Australian Government

Department of Health and Ageing

SCHEDULE OF PHARMACEUTICAL BENEFITS

SUMMARY OF CHANGES

EFFECTIVE 1 NOVEMBER 2009

PHARMACEUTICAL BENEFITS

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 November 2009. 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 2009 and are included, where applicable, in prices published in the Schedule—

Dispensing Fees:	Ready-prepared	$6.42
	Dangerous drug fee	$2.71
	Extemporaneously-prepared	$8.46
	Allowable additional patient charge*	$3.79
Additional Fees (for safety net prices):	Ready-prepared	$1.05
	Extemporaneously-prepared	$1.38
Patient Co-payments:	General	$32.90
	Concessional	$5.30
Safety Net Thresholds:	General	$1264.90
	Concessional	$318.00
Safety Net Card Issue Fee:		$8.25

*The allowable additional patient charge is a discretionary charge to general patients if a pharmaceutical item has a dispensed price for maximum quantity less than the general patient co-payment. The pharmacist may charge general patients the allowable additional fee but the fee cannot take the cost of the prescription above the general patient co-payment for the medicine. This fee does not count towards the Safety Net threshold.

SUMMARY OF CHANGES

ADDITIONS

Additions — Items

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

9483D **Ezetimibe with simvastatin**, Tablet 10 mg-10 mg (*Vytorin*)

9484E **Ezetimibe with simvastatin**, Tablet 10 mg-20 mg (*Vytorin*)

9480Y **Tobramycin sulfate**, Injection 500 mg (base) in 5 mL (without preservative) (*Tobra-Day*)

9481B **Valsartan with hydrochlorothiazide**, Tablet 320 mg-12.5 mg (*Co-Diovan 320/12.5*)

9482C **Valsartan with hydrochlorothiazide**, Tablet 320 mg-25 mg (*Co-Diovan 320/25*)

Additions — Brands

8256M *Carvedilol Sandoz, SZ* — **Carvedilol**, Tablet 6.25 mg

8257N *Carvedilol Sandoz, SZ* — **Carvedilol**, Tablet 12.5 mg

8258P *Carvedilol Sandoz, SZ* — **Carvedilol**, Tablet 25 mg

1300K *Diclofenac-GA, GM* — **Diclofenac sodium**, Tablet 50 mg (enteric coated)

5365J *Diclofenac-GA, GM* — **Diclofenac sodium**, Tablet 50 mg (enteric coated) **(Palliative Care)**

5362F *Diclofenac-GA, GM* — **Diclofenac sodium**, Tablet 50 mg (enteric coated) **(Palliative Care) (Diff. Max. Rpts)**

5077F *Diclofenac-GA, GM* — **Diclofenac sodium**, Tablet 50 mg (enteric coated) **(Dental)**

3466K *Frusemide-Claris, AE* — **Frusemide**, Injection 20 mg in 2 mL **(Doctor's Bag)**

2413B *Frusemide-Claris, AE* — **Frusemide**, Injection 20 mg in 2 mL

8049P *Gemcitabine Actavis, GQ* — **Gemcitabine hydrochloride**, Powder for I.V. infusion 200 mg (base)

8050Q *Gemcitabine Actavis, GQ* — **Gemcitabine hydrochloride**, Powder for I.V. infusion 1 g (base)

8787L *Resdone 0.5, CR* — **Risperidone**, Tablet 0.5 mg

8869T *Resdone 0.5, CR* — **Risperidone**, Tablet 0.5 mg **(Diff. Max. Rpts)**

8789N *Resdone 1, CR* — **Risperidone**, Tablet 1 mg

3169T *Resdone 1, CR* — **Risperidone**, Tablet 1 mg **(Diff. Max. Rpts)**

9079W *Resdone 2, CR* — **Risperidone**, Tablet 2 mg

3170W *Resdone 2, CR* — **Risperidone**, Tablet 2 mg **(Diff. Max. Rpts)**

3171X *Resdone 3, CR* — **Risperidone**, Tablet 3 mg

3172Y *Resdone 4, CR* — **Risperidone**, Tablet 4 mg

DELETIONS

Deletions — Items

2240X **Lansoprazole**, Capsule 30 mg (*Zoton*)

