Australian Government

Department of Health and Ageing

# SCHEDULE OF PHARMACEUTICAL BENEFITS FOR APPROVED PHARMACISTS AND MEDICAL PRACTITIONERS

# SUMMARY OF CHANGES

**EFFECTIVE 1 JUNE 2007**

# PHARMACEUTICAL BENEFITS

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 June 2007. The Schedule is updated on the first day of each month and is available on the Internet at www.pbs.gov.au.

## Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 June 2007 and are included, where applicable, in prices published in the Schedule—

| | | |
|---|---|---|
| Dispensing Fees: | Ready-prepared | $5.15 |
| | Dangerous drug fee | $2.71 |
| | Extemporaneously-prepared | $7.19 |
| Additional Fees (for safety net prices): | Ready-prepared | $0.99 |
| | Extemporaneously-prepared | $1.38 |
| Patient Co-payments: | General | $30.70 |
| | Concessional | $4.90 |
| Safety Net Thresholds: | General | $1059.00 |
| | Concessional | $274.40 |
| Safety Net Card Issue Fee: | | $7.72 |

# SUMMARY OF CHANGES

## ADDITIONS

*Additions - Items*

*(see under 'RESTRICTIONS' and 'NOTES' for items where a restriction and/or a note applies)*

9085E **Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*) [for the treatment of adult patients with active ankylosing spondylitis]

9086F **Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*) [for the treatment of adult patients with active ankylosing spondylitis] **(Diff. Max. Rpts)**

9087G **Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*) [for the treatment of adult patients with severe active psoriatic arthritis]

9088H **Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*) [for the treatment of adult patients with severe active psoriatic arthritis] **(Diff. Max. Rpts)**

9089J **Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*) [for the treatment of adult patients with severe active rheumatoid arthritis]

9090K **Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*) [for the treatment of adult patients with severe active rheumatoid arthritis] **(Diff. Max. Rpts)**

9091L **Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*) [for the treatment of adult patients with severe chronic plaque psoriasis]

1820T **Glucose indicator—blood**, Electrode strips, 50 (*Glucoboy*)

2147B **Olmesartan medoxomil**, Tablet 20 mg (*Olmetec*)

2148C **Olmesartan medoxomil**, Tablet 40 mg (*Olmetec*)

2161R **Olmesartan medoxomil with hydrochlorothiazide**, Tablet 20 mg-12.5 mg (*Olmetec Plus*)

2166B **Olmesartan medoxomil with hydrochlorothiazide**, Tablet 40 mg-12.5 mg *(Olmetec Plus)*

2170F **Olmesartan medoxomil with hydrochlorothiazide**, Tablet 40 mg-25 mg (*Olmetec Plus*)

*Additions - Brands*

1007B *Aciclovir 200, CR* — **Aciclovir**, Tablet 200 mg

1052J *Aciclovir 800, CR* — **Aciclovir**, Tablet 800 mg

8465M *Prexaton, AF* — **Bupropion hydrochloride**, Tablet 150 mg (sustained release)

8710K *Prexaton, AF* — **Bupropion hydrochloride**, Tablet 150 mg (sustained release) **(Diff. Max. Qty)**

1835N *Gabapentin 400, CR* — **Gabapentin**, Capsule 400 mg

8535F *Oziclide MR, RA* — **Gliclazide**, Tablet 30 mg (modified release)

2242B *Paroxetine 20, CR* — **Paroxetine hydrochloride**, Tablet 20 mg (base)

2833D *Pravastatin 10, CR; Pravastatin Winthrop, WA* — **Pravastatin sodium**, Tablet 10 mg

2834E *Pravastatin 20, CR; Pravastatin Winthrop, WA* — **Pravastatin sodium**, Tablet 20 mg

8197K *Pravastatin 40, CR; Pravastatin Winthrop, WA* — **Pravastatin sodium**, Tablet 40 mg

1944H *Prilace 1.25, AW* — **Ramipril**, Tablet 1.25 mg

1945J *Prilace 2.5, AW* — **Ramipril**, Tablet 2.5 mg

1946K *Prilace 5, AW* — **Ramipril**, Tablet 5 mg

8470T *Prilace 10, AW* — **Ramipril**, Capsule 10 mg

2013Y *Simvasyn, CR* — **Simvastatin**, Tablet 5 mg

2011W *Simvasyn, CR* — **Simvastatin**, Tablet 10 mg

2012X *Simvasyn, CR* — **Simvastatin**, Tablet 20 mg

8173E *Simvasyn, CR* — **Simvastatin**, Tablet 40 mg

8313M *Simvasyn, CR* — **Simvastatin**, Tablet 80 mg

2804N *Terbinafine 250, CR* — **Terbinafine hydrochloride**, Tablet 250 mg (base)

## BIOEQUIVALENCE INDICATORS

The bioequivalence indicator ([a]) has been added to the following brand:

8535F *Diamicron MR, SE* — **Gliclazide**, Tablet 30 mg (modified release)

## DELETIONS

*Deletion - Item*

2978R **Cholestyramine**, Sachets 9.4 g (equivalent to 8 g cholestyramine), 50 (*Questran Lite*)

*Deletions - Brands*

2422L *Carbamazepine-BC, BG* — **Carbamazepine**, Tablet 100 mg

5039F *Carbamazepine-BC, BG* — **Carbamazepine**, Tablet 100 mg **(Dental)**

2419H *Carbamazepine-BC, BG* — **Carbamazepine**, Tablet 200 mg

5040G *Carbamazepine-BC, BG* — **Carbamazepine**, Tablet 200 mg **(Dental)**

## ALTERATIONS

*Alterations - Manufacturer's Codes*

| | | *From* | *To* |
|---|---|---|---|
| 8220P | **Citalopram hydrobromide**, Tablet 20 mg (base) (*Citalopram Winthrop*) | SL | WA |
| 1370D | **Enalapril maleate**, Tablet 5 mg (*Enalapril Winthrop*) | SL | WA |
| 1368B | **Enalapril maleate**, Tablet 10 mg (*Enalapril Winthrop*) | SL | WA |
| 1369C | **Enalapril maleate**, Tablet 20 mg (*Enalapril Winthrop*) | SL | WA |
| 2487X | **Famotidine**, Tablet 20 mg (*Famohexal*) | HX | SZ |
| 2488Y | **Famotidine**, Tablet 40 mg (*Famohexal*) | HX | SZ |
| 1900B | **Moclobemide**, Tablet 150 mg (*Mohexal*) | HX | SZ |
| 8003F | **Moclobemide**, Tablet 300 mg (*Mohexal*) | HX | SZ |
| 1760P | **Roxithromycin**, Tablet 150 mg (*Roxide*) | HX | SZ |
| 8016X | **Roxithromycin**, Tablet 300 mg (*Roxide*) | HX | SZ |
| 2236Q | **Sertraline hydrochloride**, Tablet 50 mg (base) (*Sertraline Winthrop*) | SL | WA |
| 2237R | **Sertraline hydrochloride**, Tablet 100 mg (base) (*Sertraline Winthrop*) | SL | WA |
| 2013Y | **Simvastatin**, Tablet 5 mg (*Simvastatin Winthrop*) | SL | WA |
| 2011W | **Simvastatin**, Tablet 10 mg (*Simvastatin Winthrop*) | SL | WA |
| 2012X | **Simvastatin**, Tablet 20 mg (*Simvastatin Winthrop*) | SL | WA |
| 8173E | **Simvastatin**, Tablet 40 mg (*Simvastatin Winthrop*) | SL | WA |
| 8313M | **Simvastatin**, Tablet 80 mg (*Simvastatin Winthrop*) | SL | WA |

## SECTION 100 - HUMAN GROWTH HORMONE PROGRAM

## ALTERATIONS

*Alteration - Note*
*(see under 'NOTES' for full details)*

**Somatropin (Recombinant human growth hormone)**

## SECTION 100 - IVF/GIFT PROGRAM
## ADDITIONS

*Additions - Items*

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

9608Q **Progesterone**, Pessary 100 mg (*ON*)

9609R **Progesterone**, Pessary 200 mg (*ON*)

## ADVANCE NOTICES

*Advance Notices - Deletion of Items*

The following items will be deleted from the Schedule of Pharmaceutical Benefits on 1 **October** 2007:

Items discontinued by the manufacturer -

1425B **Insulin neutral—insulin isophane (n.p.h.), (mixed) (biphasic isophane)**, Injection (human) 100 units (50 units-50 units) per mL, 10 mL (*Mixtard 50/50*)

8006J **Insulin neutral—insulin isophane (n.p.h.), (mixed) (biphasic isophane)**, Injections (human) 100 units (20 units-80 units) per mL, 3 mL, 5 (*Mixtard 20/80 Penfill 3 mL*)

*Advance Notice - Deletion of Brand*

The following brand will be deleted from the Schedule of Pharmaceutical Benefits on 1 **October** 2007:

Brand discontinued by the manufacturer -

1426C *Mixtard 30/70, NO* — **Insulin neutral—insulin isophane (n.p.h.), (mixed) (biphasic isophane)**, Injection (human) 100 units (30 units-70 units) per mL, 10 mL

# RESTRICTIONS

## Details of restriction text for new items:

9085E **Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*)

**Authority required**

Initial 1 (new patients)
First course of PBS-subsidised treatment with etanercept, by a rheumatologist, of an adult with active ankylosing spondylitis who has radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis and who has not received any PBS-subsidised treatment with either adalimumab, etanercept or infliximab in this treatment cycle; AND
(a) who has at least 2 of the following:
(i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or
(ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI) [for further information on the BASMI please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; or
(iii) limitation of chest expansion relative to normal values for age and gender [for chest expansion normal values please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; AND
(b) who has failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

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

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Medicare Australia website at www.medicareaustralia.gov.au.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:
(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND
(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which must include the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
(ii) a completed BASDAI Assessment Form [www.medicareaustralia.gov.au]; and
(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
(iv) a signed patient acknowledgment form. Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment with the TNF-alfa antagonists (adalimumab, etanercept or infliximab) for ankylosing spondylitis 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.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 16 weeks of treatment with etanercept will be approved under this criterion.

