Australian Government

Department of Health and Ageing

SCHEDULE OF PHARMACEUTICAL BENEFITS FOR APPROVED PHARMACISTS AND MEDICAL PRACTITIONERS

SUMMARY OF CHANGES

EFFECTIVE 1 MAY 2007 — 31 MAY 2007

PHARMACEUTICAL BENEFITS

This Schedule will take effect on 1 May 2007 and all previous issues are cancelled. New Schedules will take effect monthly on the first day of each month.

Internet

The Schedule of Pharmaceutical Benefits is also available on the Internet. The address of the Schedule is www.pbs.gov.au

Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 May 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)

2650L **Amino acid formula with vitamins and minerals without lysine and low in tryptophan**, Infant formula, powder 400 g (*XLYS, LOW TRY Analog*)

2646G **Amino acid formula with vitamins and minerals without lysine and low in tryptophan**, Powder 500 g (*XLYS, LOW TRY Maxamaid*)

9081Y **Etanercept**, Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*) [for the treatment of adult patients with active ankylosing spondylitis]

9082B **Etanercept**, Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*) [for the treatment of adult patients with active ankylosing spondylitis] **(Diff. Max. Rpts)**

9083C **Etanercept**, Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*) [for the treatment of adult patients with active psoriatic arthritis]

9084D **Etanercept**, Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*) [for the treatment of adult patients with active psoriatic arthritis] **(Diff. Max. Rpts)**

2863Q **Fluvastatin sodium**, Tablet 80 mg (fluvastatin) (prolonged release) (*Lescol XL*)

2979T **Glucose indicator—blood**, Electrode strips, 50 (*Accu-Chek Performa*)

2860M **Glucose indicator—blood**, Reagent strips, 50 (*Betachek G5*)

2695W **Hydroxocobalamin acetate**, Injection 1 mg (base) in 1 mL (*Goldshield Hydroxocobalamin*)

2845R **Perindopril with indapamide hemihydrate**, Tablet containing 5 mg perindopril arginine-1.25 mg indapamide hemihydrate (*Coversyl Plus 5mg/1.25mg*)

2857J **Trandolapril with verapamil hydrochloride**, Tablet 4 mg-240 mg (sustained release) (*Tarka 4/240*)

Additions - Brands

1377L *MX* — **Epirubicin hydrochloride**, Solution for injection 50 mg in 25 mL

8817C *MX* — **Epirubicin hydrochloride**, Solution for injection 100 mg in 50 mL

1760P *Roxithromycin-RL, RE* — **Roxithromycin**, Tablet 150 mg

8016X *Roxithromycin-RL, RE* — **Roxithromycin**, Tablet 300 mg

2013Y *Simvastatin Winthrop, SL* — **Simvastatin**, Tablet 5 mg

2011W *Simvastatin Winthrop, SL* — **Simvastatin**, Tablet 10 mg

2012X *Simvastatin Winthrop, SL* — **Simvastatin**, Tablet 20 mg

8173E *Simvastatin Winthrop, SL* — **Simvastatin**, Tablet 40 mg

8313M *Simvastatin Winthrop, SL* — **Simvastatin**, Tablet 80 mg

BIOEQUIVALENCE INDICATORS

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

8449Q **Perindopril with indapamide hemihydrate**, Tablet containing 4 mg perindopril erbumine-1.25 mg indapamide hemihydrate (*Coversyl Plus 4/1.25*)

2845R **Perindopril with indapamide hemihydrate**, Tablet containing 5 mg perindopril arginine-1.25 mg indapamide hemihydrate (*Coversyl Plus 5mg/1.25mg*)

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

8817C *Epirubicin Ebewe, IT* — **Epirubicin hydrochloride**, Solution for injection 100 mg in 50 mL

DELETIONS

Deletions - Items

1205K **Metoclopramide hydrochloride**, Syrup 5 mg per 5 mL, 100 mL (*Maxolon*)

5152E **Metoclopramide hydrochloride**, Syrup 5 mg per 5 mL, 100 mL (*Maxolon*) **(Dental)**

