Australian Government

Department of Health and Ageing

**SCHEDULE OF PHARMACEUTICAL BENEFITS FOR APPROVED PHARMACISTS AND MEDICAL PRACTITIONERS**

# SUMMARY OF CHANGES

**EFFECTIVE 1 NOVEMBER 2007**

# PHARMACEUTICAL BENEFITS

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 November 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 November 2007 and are included, where applicable, in prices published in the Schedule—

| | | |
|---|---|---|
| Dispensing Fees: | Ready-prepared | $5.44 |
| | Dangerous drug fee | $2.71 |
| | Extemporaneously-prepared | $7.48 |
| Additional Fees (for safety net prices): | Ready-prepared | $1.01 |
| | Extemporaneously-prepared | $1.40 |
| 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' below for items where a restriction applies)*

2250K **Amino acids—synthetic, formula**, Compound powder 400 g (*EleCare*)

9117W **Bortezomib**, Powder for injection 3.5 mg (solvent required) (*Velcade*)

9118X **Bortezomib**, Powder for injection 3.5 mg (solvent required) (*Velcade*) **(Diff. Max. Rpts)**

2263D **Glucose indicator—blood**, Electrode strips, 50 (*Optium Omega*)

9111M **Imatinib**, Tablet 100 mg (as mesylate) (*Glivec*)

9112N **Imatinib**, Tablet 400 mg (as mesylate) (*Glivec*)

9113P **Imatinib**, Tablet 100 mg (as mesylate) (*Glivec*) **(Diff. Restr)**

9114Q **Imatinib**, Tablet 400 mg (as mesylate) (*Glivec*) **(Diff. Restr)**

9115R **Imatinib**, Tablet 100 mg (as mesylate) (*Glivec*) **(Diff. Restr)**

9116T **Imatinib**, Tablet 400 mg (as mesylate) (*Glivec*) **(Diff. Restr)**

2248H **Tamarindus indica seed polysaccharide**, Eye drops 10 mg per mL (1%), 0.5 mL, 20 (*Visine Professional*)

2269K **Vancomycin**, Powder for injection 1 g (1,000,000 i.u.) vancomycin activity (*MX*)

2270L **Vancomycin**, Powder for injection 1 g (1,000,000 i.u.) vancomycin activity (*MX*) **(Diff. Max. Qty)**

5083M **Vancomycin**, Powder for injection 1 g (1,000,000 i.u.) vancomycin activity (*MX*) **(Dental)**

*Additions - Brands*

1784X *XF* — **Ceftriaxone**, Powder for injection 1 g

3058Y *Cephalexin-Lupin, XF* — **Cephalexin**, Capsule 250 mg

3317N *Cephalexin-Lupin, XF* — **Cephalexin**, Capsule 250 mg **(Dental)**

3119E *Cephalexin-Lupin, XF* — **Cephalexin**, Capsule 500 mg

3318P *Cephalexin-Lupin, XF* — **Cephalexin**, Capsule 500 mg **(Dental)**

8561N *Pharmacor Meloxicam 7.5, CR; Meloxicam Ranbaxy, RA; Meloxibell, BF* — **Meloxicam**, Tablet 7.5 mg

8562P *Pharmacor Meloxicam 15, CR; Meloxicam Ranbaxy, RA; Meloxibell, BF* — **Meloxicam**, Tablet 15 mg

8513C *GenRx Mirtazapine, GX; Chem mart Mirtazapine, CH; Terry White Chemists Mirtazapine, TW* — **Mirtazapine**, Tablet 30 mg

8449Q *Perindo Combi 4/1.25,* AF — **Perindopril with indapamide hemihydrate**, Tablet containing 4 mg perindopril erbumine-1.25 mg indapamide hemihydrate

2834E *Vastoran, RA* — **Pravastatin sodium**, Tablet 20 mg

8197K *Vastoran, RA* — **Pravastatin sodium**, Tablet 40 mg

## DELETIONS

*Deletion - Brand*

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

## ALTERATIONS

*Alterations - Brand Names*

*From:*
3130R **Vancomycin,** Powder for injection 500 mg (500,000 i.u.) vancomycin activity (Vancocin)
*To:*
3130R **Vancomycin,** Powder for injection 500 mg (500,000 i.u.) vancomycin activity (Vancocin CP)

*From:*
3131T **Vancomycin,** Powder for injection 500 mg (500,000 i.u.) vancomycin activity **(Diff. Max. Qty)** (Vancocin)
*To:*
3131T **Vancomycin,** Powder for injection 500 mg (500,000 i.u.) vancomycin activity **(Diff. Max. Qty)** (Vancocin CP)

*From:*
3323X **Vancomycin,** Powder for injection 500 mg (500,000 i.u.) vancomycin activity **(Dental)** (Vancocin)
*To:*
3323X **Vancomycin,** Powder for injection 500 mg (500,000 i.u.) vancomycin activity **(Dental)** (Vancocin CP)