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone

**Authority required**

Initial 2 (change or re-commencement for all patients)
Initial course of PBS-subsidised treatment with etanercept, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who, in this treatment cycle, has received prior PBS-subsidised treatment with either adalimumab, etanercept or infliximab for this condition and has not failed PBS-subsidised therapy with etanercept.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction after 1 March 2007, the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction prior to 1 March 2007, the patient must have been assessed for response to that course following at least 4 weeks of treatment. These assessments must be provided to Medicare Australia no later than 4 weeks from the date the course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which includes a completed BASDAI Assessment Form with certification by the prescriber and the patient that the patient did not have access to their baseline BASDAI at the time of their assessment.

A maximum of 16 weeks of treatment with etanercept will be approved under this criterion.

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone

9086F **Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*)

**Authority required**

Continuing treatment for all patients
Continuing PBS-subsidised treatment, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who:

(a) has demonstrated a response to treatment with etanercept; and
(b) whose most recent course of PBS-subsidised therapy in this treatment cycle was with etanercept.

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

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

For a 'grandfather' patient who does not have baselines prior to commencing treatment with a TNF-alfa antagonist, see Note 5 for a definition of response to treatment.

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

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction after 1 March 2007, the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction prior to 1 March 2007, the patient must have been assessed for response to that course following at least 4 weeks of treatment.

Applications for continuing treatment must be made in writing and should be posted to Medicare Australia no less than 2 weeks prior to the completion of the current treatment course.

Written applications for authorisation must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which includes a completed BASDAI Assessment Form with certification by the prescriber and the patient that the patient did not have access to their baseline BASDAI at the time of their continuing treatment assessment.

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

A maximum of 24 weeks of treatment with etanercept will be authorised under this criterion.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone

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

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

9088H **Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*)

**Authority required**

Initial 3
Initial PBS-subsidised supply for continuing 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) were receiving treatment with etanercept prior to 17 March 2005; and
(3) have demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with etanercept.

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 etanercept will be authorised 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).

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 qualify for PBS-subsidised treatment under this restriction once only

**Authority required**

Continuing treatment
Continuing PBS-subsidised treatment with etanercept, 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 etanercept; and

(3) who, at the time of application, demonstrate an adequate response to treatment with etanercept.

An adequate response to treatment with etanercept 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 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 the initial treatment course.

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).

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

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

**Authority required**

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, 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 that particular agent(s) only. Details of the contraindications or intolerance, including the degree of toxicity, must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrable 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).

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 Biological DMARD PBS Authority Application for Use in the Treatment of Rheumatoid Arthritis - Supporting Information Form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm and click on 'Medical Practitioners')] 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 may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm and click on 'Medical Practitioners'). Completion of this form declares that the patient understands and acknowledges that, within a single treatment cycle, PBS-subsidised treatment with any biological DMARD 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. 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**

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 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.

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.

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.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Biological DMARD PBS Authority Application for Use in the Treatment of Rheumatoid Arthritis - Supporting Information Form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm and click on 'Medical Practitioners')].

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. 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.

Once patients fail to respond to treatment with 3 bDMARDs, they 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 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*)

**Authority required**

Initial PBS-subsidised supply for continuing 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) were receiving treatment with etanercept prior to 1 March 2005; and
(c) failed to qualify for PBS-subsidised therapy after 1 August 2003 due to testing negative for rheumatoid factor; and
(d) have demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with etanercept.

Medical practitioners who wish to apply for authority to prescribe a bDMARD for patients who commenced treatment with etanercept prior to 1 March 2005 and who have not demonstrated a response to treatment should contact Medicare Australia on 1800 700 270.

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

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.

Once patients fail to respond to treatment with 3 bDMARDs, they 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 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**

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 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 Biological DMARD PBS Authority Application for Use in the Treatment of Rheumatoid Arthritis - Supporting Information Form [may be downloaded from the Medicare Australia website (visit www.medicareaustralia.gov.au/providers/forms/pbs.htm and click on 'Medical Practitioners')].

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.

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).

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.