2241Y **Lansoprazole**, Capsule 30 mg (*Zoton*) **(Diff. Max. Rpts)**

8528W **Lansoprazole**, Sachet containing granules for oral suspension, 30 mg per sachet (*Zoton*)

8529X **Lansoprazole**, Sachet containing granules for oral suspension, 30 mg per sachet (*Zoton*) **(Diff. Max. Rpts)**

8949B **Lansoprazole**, Sachet containing granules for oral suspension, 30 mg per sachet (*Zoton*) **(Diff. Restriction)**

8950C **Lansoprazole**, Sachet containing granules for oral suspension, 30 mg per sachet (*Zoton*) **(Diff. Restriction) (Diff. Max. Rpts)**

1251W **Terbutaline sulfate**, Nebuliser solution single dose units 5 mg in 2 mL, 30 (*Bricanyl Respules*)

ALTERATIONS

Alterations - Item Description

For Etanercept items 9455P, 9456Q, 9457R, 9458T, 9459W, 9460X, 9461Y and 9462B, the item description has changed:

From:

Etanercept, Injection 50 mg in 1 mL single use injection pen, 4 (*Enbrel*)

To:

Etanercept, Injection 50 mg in 1 mL single use auto-injector, 4 (*Enbrel*)

Alterations — Proprietary Name

From:

2375B **Amino acid formula with vitamins and minerals without valine, leucine and isoleucine**, Oral liquid 130 mL, 30 (*MSUD Express Cooler*)

To:

2375B **Amino acid formula with vitamins and minerals without valine, leucine and isoleucine**, Oral liquid 130 mL, 30 (*MSUD Cooler*)

From:

8370M **Naltrexone hydrochloride**, Tablet 50 mg (*Naltrexone QP*)

To:

8370M **Naltrexone hydrochloride**, Tablet 50 mg (*Naltrexone generichealth*)

Alterations — Number of Repeats

		From	*To*
9363T	**Voriconazole**, Tablet 50 mg (*Vfend*)	..	2
9364W	**Voriconazole**, Tablet 200 mg (*Vfend*)	..	2

Alterations — Manufacturer's Code

		From	*To*
1300K	**Diclofenac sodium**, Tablet 50 mg (enteric coated) (*Dinac*)	GM	GN
5365J	**Diclofenac sodium**, Tablet 50 mg (enteric coated) (*Dinac*) **(Palliative Care)**	GM	GN
5362F	**Diclofenac sodium**, Tablet 50 mg (enteric coated) (*Dinac*) **(Palliative Care) (Diff. Max. Rpts)**	GM	GN
5077F	**Diclofenac sodium**, Tablet 50 mg (enteric coated) (*Dinac*) **(Dental)**	GM	GN
9184J	**Fludarabine phosphate**, Tablet 10 mg (*Fludara*)	BN	GZ
9185K	**Fludarabine phosphate**, Powder for I.V. injection 50 mg (*Fludara*)	BN	GZ
2881P	**Hydrocortisone acetate**, Cream 10 mg per g (1%), 50 g (*Cortef*)	DT	VT
5113D	**Hydrocortisone acetate**, Cream 10 mg per g (1%), 50 g (*Cortef*) **(Dental)**	DT	VT
8370M	**Naltrexone hydrochloride**, Tablet 50 mg (*Naltrexone generichealth*)	XF	GQ

Alterations — Restrictions

(see under 'RESTRICTIONS' below for full details)

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

9117W **Bortezomib**, Powder for injection 3.5 mg (solvent required) (*Velcade*) **(Diff. Max. Rpts)**

2480M **Ciprofloxacin**, Ear drops 3 mg per mL (0.3%), 5 mL (*Ciloxan*)

The following is now an "Authority required (STREAMLINED)" item:

2700D **Thyrotropin alfa**, Powder for injection 0.9 mg, 2 (*Thyrogen*)