*Alterations - Manufacturer Codes*

| | | *From* | *To* |
|---|---|---|---|
| 2157M | **Aluminium hydroxide with magnesium hydroxide**, Oral suspension 200 mg-200 mg per 5 mL, 500 mL (*Mylanta P*) | PC | JT |
| 2576N | **Aluminium hydroxide with magnesium hydroxide**, Tablet 200 mg-200 mg (*Mylanta P*) | PC | JT |
| 1889K | **Amoxycillin**, Capsule 500 mg (*Moxacin*) | CS | AS |
| 3300Q | **Amoxycillin**, Capsule 500 mg (*Moxacin*) **(Dental)** | CS | AS |
| 8864M | **Coal tar - prepared**, Gel 10 mg per g (1%), 100 mL (*Exorex*) | EP | GM |
| 1524F | **Flucloxacillin**, Powder for injection 500 mg (*Flopen*) | CS | LN |
| 5094D | **Flucloxacillin**, Powder for injection 500 mg (*Flopen*) **(Dental)** | CS | LN |
| 1525G | **Flucloxacillin**, Powder for injection 1 g (*Flopen*) | CS | LN |
| 5095E | **Flucloxacillin**, Powder for injection 1 g (*Flopen*) **(Dental)** | CS | LN |
| 1526H | **Flucloxacillin**, Capsule 250 mg (*Flopen*) | CS | AS |
| 5090X | **Flucloxacillin**, Capsule 250 mg (*Flopen*) **(Dental)** | CS | AS |
| 1527J | **Flucloxacillin**, Capsule 500 mg (*Flopen*) | CS | AS |
| 5091Y | **Flucloxacillin**, Capsule 500 mg (*Flopen*) **(Dental)** | CS | AS |
| 1529L | **Flucloxacillin**, Powder for syrup 250 mg per 5 mL, 100 mL (*Flopen*) | CS | AS |
| 5093C | **Flucloxacillin**, Powder for syrup 250 mg per 5 mL, 100 mL (*Flopen*) **(Dental)** | CS | AS |
| 9024Y | **Ketoconazole**, Cream 20 mg per g (2%), 30 g (*Nizoral 2% Cream*) | JC | JT |
| 9025B | **Ketoconazole**, Shampoo 10 mg per g (1%), 100 mL (*Nizoral 1%*) | JC | JT |
| 1574W | **Ketoconazole**, Shampoo 20 mg per g (2%), 60 mL (*Nizoral 2%*) | JC | JT |
| 1571Q | **Loperamide hydrochloride**, Capsule 2 mg (*Imodium*) | JC | JT |
| 9031H | **Miconazole**, Tincture 20 mg per mL (2%), 30 mL (*Daktarin*) | JC | JT |
| 9026C | **Miconazole nitrate**, Cream 20 mg per g (2%), 15 g (*Daktarin*) | JC | JT |
| 9027D | **Miconazole nitrate**, Cream 20 mg per g (2%), 30 g (*Daktarin*) | JC | JT |
| 9028E | **Miconazole nitrate**, Cream 20 mg per g (2%), 70 g (*Daktarin*) | JC | JT |
| 9029F | **Miconazole nitrate**, Powder 20 mg per g (2%), 30 g (*Daktarin*) | JC | JT |
| 9030G | **Miconazole nitrate**, Lotion 20 mg per mL (2%), 30 g (*Daktarin*) | JC | JT |
| 3054R | **Permethrin**, Cream 50 mg per g (5%), 30 g (*Lyclear*) | PC | JT |
| 1789E | **Phenoxymethylpenicillin**, Capsule 250 mg (*LPV*) | CS | AS |
| 2965C | **Phenoxymethylpenicillin**, Capsule 500 mg (*LPV*) | CS | AS |

| | | | |
|---|---|---|---|
| 1705R | **Phenoxymethylpenicillin**, Capsule 250 mg (*LPV*) **(Diff. Max. Rpts)** | CS | AS |
| 3363B | **Phenoxymethylpenicillin**, Capsule 250 mg (*LPV*) **(Dental)** | CS | AS |
| 3364C | **Phenoxymethylpenicillin**, Capsule 500 mg (*LPV*) **(Dental)** | CS | AS |
| 2091C | **Sorbitol with sodium citrate and sodium lauryl sulfoacetate**, Enemas 3.125 g-450 mg-45 mg in 5 mL, 12 (*Microlax*) | PH | JT |
| 5331N | **Sorbitol with sodium citrate and sodium lauryl sulfoacetate**, Enemas 3.125 g-450 mg-45 mg in 5 mL, 12 (*Microlax*) **(Palliative Care)** | PH | JT |
| 5332P | **Sorbitol with sodium citrate and sodium lauryl sulfoacetate**, Enemas 3.125 g-450 mg-45 mg in 5 mL, 12 (*Microlax*) **(Palliative Care) (Diff. Max. Rpts)** | PH | JT |

*Alterations - Maximum Quantity*

| | | *From* | *To* |
|---|---|---|---|
| 3138E | **Clindamycin**, Capsule 150 mg (*Cleocin, Dalacin C*) | 25 | 24 |
| 5057E | **Clindamycin**, Capsule 150 mg (*Cleocin, Dalacin C*) **(Dental)** | 25 | 24 |

*Alterations - Restrictions*

*(see under 'RESTRICTIONS' below for full details)*

| | |
|---|---|
| 8071T | **Docetaxel**, Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL and 1 single use vial solvent 1.5 mL (*Taxotere*) |
| 8074Y | **Docetaxel**, Injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL and 1 single use vial solvent 6 mL (*Taxotere*) |
| 9000Q | **Efalizumab**, Injection set containing 4 vials powder for injection 125 mg and 4 pre-filled syringes diluent 1.3 mL (*Raptiva*) |
| 9001R | **Efalizumab**, Injection set containing 4 vials powder for injection 125 mg and 4 pre-filled syringes diluent 1.3 mL (*Raptiva*) **(Diff. Max. Rpts)** |
| 9037P | **Etanercept**, Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*) |
| 9038Q | **Etanercept**, Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*) |
| 9091L | **Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*) |
| 8283Y | **Milk powder—lactose free formula**, Infant formula powder 900 g (*S-26 LF*) |
| 2349P | **Milk powder—lactose free formula**, Lactose-predigested powder infant formula 900 g (*Karicare De-Lact*) |
| 2357C | **Milk powder—lactose modified**, Lactose-predigested powder 900 g (*Digestelact*) |
| 2313R | **Minoxidil**, Tablet 10 mg (*Loniten*) |
| 8449Q | **Perindopril with indapamide hemihydrate**, Tablet containing 4 mg perindopril erbumine-1.25 mg indapamide hemihydrate (*Chem mart Perindopril/ Indapamide 4/1.25, GenRx Perindopril/ Indapamide 4/1.25, Perindo Combi 4/1.25, Terry White Chemists Perindopril/ Indapamide 4/1.25*) |
| 2845R | **Perindopril with indapamide hemihydrate**, Tablet containing 5 mg perindopril arginine-1.25 mg indapamide hemihydrate (*Coversyl Plus 5mg/1.25mg*) |
| 3036T | **Strontium ranelate**, Sachet containing granules for oral suspension 2 g (*Protos 2 g*) |