Once patients fail to respond to treatment with 3 bDMARDs, they 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 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

9091L **Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*)

**Authority required**

Initial treatment [Initial 1, Whole body (New patients — No prior biological agent)]
Initial treatment as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin) by a dermatologist for adults 18 years and over who:
(a) have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; and
(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have signed a patient acknowledgement form indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); and
(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:
(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or
(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or
(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or
(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, 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, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Patients for whom a PASI assessment for any prior course of treatment, where that course of treatment was completed prior to 16 March 2006, is not available, may contact Medicare Australia on 1800 700 270 for advice.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) a copy of the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and whole body area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
(iii) a copy of the signed patient acknowledgement form.

A maximum of 12 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 2 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 12 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). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 12 weeks.

A PASI assessment of the patient's response must be made at the completion of this 12 week initial treatment course. 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 demonstrate a response to treatment according to the response criterion included in the continuing treatment restriction for etanercept, may access continuing treatment with etanercept following a biological treatment-free period of at least 12 weeks. Patients who fail to demonstrate such a response to etanercept treatment may trial an alternate biological agent or a further course of etanercept according to the interchangeability arrangements for biological agents for the treatment of severe chronic plaque psoriasis, without having to have a 12 week treatment-free period before doing so

**Authority required**

Initial or re-Treatment [Initial 2, Whole body (Received prior biological agent under PBS)]
Treatment as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin) by a dermatologist for adults 18 years and over who:
(a) have a documented history of severe chronic plaque psoriasis; and
(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have not failed PBS-subsidised therapy with etanercept for the treatment of this condition more than once in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) a copy of the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and whole body area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of prior biological treatment, including dosage, date and duration of treatment.

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.

A maximum of 12 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 2 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 12 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). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 12 weeks.

A PASI assessment of the patient's response must be made at the completion of this 12 week course of treatment. 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 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 demonstrate a response to treatment according to the response criterion included in the continuing treatment restriction for etanercept, may access continuing treatment with etanercept following a biological treatment-free period of at least 12 weeks. Patients who fail to demonstrate such a response to etanercept treatment and who qualify to trial an alternate biological agent or a further course of etanercept according to the interchangeability arrangements for biological agents for the treatment of severe chronic plaque psoriasis, may do so without having to have a 12 week treatment-free period.

Patients who fail to demonstrate a response to treatment with the biological agents, efalizumab and etanercept, on a total of 3 occasions 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

**Authority required**

Initial treatment [Initial 3, Whole body (Grandfather patients)]
Initial PBS-subsidised supply for continuing treatment as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin) by a dermatologist for adults 18 years and over who:
(a) have a documented history of severe chronic plaque psoriasis and were receiving treatment with etanercept prior to 16 March 2006; and
(b) had a Psoriasis Area and Severity Index (PASI) score of greater than 15 prior to commencing treatment with etanercept; and
(c) have signed a patient acknowledgement form indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); and
(d) have demonstrated a response as specified in the criterion included in the restriction for continuing PBS-subsidised treatment with etanercept (whole body).

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) a copy of the completed Psoriasis Area and Severity Index (PASI) calculation sheet and whole body area diagrams including the date of the assessment of the patient's condition at baseline (prior to initiation of etanercept therapy) and the most recent PASI assessment [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
(iii) a copy of the signed patient acknowledgement form.

The most recent PASI assessment must be no more than 1 month old at the time of application.

A maximum of 12 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 12 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).

A PASI assessment of the patient's response must be made at the completion of this 12 week initial treatment course. 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 demonstrate a response to treatment according to the response criterion included in the continuing treatment restriction for etanercept, may access continuing treatment with etanercept following a biological treatment-free period of at least 12 weeks. Patients who fail to demonstrate such a response to etanercept treatment may trial an alternate biological agent or a further course of etanercept according to the interchangeability arrangements for biological agents for the treatment of severe chronic plaque psoriasis, without a 12 week treatment-free period before doing so.

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

**Authority required**

Continuing treatment (Whole body)
Continuing PBS-subsidised treatment as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin) by a dermatologist for adults 18 years and over:
(a) who have a documented history of severe chronic plaque psoriasis; and
(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with etanercept; and
(c) who have demonstrated an adequate response to their most recent course of treatment with etanercept.

An adequate response to treatment is defined as:
A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, after at least 12 weeks of etanercept treatment, compared with the pre-biological treatment baseline value for this Treatment Cycle.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) a copy of the completed Psoriasis Area and Severity Index (PASI) calculation sheet and whole body area diagrams along with the date of the assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Approval will be based on the PASI assessment of response to the most recent course of active treatment with etanercept, which must have been undertaken at the completion of this course of active treatment.

A maximum of 12 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 2 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 12 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).

A PASI assessment of the patient's response must be made at the completion of each 12 week active treatment course. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this 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 demonstrate a response to treatment according to the response criterion included in this restriction, may access further continuing treatment with etanercept, following a biological treatment-free period of at least 12 weeks.

