 3 bDMARDs in a Treatment Cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same Treatment Cycle.

A patient who has failed fewer than 3 bDMARDs in a Treatment Cycle and who has a break in therapy of more than 5 years, may commence a new Treatment Cycle.

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

If patients fail to respond to a particular bDMARD within a single Treatment Cycle, they are not eligible to receive further PBS-subsidised treatment with that drug until they commence the next Cycle.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 March 2008.

(a) Initial treatment.

Applications for initial treatment should be made where:

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

(ii) 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

(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for etanercept, adalimumab, anakinra and abatacept, 22 weeks of therapy for infliximab and 2 infusions of rituximab.

From 1 March 2008, 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 within the same Treatment Cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements. 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 within the same Treatment Cycle.

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 within a Treatment Cycle 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.

The baseline joint and blood counts should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent Treatment Cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 non-biological DMARD, at an adequate dose, for a minimum of 3 months at the time the ESR and/or CRP levels and the active joint count are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with rituximab or abatacept.

From 1 March 2008, a patient who commenced treatment with rituximab for severe rheumatoid arthritis prior to 7 March 2007 or abatacept for severe rheumatoid arthritis prior to 1 November 2007 and who was 'grandfathered' on to PBS-subsidised therapy, and who continues to receive treatment in the same Treatment Cycle, will have further applications for treatment with rituximab or abatacept assessed under the continuing treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with abatacept will be authorised under this criterion.

'Grandfather' arrangements will only apply for the first Treatment Cycle. For the second and subsequent Cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that applies to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

The following note applies to Adalimumab (9033K, 9101B, 9034L and 9102C), Etanercept (9035M, 9083C, 9087G, 9036N, 9084D and 9088H) and Infliximab (6496X).

NOTE:

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents (adalimumab, etanercept and infliximab) for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept and infliximab.

From 1 August 2006, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept or infliximab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis after 1 August 2006.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1);

and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2)

[further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment 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. Where a response assessment is not submitted to

Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients.

Applications for patients who commenced treatment with etanercept prior to 17 March 2005 or adalimumab and infliximab prior to 16 March 2006, may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

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

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
- (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS.

To ensure patients receive 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.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent.

However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a treatment Cycle 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. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

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

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity.

Patients must have received treatment with methotrexate or sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Adefovir dipivoxil

NOTE:

Patients should have undergone a liver biopsy at some point since initial diagnosis to obtain histological evidence of chronic hepatitis.

Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

Bupropion hydrochloride

NOTE:

Only one course of PBS-subsidised bupropion hydrochloride will be authorised per 12 months. The period between commencing a course of bupropion hydrochloride and varenicline tartrate must be at least 6 months. A course of treatment with bupropion hydrochloride is 9 weeks. No increased maximum quantities or repeats will be authorised.

Clinical review is recommended within 2 to 3 weeks of the original prescription being requested.

Varenicline

NOTE:

Only one course of PBS-subsidised varenicline tartrate will be authorised per year. The period between commencing a course of varenicline tartrate and bupropion hydrochloride must be at least 6 months. A course of treatment with varenicline tartrate is 12 weeks. No increased maximum quantities or repeats will be authorised. Clinical review is recommended within 2 to 3 weeks of the original prescription being requested.

REPATRIATION PHARMACEUTICAL BENEFITS

This Schedule is effective from 1 March 2008 and all previous issues are cancelled.

New Schedules take effect on the first day of each month.

SUMMARY OF CHANGES

ADDITIONS

Additions - Items

- 4642H **Dressing—foam with silicone—heavy exudate**, Dressings 7.5 cm x 7.5 cm, 5 (*Mepilex Border 295200*)
- 4643J **Dressing—foam with silicone—heavy exudate**, Dressings 10 cm x 10 cm, 5 (*Mepilex Border 295300*)
- 4644K **Dressing—foam with silicone—light exudate**, Dressings 6 cm x 8.5 cm, 5 (*Mepilex Lite 284000*)
- 4645L **Dressing—foam with silicone—light exudate**, Dressings 10 cm x 10 cm, 5 (*Mepilex Lite 284100*)
- 4626L **Dressing—foam with silicone—moderate exudate**, Dressings 10 cm x 10 cm, 5 (*Mepilex 294100*)
- 4646M **Dressing with silver**, Hydroactive dressings non-adhesive 10 cm x 10 cm, 5 (*Contreet Foam Non-Adhesive 9622*)
- 4647N **Dressing with silver**, Hydroactive dressings adhesive 12.5 cm x 12.5 cm, 5 (*Contreet Foam Adhesive 9632*)
- 4648P **Dressing with silver**, Tulle dressings 10 cm x 10 cm, 3 (*Atrauman Ag 499572*)
- Dressing with silver**
- Authority required**
- For wounds where there is evidence of critical colonisation and for well-assessed chronic wounds that have not responded to conventional dressings