## SECTION 100 - HIGHLY SPECIALISED DRUGS PROGRAM

### ADDITIONS

*Additions - Items*

*(see under 'RESTRICTIONS' below for full details)*

9614B **Atazanavir**, Capsule 300 mg (as sulfate) (*Reyataz*)

9615C **Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*)

### ALTERATIONS

*Alterations - Item Descriptions*

*From:*
6451M **Atazanavir sulfate**, Capsule 150 mg (base) (*Reyataz*)
*To:*
6451M **Atazanavir**, Capsule 150 mg (as sulfate) (*Reyataz*)
*From:*
6452N **Atazanavir sulfate**, Capsule 200 mg (base) (*Reyataz*)
*To:*
6452N **Atazanavir**, Capsule 200 mg (as sulfate) (*Reyataz*)

## SECTION 100 - SPECIAL AUTHORITY PROGRAM

### DELETIONS

*Deletions - Items*

6440Y **Imatinib mesylate**, Tablet 100 mg (base) (*Glivec*)

6441B **Imatinib mesylate**, Tablet 400 mg (base) (*Glivec*)
6444E **Imatinib mesylate**, Tablet 100 mg (base) (*Glivec*)
6445F **Imatinib mesylate**, Tablet 400 mg (base) (*Glivec*)
6446G **Imatinib mesylate**, Tablet 100 mg (base) (*Glivec*)

6447H **Imatinib mesylate**, Tablet 400 mg (base) (*Glivec*)

### ALTERATIONS

*Alteration - Restriction*

*(see under 'RESTRICTIONS' below for full details)*

6497Y **Trastuzumab**, Powder for I.V. infusion 150 mg (*Herceptin*)

## ADVANCE NOTICES

*Advance Notices - Deletion of Items*

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

Items discontinued by the manufacturer -

| | |
|---|---|
| 8012Q | **Oestradiol**, Transdermal patches 3.28 mg (releasing approximately 37.5 micrograms per 24 hours), 8 (*Menorest 37.5*) |
| 8013R | **Oestradiol**, Transdermal patches 4.33 mg (releasing approximately 50 micrograms per 24 hours), 8 (*Menorest 50*) |
| 8014T | **Oestradiol**, Transdermal patches 6.57 mg (releasing approximately 75 micrograms per 24 hours), 8 (*Menorest 75*) |
| 8041F | **Oestradiol**, Transdermal patches 8.66 mg (releasing approximately 100 micrograms per 24 hours), 8 (*Menorest 100*) |
| 2163W | **Thioridazine hydrochloride**, Tablet 10 mg (*Aldazine 10*) |
| 2359E | **Thioridazine hydrochloride**, Tablet 25 mg (*Aldazine 25*) |
| 2164X | **Thioridazine hydrochloride**, Tablet 50 mg (*Aldazine 50*) |
| 2165Y | **Thioridazine hydrochloride**, Tablet 100 mg (*Aldazine 100*) |

# RESTRICTIONS

## The text of restrictions mentioned above:

2250K **Amino acids—synthetic, formula**, Compound powder 400 g (*EleCare*)

**Authority required**

Initial treatment for up to 3 months, by a clinical immunologist, suitably qualified allergist or gastroenterologist in a patient 18 years of age or less with eosinophilic oesophagitis who requires an amino acid based formula as a component of a dietary elimination programme. Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and

(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and

(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority

**Authority required**

Continuing treatment by a clinical immunologist, suitably qualified allergist or gastroenterologist in a patient 18 years of age or less with eosinophilic oesophagitis who has responded to an initial course of PBS-subsidised treatment. Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment

**NOTE:**

Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.

9614B **Atazanavir**, Capsule 300 mg (as sulfate) (*Reyataz*)

**Private hospital authority required**

Treatment, in combination with 2 or more other antiretroviral drugs, of HIV infection in patients with

(a) CD4 cell counts of less than 500 per cubic millimetre

(b) viral load of greater than 10,000 copies per mL

**Bortezomib**

**NOTE:**

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

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

Applications for authority to prescribe bortezomib should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

9117W **Bortezomib**, Powder for injection 3.5 mg (solvent required) ( *Velcade*)

**Authority required**

Initial PBS-subsidised treatment, as monotherapy or in combination with a corticosteroid, of multiple myeloma in a patient with a WHO performance status of 2 or less, who has progressive disease, who has received at least 1 prior therapy (other than thalidomide), who has undergone or is ineligible for a primary stem cell transplant and who has experienced treatment failure after a trial of at least four (4) weeks of thalidomide at a dose of at least 100 mg daily.

If the dosing requirement for thalidomide cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Thalidomide treatment failure is defined as:
(1) confirmed disease progression during or within 6 months of discontinuing thalidomide treatment; or
(2) severe intolerance or toxicity unresponsive to clinically appropriate dose adjustment.