Continuing treatment is available in the form of 12 weeks of active etanercept treatment followed by a treatment-free period of at least 12 weeks. Patients are eligible to receive continuing treatment with etanercept on this cyclical basis, for as long as they continue to sustain a response. Continuing applications for treatment must be submitted at least 12 weeks after cessation of the most recent course of etanercept treatment.

Patients who fail to demonstrate such a response to etanercept treatment and who qualify to trial an alternate biological agent or a further initial course of etanercept according to the interchangeability arrangements for biological agents for the treatment of severe chronic plaque psoriasis, may do so without having to have a 12 week treatment-free period.

Patients who fail to demonstrate a response to treatment with the biological agents, efalizumab and etanercept, on a total of 3 occasions 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

**Authority required**

Initial treatment [Initial 1, Face, hand, foot (New patients — No prior biological agent)]
Initial treatment as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin) by a dermatologist for adults 18 years and over who:
(a) have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and
(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have signed a patient acknowledgement form indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot); and
(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:
(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or
(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or
(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or
(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, 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, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:
(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Patients for whom a PASI assessment for any prior course of treatment, where that course of treatment was completed prior to 16 March 2006, is not available, may contact Medicare Australia on 1800 700 270 for advice.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) a copy of the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
(iii) a copy of the signed patient acknowledgement form.

A maximum of 12 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 2 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 12 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). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 12 weeks.

A PASI assessment of the patient's response must be made at the completion of this 12 week initial treatment course. 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 demonstrate a response to treatment according to the response criterion included in the continuing treatment restriction for etanercept, may access continuing treatment with etanercept following a biological treatment-free period of at least 12 weeks. Patients who fail to demonstrate such a response to etanercept treatment may trial an alternate biological agent or a further course of etanercept according to the interchangeability arrangements for biological agents for the treatment of severe chronic plaque psoriasis, without having to have a 12 week treatment-free period before doing so.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline

**Authority required**

Initial or re-Treatment [Initial 2, Face, hand, foot (Received prior biological agent under PBS)]
Treatment as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin) by a dermatologist for adults 18 years and over who:
(a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and
(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have not failed PBS-subsidised therapy with etanercept for the treatment of this condition more than once in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) a copy of the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of prior biological treatment, including dosage, date and duration of treatment.

The PASI assessment must be performed on the same affected area as assessed at baseline.

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 12 week course of PBS-subsidised etanercept treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 12 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 2 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 12 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). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 12 weeks.

A PASI assessment of the patient's response must be made at the completion of this 12 week treatment course. 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 demonstrate a response to treatment according to the response criterion included in the continuing treatment restriction for etanercept, may access continuing treatment with etanercept following a biological treatment-free period of at least 12 weeks. Patients who fail to demonstrate such a response to etanercept treatment and who qualify to trial an alternate biological agent or a further course of etanercept according to the interchangeability arrangements for biological agents for the treatment of chronic plaque psoriasis, may do so without having to have a 12 week treatment-free period.

Patients who fail to demonstrate a response to treatment with the biological agents, efalizumab and etanercept, on a total of 3 occasions 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

**Authority required**

Initial treatment [Initial 3, Face, hand, foot (Grandfather patients)]
Initial PBS-subsidised supply for continuing treatment as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin) by a dermatologist for adults 18 years and over:
(a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot and were receiving treatment with etanercept prior to 16 March 2006; and
(b) whose disease, prior to treatment with etanercept, was of a severity as defined in the initiation criterion included in the initial treatment restriction (Initial 1, New patients — face, hand, foot); and
(c) who have signed a patient acknowledgement form indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot); and
(d) who have demonstrated a response as specified in the criterion included in the restriction for continuing PBS-subsidised treatment with etanercept (face, hand, foot).

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) a copy of the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment of the patient's condition at baseline (prior to initiation of etanercept therapy) and the most recent PASI assessment [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
(iii) a copy of the signed patient acknowledgement form.

The PASI assessment must be performed on the same affected area as assessed prior to initiation of etanercept treatment.

The most recent PASI assessment must be no more than 1 month old at the time of application.

A maximum of 12 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 12 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).

A PASI assessment of the patient's response must be made at the completion of this 12 week initial treatment course. 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 demonstrate a response to treatment according to the response criterion included in the continuing treatment restriction for etanercept, may access continuing treatment with etanercept following a biological treatment-free period of at least 12 weeks. Patients who fail to demonstrate such a response to etanercept treatment may trial an alternate biological agent or a further course of etanercept according to the interchangeability arrangements for biological agents for the treatment of severe chronic plaque psoriasis, without having to have a 12 week treatment-free period before doing so.