1124E **Sodium cromoglycate**, Solution for inhalation 20 mg in 2 mL ampoule (*Intal*)

Deletions - Brands

1891M *Muric 500/ 125, SL* — **Amoxycillin with clavulanic acid**, Tablet 500 mg-125 mg

5008N *Muric 500/ 125, SL* — **Amoxycillin with clavulanic acid**, Tablet 500 mg-125 mg **(Dental)**

8254K *Muric 875/ 125, SL* — **Amoxycillin with clavulanic acid**, Tablet 875 mg-125 mg

5006L *Muric 875/ 125, SL* — **Amoxycillin with clavulanic acid**, Tablet 875 mg-125 mg **(Dental)**

1299J *Diclofenac-BC, BG* — **Diclofenac sodium**, Tablet 25 mg (enteric coated)

5361E *Diclofenac-BC, BG* — **Diclofenac sodium**, Tablet 25 mg (enteric coated) **(Palliative Care)**

5364H *Diclofenac-BC, BG* — **Diclofenac sodium**, Tablet 25 mg (enteric coated) **(Palliative Care) (Diff. Max. Rpts)**

5076E *Diclofenac-BC, BG* — **Diclofenac sodium**, Tablet 25 mg (enteric coated) **(Dental)**

ALTERATIONS

Alterations - Notes

(see under 'NOTES' for full details)

Notes have been added in respect of the following:

Perindopril with Indapamide Hemihydrate

Alterations - Item Description

From:

8449Q **Perindopril erbumine with indapamide hemihydrate**, Tablet 4 mg-1.25 mg (*Coversyl Plus 4/1.25*)

To:

8449Q **Perindopril with indapamide hemihydrate**, Tablet containing 4 mg perindopril erbumine-1.25 mg indapamide hemihydrate (*Coversyl Plus 4/1.25*)

Alterations - Manufacturer's Code

		From	*To*
	All products previously listed under Aventis Pharma Pty Limited	AV	SW
	All products previously listed under Dakota Pharmaceuticals A Division of Sanofi-Synthelabo Australia Pty Limited	DK	AV
	All products previously listed under Hoechst Division of Aventis Pharma Pty Limited	HP	AV
	All products previously listed under Marion Division of Aventis Pharma Pty Limited	ML	AV
2781J	**Dexamethasone with framycetin sulfate and gramicidin**, Ear drops 500 micrograms-5 mg-50 micrograms per mL, 8 mL (*Otodex*)	QM	AV
8331L	**Omeprazole**, Tablet 20 mg (*Omeprazole Winthrop*)	SL	WA
8333N	**Omeprazole**, Tablet 20 mg (*Omeprazole Winthrop*) **(Diff. Max. Rpts)**	SL	WA
8539K	**Oxaliplatin**, Powder for I.V. infusion 50 mg (*Winthrop Oxaliplatin*)	SW	WA
8540L	**Oxaliplatin**, Powder for I.V. infusion 100 mg (*Winthrop Oxaliplatin*)	SW	WA
1944H	**Ramipril**, Tablet 1.25 mg (*Ramipril Sandoz*)	QM	SZ
1945J	**Ramipril**, Tablet 2.5 mg (*Ramipril Sandoz*)	QM	SZ
1946K	**Ramipril**, Tablet 5 mg (*Ramipril Sandoz*)	QM	SZ
8470T	**Ramipril**, Capsule 10 mg (*Ramipril Sandoz*)	QM	SZ

SECTION 100 - HIGHLY SPECIALISED DRUGS PROGRAM

ADDITIONS

Additions - Item

(see under 'RESTRICTIONS' for details of restriction text)

9607P **Apomorphine hydrochloride**, Injection 20 mg in 2 mL (*APO-go*)

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 Notices - 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:

2650L **Amino acid formula with vitamins and minerals without lysine and low in tryptophan**, Infant formula, powder 400 g (*XLYS, LOW TRY Analog*)