Progressive disease is defined as at least 1 of the following:
(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
(c) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
(d) an increase in the size or number of lytic bone lesions (not including compression fractures); or
(e) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
(f) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Severe intolerance due to thalidomide is defined as unacceptable somnolence or sedation interfering with activities of daily living.

Toxicity from thalidomide is defined as peripheral neuropathy (Grade 2 or greater, interfering with function), drug-related seizures, serious Grade 3 or Grade 4 drug-related dermatological reactions, such as Stevens-Johnson Syndrome, or other Grade 3 or 4 toxicity.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Multiple Myeloma Authority Application - Supporting Information Form,
which includes details of prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; the patient's WHO performance status; details of thalidomide treatment failure; details of the basis of the diagnosis of progressive disease; and nomination of which disease activity parameters will be used to assess response.

To enable confirmation by Medicare Australia of response, current diagnostic reports of the following are required:
(a) the level of serum monoclonal protein; and
(b) if Bence-Jones proteinuria is present, the results of 24-hour urinary light chain M protein excretion.

If neither serum M protein or urine Bence-Jones protein are present in measurable quantities, additional diagnostic reports are required, including:
(c) bone marrow aspirate and trephine; and
(d) if present, the size and location of lytic bone lesions (not including compression fractures); or
(e) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
(f) if present, the level of hypercalcaemia, corrected for albumin concentration; or
(g) if present, the serum free light chain levels.

As these parameters will be used to determine response, results for (a) and (b) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, (c) must be provided and if relevant (d), (e) or (f). Where the prescriber plans to assess response in patients with oligo-secretory

or non-secretory multiple myeloma with free light chain assays, (g) must be provided. Where 1 or more results cannot be provided, the application must state the reason(s) these cannot be provided; and
(3) duration of thalidomide and daily dose prescribed; and
(4) a signed patient acknowledgment

**Authority required**

Continuing PBS-subsidised treatment as monotherapy or in combination with a corticosteroid, of multiple myeloma in a patient who has previously received 4 treatment cycles of bortezomib and who, at the time of application, has demonstrated at least a partial response to bortezomib.

If serum M protein and urine Bence-Jones protein levels are measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as:
(a) at least a 50% reduction in the level of serum M protein (monoclonal protein); or
(b) at least a 90% reduction in 24-hour urinary light chain M protein excretion or to less than 200 mg per 24 hours.

If serum M protein and urine Bence-Jones protein levels are unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as:
(c) at least a 50% reduction in the difference between involved and uninvolved serum free light chain (FLC) levels.

If serum M protein and urine Bence-Jones protein and serum FLC are unmeasurable/unavailable, partial response compared with baseline is defined as:
(d) at least a 50% reduction in bone marrow plasma cells; or
(e) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L; or
(f) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or
(g) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. MRI or CT-Scan).

For the purpose of assessing eligibility for continuing PBS-subsidised bortezomib treatment beyond 4 cycles, the patient must have achieved at least a partial response at the completion of cycle 4. The results of the response assessment must be included in a written application to Medicare Australia for further treatment. Where a response assessment is not submitted to Medicare Australia prior to cycle 5, patients will be deemed to have failed to respond to treatment with bortezomib. Continuing PBS-subsidised supply will not be approved if there is a gap of more than 6 months between the initial application and subsequent applications.

The same parameters provided for the diagnosis of progressive disease are to be used to demonstrate at least a partial response to treatment.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Multiple Myeloma Authority Application - Supporting Information Form; and
(3) diagnostic reports demonstrating the patient has achieved at least a partial response.

Diagnostic reports must be no more than 1 month old at the time of application.

Patients who fail to demonstrate at least a partial response after 8 cycles will not be eligible to receive further PBS-subsidised treatment with bortezomib.

No more than 2 cycles of treatment beyond the cycle at which a confirmed complete response was first achieved will be authorised. Confirmation requires 2 determinations a minimum of 6 weeks apart

9118X **Bortezomib**, Powder for injection 3.5 mg (solvent required) ( *Velcade*)

**Authority required**

Continuing PBS-subsidised treatment, as monotherapy or in combination with a corticosteroid, of multiple myeloma in a patient who has previously received 8 treatment cycles with bortezomib and who, at the time of application, has demonstrated at least a partial response to bortezomib but who has not received 2 treatment cycles after first achieving a confirmed complete response.

If serum M protein and urine Bence-Jones protein levels are measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as:
(a) at least a 50% reduction in the level of serum M protein (monoclonal protein); or
(b) at least a 90% reduction in 24-hour urinary light chain M protein excretion or to less than 200 mg per 24 hours.

If serum M protein and urine Bence-Jones protein levels are unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as:
(c) the difference between involved and uninvolved serum free light chain (FLC) levels, with at least a 50% reduction in this value.

If serum M protein and urine Bence-Jones protein levels and serum FLC are unmeasurable/unavailable, partial response compared with baseline is defined as:
(d) at least a 50% reduction in bone marrow plasma cells; or
(e) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L; or
(f) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or
(g) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. MRI or CT-Scan).

The same parameters provided for the diagnosis of progressive disease are to be used to demonstrate at least a partial response to treatment.

Diagnostic reports must be within 1 month of the date of application.

For the purpose of assessing eligibility for continuing PBS-subsidised bortezomib treatment beyond 8 cycles, the patient must have achieved at least a partial response at the completion of cycle 8. The results of the response assessment must be included in a written application to Medicare Australia for further treatment. Where a response assessment is not submitted to Medicare Australia prior to cycle 9, patients will be deemed to have failed to respond to treatment with bortezomib. Continuing PBS-subsidised supply will not be approved if there is a gap of more than 10 months between the initial application and an application following completion of 8 treatment cycles.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Multiple Myeloma Authority Application - Supporting Information Form; and
(3) diagnostic reports demonstrating the patient has achieved at least a partial response.