Alterations — Notes

(see under 'NOTES' below for full details)

9355J **Carmellose Sodium with Glycerin,** Eye drops 5 mg-9 mg per mL (0.5%-0.9%), 15 mL (*Optive)*

9356K **Carmellose Sodium with Glycerin,** Eye drops 5 mg-9 mg per mL (0.5%-0.9%), 15 mL (*Optive)* **(Diff. Max. Rpts.)**

5556K **Carmellose Sodium with Glycerin,** Eye drops 5 mg-9 mg per mL (0.5%-0.9%), 15 mL (*Optive)* **(Optometrical)**

SECTION 100

HIGHLY SPECIALISED DRUGS PROGRAM

ADDITIONS

Additions — Items

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

9647R **Apomorphine hydrochloride**, Solution for subcutaneous infusion 50 mg in 10 mL pre-filled syringe (*Apomine PFS*)

9646Q **Atazanavir**, Capsule 100 mg (as sulfate) (*Reyataz*)

9642L **Lenalidomide**, Capsule 5 mg (*Revlimid*)

9643M **Lenalidomide**, Capsule 10 mg (*Revlimid*)

9644N **Lenalidomide**, Capsule 15 mg (*Revlimid*)

9645P **Lenalidomide**, Capsule 25 mg (*Revlimid*)

DELETIONS

Deletions — Items

6389G **Ribavirin and peginterferon alfa-2a**, Pack containing 84 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 135 micrograms (*Pegasys RBV*)

6390H **Ribavirin and peginterferon alfa-2a**, Pack containing 112 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 135 micrograms (*Pegasys RBV*)

6391J **Ribavirin and peginterferon alfa-2a**, Pack containing 140 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 135 micrograms (*Pegasys RBV*)

ALTERATIONS

Alteration — Item Description

From:

9641K **Etanercept**, Injection 50 mg in 1 mL single use injection pen, 4 (*Enbrel*)

To:

9641K **Etanercept**, Injection 50 mg in 1 mL single use auto-injector, 4 (*Enbrel*)

Alterations — Restrictions

(see under 'RESTRICTIONS' below for full details)

6120D **Dornase alfa**, Solution for inhalation 2.5 mg (2,500 units) in 2.5 mL (*Pulmozyme*)

6367D **Etanercept**, Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*)

ADVANCE NOTICES

DELETIONS

Advance Notice — Deletion of Items

The following item will be deleted from the Schedule of Pharmaceutical Benefits on 1 December 2009:
Item discontinued by the manufacturer—

9194X **Paliperidone**, Tablet 12 mg (prolonged release) (*Invega*)

The following items will be deleted from the Schedule of Pharmaceutical Benefits on 1 January 2010:
Items discontinued by the manufacturer—

2737C **Amino acid formula with vitamins and minerals without phenylalanine**, Infant formula, powder 400 g (*XP Analog*)

8706F **Amino acid formula without phenylalanine**, Bars 42 g, 20 (*Phlexy-10*)

Advance Notice — Deletion of Brands

The following brands will be deleted from the Schedule of Pharmaceutical Benefits on 1 December 2009:
Brands discontinued by the manufacturer—

1157X *Tagamet, GK* — **Cimetidine**, Tablet 200 mg

8884N *Metex SR, SI* — **Metformin hydrochloride**, Tablet 500 mg (extended release)

1975Y *Quinsul, LN* — **Quinine sulfate**, Tablet 300 mg

The following brands will be deleted from the Schedule of Pharmaceutical Benefits on 1 January 2010:
Brands discontinued by the manufacturer—