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

**Authority required**

Continuing treatment (Face, hand, foot)
Continuing PBS-subsidised treatment as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin) by a dermatologist for adults 18 years and over:
(a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and
(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with etanercept; and
(c) who have demonstrated an adequate response to their most recent course of treatment with etanercept.

An adequate response to etanercept treatment is defined as the plaque or plaques assessed prior to biological treatment showing:
(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, after at least 12 weeks of etanercept treatment, as compared to the pre-biological treatment baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, after at least 12 weeks of etanercept treatment, as compared to the pre-biological treatment baseline value.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) a copy of the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Approval will be based on the PASI assessment of response to the most recent course of active treatment with etanercept, which must have been undertaken at the completion of this course of active treatment.

A maximum of 12 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 2 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 12 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).

A PASI assessment of the patient's response must be made at the completion of each 12 week active treatment course. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this 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 demonstrate a response to treatment according to the response criterion included in this restriction, may access further continuing treatment with etanercept, following a biological treatment-free period of at least 12 weeks.

Continuing treatment is available in the form of 12 weeks of active etanercept treatment followed by a treatment-free period of at least 12 weeks. Patients are eligible to receive continuing treatment with etanercept on this cyclical basis, for as long as they continue to sustain a response. Continuing applications can only be submitted at least 12 weeks after cessation of the most recent course of etanercept treatment.

Patients who fail to demonstrate such a response to etanercept treatment and who qualify to trial an alternate biological agent or a further initial course of etanercept according to the interchangeability arrangements for biological agents for the treatment of severe chronic plaque psoriasis, may do so without having to have a 12 week treatment-free period.

Patients who fail to demonstrate a response to treatment with the biological agents, efalizumab and etanercept, on a total of 3 occasions 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

2161R **Olmesartan medoxomil with hydrochlorothiazide**, Tablet 20 mg-12.5 mg (*Olmetec Plus*)
2166B **Olmesartan medoxomil with hydrochlorothiazide**, Tablet 40 mg-12.5 mg (*Olmetec Plus*)
2170F **Olmesartan medoxomil with hydrochlorothiazide**, Tablet 40 mg-25 mg (*Olmetec Plus*)

**Restricted benefit**

Hypertension in patients who are not adequately controlled with either hydrochlorothiazide or olmesartan medoxomil monotherapy

9608Q **Progesterone**, Pessary 100 mg (*ON*)
9609R **Progesterone**, Pessary 200 mg (*ON*)

For luteal phase support in patients who are receiving medical treatment as described in item 13200 of the Medicare Benefits Schedule. The luteal phase is defined as the time span from embryo transfer until implantation confirmed by positive B-hCG measurement

# NOTES

## Details of note text for new items and note alterations:

**Etanercept**

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

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

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

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

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

9085E **Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*)

9086F **Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*)

TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and infliximab for adult patients with active ankylosing spondylitis. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab, etanercept and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 TNF-alfa antagonists at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

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 TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 TNF-alfa antagonists 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 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 March 2007.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist 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 TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for etanercept and adalimumab and 18 weeks of treatment for infliximab.

From 1 March 2007, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to 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, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist 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 posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alfa antagonist, 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 TNF-alfa antagonist 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 TNF-alfa antagonist 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.

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 TNF-alfa antagonist.

(2) Swapping therapy.

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

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

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

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

(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 BASDAI, ESR and/or CRP submitted with the first authority application for a TNF-alfa antagonist. 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.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program. However, this is not required for any subsequent BASDAI results for these patients, nor for patients who were 'grandfathered' on to TNF-alfa antagonist treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be 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.

(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 TNF-alfa antagonist 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 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with etanercept.

From 1 March 2007, a patient who commenced treatment with etanercept for active ankylosing spondylitis prior to 1 July 2004 and who was 'grandfathered' onto PBS-subsidised therapy, and who continues to receive treatment in the same treatment cycle, will have further applications for treatment with etanercept assessed under the continuing treatment restriction.

Where pre-TNF-alfa antagonist treatment baselines were not provided, the following criteria must be met to demonstrate a response to treatment:

The BASDAI score must be either:

(i) no more than 20% greater than the score included in the initial application for PBS-subsidised treatment; or

(ii) no greater than 2.

AND

One of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L.

'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 apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

9087G **Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*)
9088H **Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*)

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 either methotrexate or sulfasalazine, 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.

9089J **Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*)
9090K **Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*)

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the tumour necrosis factor (TNF) alfa antagonists (adalimumab, etanercept and infliximab) and the interleukin-1 inhibitor (anakinra) for adult patients with severe rheumatoid arthritis.