No more than 2 cycles of treatment beyond the cycle at which the complete response was first achieved will be authorised. Confirmation requires 2 determinations a minimum of 6 weeks apart.

Applications for PBS-subsidised treatment with bortezomib that extends beyond 11 cycles will not be approved

**Authority required**

Initial PBS-subsidised treatment of multiple myeloma in patients receiving treatment with bortezomib prior to 1 November 2007.

Patients who fail to demonstrate at least a partial response after 4 cycles will not be eligible to receive further PBS-subsidised treatment with bortezomib.

Diagnostic reports demonstrating at least a partial response must be within 1 month of the date of application.

Patients may qualify for PBS-subsidised treatment under this restriction for a maximum of 3 cycles. To receive further treatment the patient must qualify under the continuing treatment criteria.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Multiple Myeloma Authority Application - Supporting Information Form; and
(3) a signed patient acknowledgment; and
(4) details including relevant reports of the basis of the diagnosis of progressive disease and nomination of which disease activity parameters will be used to assess response; and

(5) if relevant, details including relevant reports for patients who have demonstrated a partial response and who have received 4 or more cycles

8071T **Docetaxel**, Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL and 1 single use vial solvent 1.5 mL (*Taxotere*)

8074Y **Docetaxel**, Injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL and 1 single use vial solvent 6 mL (*Taxotere*)

**Authority required**

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

**Authority required**

Advanced breast cancer after failure of prior therapy which includes an anthracycline

**Authority required**

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

**Authority required**

Locally advanced or metastatic non-small cell lung cancer

**Authority required**

Treatment of HER2 positive early breast cancer in combination with trastuzumab

**Authority required**

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

**Authority required**

Treatment of androgen independent (hormone refractory) metastatic carcinoma of the prostate in a patient with a Karnofsky performance-status score of at least 60%, where the patient was receiving prior treatment with other chemotherapy for androgen independent (hormone refractory) metastatic carcinoma of the prostate at 1 November 2007. Docetaxel must be administered in three weekly cycles

**NOTE:**

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

**Efalizumab**

**NOTE:**

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

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

Applications for authority to prescribe efalizumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs
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**NOTE:**

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 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.

**NOTE:**

No applications for increased repeats will be authorised.

9000Q **Efalizumab**, Injection set containing 4 vials powder for injection 125 mg and 4 pre-filled syringes diluent 1.3 mL ( *Raptiva*)

**Authority required**

Initial treatment [Initial 1, Whole body (New patients — No prior biological agent)]
Initial treatment as systemic monotherapy (other than methotrexate) 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 10 November 2005, 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 16 weeks of treatment with efalizumab will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the authority 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). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment,

which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with efalizumab. Applications for continuing treatment should be made prior to the completion of this course of treatment to ensure continuity of treatment for those patients who meet the continuation criterion

**Authority required**

Initial or re-Treatment [Initial 2, Whole body (Received prior biological agent under PBS)]
Treatment as systemic monotherapy (other than methotrexate) 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 efalizumab 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 efalizumab treatment within this Treatment Cycle and who wish to re-commence efalizumab 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 efalizumab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

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

Where fewer than 3 repeats are requested at the time of the authority 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). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this 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 efalizumab. Applications for continuing treatment should be made prior to the completion of this course of treatment to ensure continuity of treatment for those patients who meet the continuation criterion.

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 (other than methotrexate) 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 10 November 2005, 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 16 weeks of treatment with efalizumab will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the authority 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). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with efalizumab. Applications for continuing treatment should be made prior to the completion of this course of treatment to ensure continuity of treatment for those patients who meet the continuation criterion.

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 (other than methotrexate) 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 efalizumab 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 efalizumab treatment within this Treatment Cycle and who wish to re-commence efalizumab 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 efalizumab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

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

Where fewer than 3 repeats are requested at the time of the authority 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). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

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

patient will be deemed to have failed to respond to treatment with efalizumab. Applications for continuing treatment should be made prior to the completion of this course of treatment to ensure continuity of treatment for those patients who meet the continuation criterion.

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

9001R **Efalizumab**, Injection set containing 4 vials powder for injection 125 mg and 4 pre-filled syringes diluent 1.3 mL (*Raptiva*)

**Authority required**

Initial treatment [Initial 3, Whole body (Grandfather patients)]
Initial PBS-subsidised supply for continuing treatment as systemic monotherapy (other than methotrexate) 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 efalizumab prior to 10 November 2005; and
(b) had a Psoriasis Area and Severity Index (PASI) score of greater than 15 prior to commencing treatment with efalizumab; 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 efalizumab (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 efalizumab 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 24 weeks of treatment with efalizumab will be authorised under this restriction.

Where fewer than 5 repeats are requested at the time of 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).

A PASI assessment of the patient's response to this initial PBS-subsidised course of therapy must be conducted within 4 weeks prior to completion of this 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 efalizumab. Applications for continuing treatment should be made prior to the completion of this course of treatment in order to ensure continuity of treatment for those patients who meet the continuation criterion included in the restriction for continuing PBS-subsidised treatment with efalizumab.

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 (other than methotrexate) 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 efalizumab; and
(c) who have demonstrated an adequate response to their most recent course of treatment with efalizumab.

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 efalizumab 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 treatment with efalizumab.

A maximum of 24 weeks of treatment with efalizumab will be authorised under this restriction.

Where fewer than 5 repeats are requested at the time of the authority 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).