Restricted benefit

An infant or young child with proven glutaric aciduria type 1

2646G **Amino acid formula with vitamins and minerals without lysine and low in tryptophan**, Powder 500 g (*XLYS, LOW TRY Maxamaid*)

Restricted benefit

A child aged less than 7 years with proven glutaric aciduria type 1

9607P **Apomorphine hydrochloride**, Injection 20 mg in 2 mL (*APO-go*)

Authority required

Parkinson's disease in patients severely disabled by motor fluctuations which do not respond to other therapy

9081Y **Etanercept**, Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*)

Authority required

Initial 1 (new patients)
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

9082B **Etanercept**, Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (*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

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

Authority required

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

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

9084D **Etanercept**, Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (*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

2863Q **Fluvastatin sodium**, Tablet 80 mg (fluvastatin) (prolonged release) (*Lescol XL*)

Restricted benefit

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

2695W **Hydroxocobalamin acetate**, Injection 1 mg (base) in 1 mL (*Goldshield Hydroxocobalamin*)

Restricted benefit

Pernicious anaemia

Restricted benefit

Other proven vitamin B_{12} deficiencies

Restricted benefit

Prophylaxis after gastrectomy

2845R **Perindopril with indapamide hemihydrate**, Tablet containing 5 mg perindopril arginine-1.25 mg indapamide hemihydrate (*Coversyl Plus 5mg/1.25mg*)

Restricted benefit

Hypertension in patients who are not adequately controlled with either indapamide hemihydrate or perindopril monotherapy

2857J **Trandolapril with verapamil hydrochloride**, Tablet 4 mg-240 mg (sustained release) (*Tarka 4/240*)

Restricted benefit

Hypertension in a patient who is stabilised on treatment with trandolapril 4 mg and verapamil hydrochloride sustained release 240 mg

NOTES

Details of note text for new items and note alterations:

Etanercept

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

Hydroxocobalamin acetate

One injection of hydroxocobalamin 1 mg every three months provides appropriate maintenance therapy in vitamin B_{12} deficiencies.

8449Q **Perindopril with indapamide hemihydrate**, tablet containing 4 mg perindopril erbumine - 1.25 mg indapamide hemihydrate

2845R **Perindopril with indapamide hemihydrate**, tablet containing 5 mg perindopril arginine - 1.25 mg indapamide hemihydrate

Bioequivalence has been demonstrated between these two products.

REPATRIATION PHARMACEUTICAL BENEFITS

This Schedule will take effect on 1 May 2007 and all previous issues are cancelled.

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

SUMMARY OF CHANGES

ALTERATIONS

Alterations - Manufacturer's Code

		From	*To*
4237B	**Fexofenadine hydrochloride**, Tablet 60 mg (*Telfast*)	AV	SW
4238C	**Fexofenadine hydrochloride**, Tablet 120 mg (*Telfast 120*)	AV	SW
4036K	**Hydrocortisone with cinchocaine hydrochloride**, Ointment 5 mg-5 mg per g (0.5%-0.5%), 30 g (*Proctosedyl*)	AV	SW
4038M	**Hydrocortisone with cinchocaine hydrochloride**, Suppositories 5 mg-5 mg, 12 (*Proctosedyl*)	AV	SW
4072H	**Promethazine hydrochloride**, Tablet 10 mg (*Phenergan*)	AV	SW
4073J	**Promethazine hydrochloride**, Tablet 25 mg (*Phenergan*)	AV	SW
4443W	**Risedronate sodium**, Tablet 5 mg (*Actonel*)	AV	SW
4444X	**Risedronate sodium**, Tablet 35 mg (*Actonel Once-a-Week*)	AV	SW
4468E	**Sodium cromoglycate**, Nasal spray metered dose pump 20 mg per mL (2%), 26 mL (*Rynacrom*)	AV	SW
4043T	**Thiamine hydrochloride**, Tablet 100 mg (*Betamin*)	AV	SW
4522B	**Zopiclone**, Tablet 7.5 mg (*Imovane*)	AV	SW