8118G *Alprazolam-DP, GN* — **Alprazolam**, Tablet 2 mg

3161J *Ducene, SU* — **Diazepam**, Tablet 2 mg
3162K *Ducene, SU* — **Diazepam**, Tablet 5 mg
5357Y *Ducene, SU* — **Diazepam**, Tablet 2 mg **(Palliative Care)**
5355W *Ducene, SU* — **Diazepam**, Tablet 2 mg **(Palliative Care) (Diff. Max. Rpts)**
5358B *Ducene, SU* — **Diazepam**, Tablet 5 mg **(Palliative Care)**
5356X *Ducene, SU* — **Diazepam**, Tablet 5 mg **(Palliative Care) (Diff. Max. Rpts)**
5071X *Ducene, SU* — **Diazepam**, Tablet 2 mg **(Dental)**
5072Y *Ducene, SU* — **Diazepam**, Tablet 5 mg **(Dental)**

The following brand will be deleted from the Schedule of Pharmaceutical Benefits on 1 February 2010:
Brand discontinued by the manufacturer—

1300K *Dinac, GN* — **Diclofenac sodium**, Tablet 50 mg (enteric coated)

The following brand will be deleted from the Schedule of Pharmaceutical Benefits on 1 April 2010:
Brand discontinued by the manufacturer—

3012M *K-Sol, LN* — **Potassium chloride with potassium bicarbonate**, Effervescent tablet 14 mmol potassium and 8 mmol chloride

RETENTION OF ITEM

Contrary to previous advice, the following item will not be deleted from the Schedule of Pharmaceutical Benefits on 1 November 2009:

9012H **Alendronate sodium with colecalciferol**, Tablet equivalent to 70 mg alendronic acid with 70 micrograms colecalciferol

RESTRICTIONS

The text of restrictions mentioned above:

9647R **Apomorphine hydrochloride**, Solution for subcutaneous infusion 50 mg in 10 mL pre-filled syringe (*Apomine PFS*)

Private hospital authority required

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

9646Q **Atazanavir**, Capsule 100 mg (as sulfate) (*Reyataz*)

Private hospital authority required

Treatment, in combination with 2 or more other antiretroviral drugs, of HIV infection in patients with CD4 cell counts of less than 500 per cubic millimetre

Private hospital authority required

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

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 and/or cyclophosphamide, 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) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or
(f) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. MRI or CT-Scan); or
(g) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L.

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

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 and/or cyclophosphamide, of a patient with a histological diagnosis of multiple myeloma who has progressive disease after at least 1 prior therapy and who has undergone or is ineligible for a primary stem cell transplant. The patient must have experienced treatment failure after a trial of at least four (4) weeks of thalidomide at a dose of at least 100 mg daily or have failed to achieve at least a minimal response after eight (8) or more weeks of thalidomide-based therapy for progressive disease.

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

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) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
(d) 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
(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
(f) 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
(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein and less than 200 mg per 24 hour Bence-Jones proteinuria.

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

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.

Any queries concerning additional details about treatment failure may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday.

Failure to achieve at least a minimal response after 8 or more weeks of thalidomide-based therapy for progressive disease is defined as:
(1) less than a 25% reduction in serum or urine M protein; or
(2) in oligo-secretory and non-secretory myeloma patients only, less than a 25% reduction in the difference between involved and uninvolved serum free light chain levels.

Bortezomib will only be subsidised for patients with multiple myeloma who are not receiving concomitant PBS-subsidised lenalidomide.

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 the histological diagnosis of multiple myeloma, 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; details of thalidomide treatment failure; details of the basis of the diagnosis of progressive disease or failure to respond; and nomination of which disease activity parameters will be used to assess response.

To enable confirmation by Medicare Australia, current diagnostic reports of at least one of the following are required:
(a) the level of serum monoclonal protein; or
(b) Bence-Jones proteinuria — the results of 24-hour urinary light chain M protein excretion; or
(c) the serum level of free kappa and lambda light chains; or
(d) bone marrow aspirate or trephine; or
(e) if present, the size and location of lytic bone lesions (not including compression fractures); or
(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (either previous or current serum M protein less than 10 g per L and urinary Bence-Jones protein undetectable or less than 200 mg per 24 hours) must 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 and/or cyclophosphamide, 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) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or
(f) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. MRI or CT-Scan); or
(g) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L.