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. 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 efalizumab. Applications for further continuing treatment should be made prior to the completion of this treatment course, to ensure continuity of treatment for those patients who meet the continuation criterion included in the restriction for continuing PBS-subsidised treatment with efalizumab.

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 (other than methotrexate) 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 efalizumab prior to 10 November 2005; and
(b) whose disease, prior to treatment with efalizumab, 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 efalizumab (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 efalizumab 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 efalizumab treatment.

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

A maximum of 24 weeks of treatment with efalizumab will be authorised under this restriction.

Where fewer than 5 repeats are requested at the time of 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).

A PASI assessment of the patient's response to this initial PBS-subsidised course of therapy must be conducted within 4 weeks prior to completion of this 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 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 efalizumab. Applications for continuing treatment should be made prior to the completion of this course of treatment in order to ensure continuity of treatment for those patients who meet the continuation criterion included in the restriction for continuing PBS-subsidised treatment with efalizumab.

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 (other than methotrexate) 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 efalizumab; and
(c) who have demonstrated an adequate response to their most recent course of treatment with efalizumab.

An adequate response to efalizumab 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 efalizumab 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 efalizumab 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 treatment with efalizumab.

A maximum of 24 weeks of treatment with efalizumab will be authorised under this restriction.

Where fewer than 5 repeats are requested at the time of the authority 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).

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. 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 efalizumab. Applications for further continuing treatment should be made prior to the completion of this treatment course, to ensure continuity of treatment for those patients who meet the continuation criterion included in the restriction for continuing PBS-subsidised treatment with efalizumab.

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

**Etanercept**

**NOTE:**

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

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.

9615C **Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*)

**Public and private hospital authority required**

Continuing PBS-subsidised treatment by a rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of severe active polyarticular course juvenile chronic arthritis in patients 18 years or older who have demonstrated an adequate response to treatment with etanercept as manifested by:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; OR

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; OR

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

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

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

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 the joint assessment must be provided.

Only 6 months of treatment per application will be approved. 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.

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.

Withdrawal of treatment with etanercept should be considered in patients who have achieved and sustained complete remission of disease for 12 months. Subsequent applications for PBS-subsidised re-treatment with etanercept will be subject to the authority conditions applying to initial treatment and will not be authorised within 12 months of the date on which treatment with etanercept 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.

Where a patient with severe active polyarticular course juvenile chronic arthritis continues treatment with etanercept and is 18 years or older, etanercept 50 mg may be prescribed

**Etanercept** *(the following Notes apply to codes: 9037P, 9038Q, 9091L)*

**NOTE:**

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 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.

**NOTE:**

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

9037P **Etanercept**, Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*)

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

9038Q **Etanercept**, Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*)

**Authority required**

Initial treatment [Initial 1, Whole body (New patients — No prior biological agent)]
Initial treatment as systemic monotherapy (other than methotrexate) 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 (other than methotrexate) 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 (other than methotrexate) 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 (other than methotrexate) 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 (other than methotrexate) 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 (other than methotrexate) 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 (other than methotrexate) 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 (other than methotrexate) 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

**Imatinib**

**NOTE:**

Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 700 270.

Written applications for authority to prescribe imatinib mesylate should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**NOTE:**

Imatinib mesylate is not PBS-subsidised for the treatment of patients with resectable malignant gastrointestinal stromal tumours.

**Imatinib** *(the following Note applies to codes: 9111M, 9112N)*

**NOTE:**

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

9111M **Imatinib**, Tablet 100 mg (as mesylate) (*Glivec*)
9112N **Imatinib**, Tablet 400 mg (as mesylate) (*Glivec*)

**Authority required**

Initial PBS-subsidised treatment, for up to 3 months, of adult patients with a metastatic or unresectable malignant gastrointestinal stromal tumour which has been histologically confirmed by the detection of CD117 on immunohistochemical staining.

Patients who have not previously been treated with imatinib mesylate for a metastatic or unresectable malignant gastrointestinal stromal tumour must commence treatment at a dose not exceeding 400 mg per day for at least 3 months. Authority prescriptions for a higher dose will not be approved during this initial 3 month treatment period.

Patients who have previously been treated with non-PBS-subsidised imatinib mesylate for a metastatic or unresectable malignant gastrointestinal stromal tumour are eligible to receive up to 3 months treatment at a dose of up to 600 mg per day.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in the Treatment of Gastrointestinal Stromal Tumour - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a copy of a pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining; and

(ii) a copy of the most recent (within 2 months of the application) computed tomography (CT) scan, magnetic resonance imaging (MRI) or ultrasound assessment of the tumour(s), including whether or not there is evidence of metastatic disease; and

(iii) where the application for authority to prescribe is being sought on the basis of an unresectable tumour, written evidence in support of that claim must be provided; and

(iv) for patients who commenced treatment with imatinib mesylate for a metastatic or unresectable malignant gastrointestinal stromal tumour prior to 1 December 2004, the date on which therapy with imatinib mesylate was commenced

**Authority required**

Continuing PBS-subsidised treatment, at a dose of up to 600 mg per day, of adult patients with a metastatic or unresectable malignant gastrointestinal stromal tumour who have previously been issued with an authority prescription for this drug.

Applications for continuing treatment may be made by telephone (1800 700 270, hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**NOTE:**

Patients who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

**Imatinib** *(the following Note applies to codes: 9113P, 9114Q, 9115R, 9116T)*

**NOTE:**

No applications for increased repeats will be authorised.