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

1. Patients who have received no prior PBS-subsidised bDMARD treatment at 1 December 2004.

From 1 December 2004, the arrangements for prescribing the bDMARDs on the PBS have been amended to allow patients to commence a single cycle of bDMARD treatment that allows them to trial any number of bDMARDs without having to experience a disease flare when swapping between alternate bDMARDs. Within a single treatment cycle, patients may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

Once patients have either failed, or ceased to respond to, treatment with a maximum of 3 bDMARDs, they are deemed to have completed a single 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. The 5-year period will be measured from the date the last prescription for PBS-subsidised bDMARD treatment was approved in the most recent cycle to the date of the application for initial treatment with a bDMARD under the new cycle.

Patients who have failed treatment with fewer than 3 bDMARDs within a particular treatment cycle, and where a period of less than 5 years duration has elapsed since the patient's previous course of PBS-subsidised bDMARD treatment in that cycle, may commence a further course of bDMARD treatment within that same treatment cycle.

Patients who have failed treatment with fewer than 3 bDMARDs within a particular treatment cycle, and who have had a break in PBS-subsidised therapy of 5 years or more, are eligible to 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.

2. Patients who have received PBS-subsidised TNF-alfa antagonist treatment prior to 1 December 2004.

Patients who commenced PBS-subsidised TNF-alfa antagonist therapy prior to 1 December 2004 are considered to be in their first cycle of bDMARD treatment on 1 December 2004.

Patients who have failed to respond to prior PBS-subsidised treatment with fewer than 3 TNF-alfa antagonists at the time the first application for treatment is made on or after 1 December 2004, will be subject to the same conditions applying to new patients detailed above.

Therefore, patients who have failed:

(a) 1 TNF-alfa antagonist will be eligible to trial further PBS-subsidised treatment with a bDMARD they have not failed in their first treatment cycle, until they fail to demonstrate a response to no more than another 2 bDMARDs;

(b) 2 TNF-alfa antagonists will be eligible to trial further PBS-subsidised treatment with a bDMARD they have not failed in their first treatment cycle, until they fail to demonstrate a response to no more than 1 other bDMARD.

Patients who have failed PBS-subsidised treatment with 3 TNF-alfa antagonists prior to 1 December 2004 or at the first assessment required after this date, will be eligible to trial PBS-subsidised treatment with anakinra if they wish. However, if they fail to demonstrate a response to anakinra, they will not be able

to trial any further PBS-subsidised bDMARD treatment until a minimum of 5 years has elapsed from the date that the prescription for the last course of anakinra therapy was approved. Arrangements to allow these patients to fail 4 bDMARDs will only be in place for the first treatment cycle. For subsequent cycles, patients will cease to be eligible to receive PBS-subsidised bDMARD treatment once they have failed to demonstrate a response to a maximum of 3 bDMARDs.

Any queries on these arrangements should be forwarded to Medicare Australia.

3. Information relevant to all patients.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised bDMARD treatment and wish to commence such therapy; or

(ii) patients have received prior PBS-subsidised (initial or continuing) bDMARD therapy and wish to trial an alternate agent [further details are under 'Swapping therapy' below]; or

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

All applications for initial treatment 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 bDMARD 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 bDMARD.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, 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 bDMARD 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 bDMARD.

(c) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised bDMARD is approved, patients may swap to an alternate bDMARD 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-bDMARD therapy requirements. However, the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients may swap to 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 or not.

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

(i) they have not received PBS-subsidised treatment with that particular bDMARD previously; or

(ii) they have demonstrated an adequate response to that particular bDMARD if they have previously trialled it on the PBS.

Therefore, to maximise the choice of bDMARD patients may alternate between, it is important that patients 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 bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(d) 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 bDMARD. 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. more than 20 active joints), response will be determined according to a reduction in the total number of active joints.

(e) 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 bDMARD 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 at least 1 non-biological DMARD, 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.

9091L **Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*)

TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents efalizumab and etanercept, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to efalizumab and etanercept.

From 1 August 2006, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial both efalizumab and etanercept 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.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent, as systemic monotherapy, at any 1 time.

Initial treatment with efalizumab consists of 16 weeks of therapy and response to treatment must be assessed after at least 12 weeks of treatment. Initial treatment with etanercept consists of 12 weeks of active therapy followed by a treatment-free period of at least 12 weeks. Response to treatment must be assessed at the completion of the 12 week active etanercept treatment course.

Following demonstration of response to initial treatment, these biological agents are available as continuing therapy. Ongoing access to continuing treatment is available for as long as the response to therapy is sustained. In the case of efalizumab, continuing treatment consists of 24 weeks of continuous active treatment. In the case of etanercept, continuing treatment consists of 12 weeks of active therapy followed by a treatment-free period of at least 12 weeks.

Patients must be assessed for response to each course of continuing treatment according to the criteria included in the relevant continuing treatment restriction.