9113P **Imatinib**, Tablet 100 mg (as mesylate) (*Glivec*)
9114Q **Imatinib**, Tablet 400 mg (as mesylate) (*Glivec*)

**Authority required**

Initial treatment of patients in the chronic phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase, and who have a primary diagnosis of chronic myeloid leukaemia.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy from the date the first application for initial treatment was approved.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in the Treatment of Chronic Myeloid Leukaemia - Supporting Information form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the bcr-abl transcript in either peripheral blood or bone marrow; and

(4) a copy of a signed patient acknowledgement form indicating that the patient understands and acknowledges that PBS-subsidised treatment with imatinib mesylate for the chronic phase of chronic myeloid leukaemia will cease if subsequent testing demonstrates that:

(i) the patient has failed to achieve a major cytogenetic response within the initial 18 months of treatment [see Note defining major cytogenetic response]; or

(ii) the patient has failed to sustain a major cytogenetic response for 12 months from the date of the last pathology report that indicated that a major cytogenetic response had been achieved [see Note defining major cytogenetic response]

**NOTE:**

Imatinib mesylate in the chronic phase of chronic myeloid leukaemia will only be subsidised for patients who are not receiving concomitant PBS-subsidised interferon alfa therapy.

Patients should be commenced on a dose of imatinib mesylate of 400 mg (base) daily and maintained on a minimum dose of imatinib mesylate of 400 mg (base) daily. Prescribing of lower doses should be carefully considered. Continuing therapy is dependent on patients demonstrating a response to imatinib

mesylate therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter, irrespective of the daily imatinib mesylate dose received.

**Authority required**

Continuing treatment of patients who have received initial treatment with imatinib mesylate as a pharmaceutical benefit for the chronic phase of chronic myeloid leukaemia and who have demonstrated either a major cytogenetic response or less than 1% bcr-abl level in the blood in the preceding 12 months.

Applications for authorisation must be in writing and must include:(1) a completed authority prescription form; and(2) demonstration of continued response to treatment as evidenced by either:(a) major cytogenetic response [see Note explaining requirements]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided; or(b) a peripheral blood level of bcr-abl of less than 1% on the international scale [see Note explaining requirements]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided

**NOTE:**

Definitions of response.

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.

A peripheral blood bcr-abl level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

Authority approval requirements.

For the purposes of assessing response to PBS-subsidised treatment with imatinib mesylate, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of bcr-abl transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with bcr-abl specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted as follows:

(i) between 10 and 12 months of the commencement of treatment with imatinib mesylate, at which time patients in whom a major cytogenetic response or peripheral blood bcr-abl level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and

(ii) within 18 months of the commencement of treatment with imatinib mesylate, in patients who have failed to demonstrate a major cytogenetic response or peripheral blood bcr-abl level of less than 1% at between 10 and 12 months (patients in whom a major cytogenetic response or peripheral blood bcr-abl level of less than 1% is demonstrable by 18 months may also receive authorisation for a further 12 months of treatment); and

(iii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood bcr-abl level of less than 1% has been sustained.

For each authority application where eligibility for continuing PBS-subsidised treatment is to be demonstrated, a copy of the cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or a copy of the quantitative PCR indicating the relative level of bcr-abl transcript in the peripheral blood using the international scale, must be submitted as described in (i) to (iii) above. For bone marrow analyses, where the standard karyotyping conducted at the time of application is not informative, a copy of a cytogenetic analysis conducted on the bone marrow using FISH with bcr-abl specific probe must be submitted with the authority application. A copy of the non-informative standard karyotype analysis must be included with the authority application.

Where a patient has previously received PBS-subsidised treatment with imatinib mesylate, no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the criteria for continuing treatment.

9115R **Imatinib**, Tablet 100 mg (as mesylate) (*Glivec*)
9116T **Imatinib**, Tablet 400 mg (as mesylate) (*Glivec*)

**Authority required**

Treatment of patients in the accelerated phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase, and who have a primary diagnosis of chronic myeloid leukaemia. Progress to the accelerated phase is defined by the presence of 1 or more of the following:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%; or

(3) Peripheral basophils greater than or equal to 20%; or

(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

Applications for authorisation must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in the Treatment of Chronic Myeloid Leukaemia - Supporting Information form, stating which of the above criteria are satisfied by the patient; and

(c) a copy of the confirming pathology report from an Approved Pathology Authority in the case of criteria (1), (2), (3) and (5) above, or details of the dates of assessments in the case of progressive splenomegaly

**Authority required**

Treatment of patients in the blast phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase, and who have a primary diagnosis of chronic myeloid leukaemia. Progress to myeloid blast crisis is defined as either:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or

(2) Extramedullary involvement other than spleen and liver.

Applications for authorisation must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in the Treatment of Chronic Myeloid Leukaemia - Supporting Information form, stating which of the above criteria are satisfied by the patient; and

(c) a copy of the confirming pathology report from an Approved Pathology Authority in the case of criterion (1) above, or details of the date of assessment in the case of extramedullary involvement

**Authority required**

Continuing treatment of patients with chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase, where the patient has previously received PBS-subsidised treatment with imatinib mesylate of:

(a) the accelerated phase of chronic myeloid leukaemia; or

(b) the blast phase of chronic myeloid leukaemia

**Milk powder — lactose free formula** *(the following Note applies to codes: 8283Y, 2349P)*

**NOTE:**

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

8283Y **Milk powder—lactose free formula**, Infant formula powder 900 g (*S-26 LF*)

2349P **Milk powder—lactose free formula**, Lactose-predigested powder infant formula 900 g (*Karicare De-Lact*)

**Authority required**

Proven chronic lactose intolerance in infants up to the age of 12 months. The date of birth of the patient must be included in the authority application. Lactose intolerance must have been proven by either:
(a) relief of symptoms on supervised withdrawal of lactose from the diet for 3 or 4 days and subsequent re-emergence of symptoms on rechallenge with lactose containing formulae or milk or food; or
(b) not less than 0.5% reducing substance in stool exudate tested with copper sulfate diagnostic compound tablet; or
(c) hydrogen breath test

**Milk powder — lactose modified** *(the following Note applies to code 2357C)*

**NOTE:**

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

2357C **Milk powder—lactose modified**, Lactose-predigested powder 900 g (*Digestelact*)

**Authority required**

Proven chronic lactose intolerance in children aged 1 year and over who are significantly malnourished. The date of birth of the patient must be included in the authority application. Lactose intolerance must have been proven by either:
(a) relief of symptoms on supervised withdrawal of lactose from the diet for 3 or 4 days and subsequent re-emergence of symptoms on rechallenge with lactose containing formulae or milk or food; or
(b) not less than 0.5% reducing substance in stool exudate tested with copper sulfate diagnostic compound tablet; or
(c) hydrogen breath test

2313R **Minoxidil**, Tablet 10 mg (*Loniten*)

**Authority required (STREAMLINED)**

**2759**

Severe refractory hypertension. Treatment must be initiated by a consultant physician

**Perindopril with indapamide hemihydrate** *(the following Note applies to codes: 8449Q, 2845R)*

**NOTE:**

Bioequivalence has been demonstrated between perindopril erbumine/indapamide hemihydrate tablet 4 mg-1.25 mg and perindopril arginine/indapamide hemihydrate tablet 5 mg-1.25 mg.

8449Q **Perindopril with indapamide hemihydrate**, Tablet containing 4 mg perindopril erbumine-1.25 mg indapamide hemihydrate (*Chem mart Perindopril/ Indapamide 4/1.25, GenRx Perindopril/ Indapamide 4/1.25, Perindo Combi 4/1.25, Terry White Chemists Perindopril/ Indapamide 4/1.25*)

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 indapamide and/or perindopril

3036T **Strontium ranelate**, Sachet containing granules for oral suspension 2 g (*Protos 2 g*)

**Authority required (STREAMLINED)**

**2758**

Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a woman aged 70 years or older with a bone mineral density (BMD) T-score of -3.0 or less.

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

**Authority required (STREAMLINED)**

**2647**

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

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

**NOTE:**

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

2248H **Tamarindus indica seed polysaccharide**, Eye drops 10 mg per mL (1%), 0.5 mL, 20 (*Visine Professional*)

**Authority required (STREAMLINED)**

**1359**

Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

**Trastuzumab**

**NOTE:**

Any queries concerning the arrangements to prescribe trastuzumab 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 trastuzumab 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.

6497Y **Trastuzumab**, Powder for I.V. infusion 150 mg (*Herceptin*)

**Authority required**

Initial treatment for HER2 positive early breast cancer commencing concurrently with adjuvant chemotherapy following surgery.

The total duration of PBS-subsidised treatment (initial plus continuing) that will be authorised is 52 weeks.

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

Trastuzumab must not be used in patients with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure. Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

Authority applications for initial treatment must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Early Breast Cancer - PBS Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes:
(i) a copy of the pathology report from an Approved Pathology Authority confirming the presence of HER2 gene amplification by in situ hybridisation (ISH); and
(ii) a copy of the signed patient acknowledgement form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

The medical practitioner should request sufficient quantity based on the weight of the patient to provide for a maximum of 3 weeks' treatment (equivalent to the loading dose for the 3 weekly regimen, and the loading dose and 2 weekly doses for the once weekly regimen)

**Authority required**

Continuing treatment for HER2 positive early breast cancer where the patient has previously received treatment with PBS-subsidised trastuzumab.

The patient is eligible to receive sufficient trastuzumab to complete 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.

Trastuzumab must not be used in patients with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure. Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, at 3 monthly intervals during treatment.

Authority applications for continuing treatment may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

The medical practitioner should request sufficient quantity based on the weight of the patient for 3 weeks' supply (equivalent to 1 dose for the 3 weekly dosing regimen, or 3 doses for the once weekly dosing regimen). Up to a maximum of 3 repeats may be authorised.

Breaks in therapy.
Where a patient has a break in trastuzumab therapy of more than 1 week but less than 6 weeks from when the last dose was due, authority approval will be granted for a new loading dose. Authority applications for new loading doses may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

2269K **Vancomycin**, Powder for injection 1 g (1,000,000 i.u.) vancomycin activity (*MX*)

5083M **Vancomycin**, Powder for injection 1 g (1,000,000 i.u.) vancomycin activity (*MX*) **(Dental)**

**Restricted benefit**

Prophylaxis of endocarditis in patients hypersensitive to penicillin

2270L **Vancomycin**, Powder for injection 1 g (1,000,000 i.u.) vancomycin activity (*MX*) **(Diff. Max. Qty)**

**Restricted benefit**

Endophthalmitis

**Restricted benefit**

Use initiated in a hospital for infections where vancomycin is an appropriate antibiotic

# REPATRIATION PHARMACEUTICAL BENEFITS

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

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

## SUMMARY OF CHANGES

### ALTERATIONS

*Alterations - Manufacturer Codes*

| | | *From* | *To* |
|---|---|---|---|
| 4008Y | **Ketoconazole**, Shampoo 20 mg per g (2%), 60 mL (*Nizoral 2%*) | JC | JT |
| 4454K | **Miconazole nitrate**, Cream 20 mg per g (2%), 30 g (*Daktarin*) | JC | JT |
| 4341L | **Miconazole**, Tincture 20 mg per mL (2%), 30 mL (*Daktarin*) | JC | JT |