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 '(6) 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 trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than twice. Therefore once a patient fails to meet the response criteria for the same PBS-subsidised biological agent on 2 occasions, they must change to the alternate agent if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular 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 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 chronic plaque psoriasis after 1 August 2006.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(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 the alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; and

(iii) patients have failed their most recent course of PBS-subsidised biological therapy and wish to trial a further course of treatment with the same agent [providing they have not failed that agent more than once] (Initial 2); and

(iv) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that 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 in the case of efalizumab and 12 weeks of therapy in the case of etanercept. Approval will be based on the criteria included in the relevant initial treatment restriction.

Grandfather patients.

Applications for patients who commenced treatment with efalizumab or etanercept prior to 10 November 2005 or 16 March 2006 respectively, 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 either 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, consisting of 24 weeks of continuous treatment in the case of efalizumab and 12 weeks of active treatment followed by a treatment-free period of at least 12 weeks in the case of etanercept. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing efalizumab, where the initial treatment course is for 16 weeks, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this 16 week treatment course. 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 efalizumab. Applications for continuing treatment with efalizumab must also be submitted to Medicare Australia prior to the completion of this initial 16 week course of therapy to ensure continuity of treatment for those patients who meet the continuation criterion and who wish to continue on treatment with efalizumab.

When prescribing etanercept, a PASI assessment must be conducted at the completion of the 12 week initial treatment course. This assessment, which will be used to determine eligibility for future treatment according to the criterion included in the relevant continuing treatment restriction, 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.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

As stated above, following the completion of a 16 week initial treatment course of efalizumab, to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with efalizumab. Patients are eligible to continue to receive continuous treatment with efalizumab in 24 week courses providing they continue to sustain a response.

Prescribers should ensure that applications for second and subsequent courses of efalizumab are submitted to Medicare Australia before patients complete their previous treatment course to ensure uninterrupted treatment.

At the completion of an initial 12 week treatment course of etanercept, to which an adequate response has been demonstrated, followed by a treatment-free period of at least 12 weeks, patients may qualify to receive continuing treatment with etanercept. Continuing treatment is available in the form of 12 weeks of active etanercept treatment followed by a treatment-free period of at least 12 weeks. Patients are eligible to receive continuing treatment with etanercept on this cyclical basis, for as long as they continue to sustain a response. Continuing applications must be submitted at least 12 weeks after cessation of the most recent course of etanercept treatment.

A PASI assessment must be conducted for each course of continuing treatment for each biological agent, according to the requirements set out in the relevant restriction. Assessment of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 1 month from the date that course was completed or treatment was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent.

**NOTE:**

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to the alternate agent within the same treatment Cycle without having to re-qualify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements. This also applies to patients who fail to achieve or sustain a response to the first PBS-subsidised biological agent approved and who wish to trial a further course of treatment with the same agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular drug on 2 occasions in the same Cycle.

Patients who commenced PBS-subsidised treatment with efalizumab prior to 1 August 2006 access these interchangeability arrangements in the same way as patients who have not. The response to treatment for these patients will be counted toward the allowable treatment failures under the interchangeability arrangements for the current Cycle.

PBS subsidy does not allow for patients to receive treatment with another biological agent during the required 12 week treatment-free period applying to patients who have demonstrated a response to their most recent course of etanercept. This means that patients who have demonstrated a response to a 12 week course of etanercept must have a biological therapy treatment-free period of at least 12 weeks, immediately following this course of treatment, before swapping to efalizumab. Patients who fail to respond to etanercept and who qualify and wish to try a course of efalizumab, or a further course of etanercept, may do so without having to have any treatment-free period.

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 agent being ceased.

(5) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment 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 subsequent response will be assessed according to this revised PASI score.

For new patients and patients commencing a new Cycle, the first baseline PASI assessment must be conducted, preferably while the patient is still receiving their most recent prior therapy, but no later than 1 month following cessation of such therapy, as outlined in the relevant restriction. This is not required for any subsequent PASI scores provided for these patients within the same Cycle, nor for patients who received initial PBS-subsidised therapy under a 'grandfather' restriction.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

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

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

**Progesterone**

Arrangements to prescribe this item should be made by medical practitioners with Medicare Australia, contact telephone number 1800 700 270.

**Somatropin (Recombinant human growth hormone)**

These guidelines may be obtained from the Department of Health and Ageing's internet site at http://www.health.gov.au/internet/wcms/publishing.nsf/Content/ pbs-hghguidelines-contents, or from:

Growth Hormone Program

Access and Systems Branch

Department of Health and Ageing

GPO Box 9848

CANBERRA ACT 2601

Contact telephone number (02) 6289 7274

# REPATRIATION PHARMACEUTICAL BENEFITS

***This Schedule is effective from 1 June 2007 and all previous issues are cancelled.***

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

# SUMMARY OF CHANGES

For 1 June 2007 there are no changes to the Repatriation Pharmaceutical Benefits Scheme listings.