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

2480M **Ciprofloxacin**, Ear drops 3 mg per mL (0.3%), 5 mL (*Ciloxan*)

Authority required

Treatment of chronic suppurative otitis media in an Aboriginal or a Torres Strait Islander person aged 1 month or older

Authority required

Treatment of chronic suppurative otitis media in a patient less than 18 years of age with perforation of the tympanic membrane

Authority required

Treatment of chronic suppurative otitis media in a patient less than 18 years of age with a grommet in situ

6120D **Dornase alfa**, Solution for inhalation 2.5 mg (2,500 units) in 2.5 mL (*Pulmozyme*)

Private hospital authority required

Use by cystic fibrosis patients who satisfy all of the following criteria:

(1) are 5 years of age or older;
(2) have a FVC greater than 40% predicted for age, gender and height;
(3) have evidence of chronic suppurative lung disease (cough and sputum most days of the week, or greater than 3 respiratory tract infections of more than 2 weeks' duration in any 12 months, or objective evidence of obstructive airways disease);
(4) are participating in a 4 week trial as detailed below or have achieved a 10% or greater improvement in FEV1 (compared to baseline established prior to dornase alfa treatment) after a 4 week trial.

In order for patients to be eligible for participation in the HSD program, the following conditions must be met:
(1) Patients must be assessed at cystic fibrosis clinics/centres which are under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis and the prescribing of dornase alfa under the HSD program is limited to such physicians. If attendance at such units is not possible because of geographical isolation, management (including prescribing) may be by specialist physician or paediatrician in consultation with such a unit;
(2) The measurement of lung function is to be conducted by independent (other than the treating doctor) experienced personnel at established lung function testing laboratories, unless this is not possible because of geographical isolation;
(3) Prior to dornase alfa therapy, a baseline measurement of FEV1 must be undertaken during a stable period of the disease;
(4) Initial therapy is limited to 4 weeks' treatment with dornase alfa at a dose of 2.5 mg daily;
(5) At or towards the end of the initial 4 weeks' trial, patients must be reassessed and a further FEV1 measurement be undertaken (single test under conditions as above). Patients who achieve a 10% or greater improvement in FEV1 (compared to baseline established prior to dornase alfa treatment) are eligible for continued subsidy under the HSD program at a dose of 2.5 mg daily;
(6) Patients who fail to meet a 10% or greater improvement in FEV1 after the initial 4 weeks' treatment at a dose of 2.5 mg daily, may have 1 further trial in the next 12 months but not before 3 months after the initial trial;
(7) Following an initial 6 months' therapy, a global assessment must be undertaken involving the patient, the patient's family (in the case of paediatric patients) and the treating physician(s) to establish that all agree that dornase alfa treatment is continuing to produce worthwhile benefits. (Dornase alfa therapy should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.) Further reassessments are to be undertaken at six-monthly intervals;
(8) Other aspects of treatment, such as physiotherapy, must be continued;
(9) Where there is documented evidence that a patient already receiving dornase alfa therapy would have met the criteria for subsidy (i.e. satisfied the criteria for the 4 week trial and achieved a 10% or greater improvement in FEV1) then the patient is eligible to continue treatment under the HSD program. Where such evidence is not available, patients will need to satisfy the initiation and continuation criteria as for new patients. (Four weeks is considered a suitable wash-out period)

Private hospital authority required

Treatment of cystic fibrosis in a patient less than 5 years of age who has:
(1) A severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring frequent hospital admissions more frequently than 3 times per year; or
(2) Significant bronchiectasis on chest high resolution computed tomography scan; or
(3) Severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines; or
(4) Severe physiological deficit measure by forced oscillation technique or multiple breath nitrogen washout and failure to respond to conventional therapy.

In order for the patient to be eligible for participation in the HSD program, the following conditions must be met:
(1) The patient must be assessed at a cystic fibrosis clinic/centre which is under the supervision of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis, and

the prescribing of dornase alfa under the HSD program is limited to such physicians. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be by specialist physician or paediatrician in consultation with such a unit;
(2) Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented involving the patient, the patient's family, the treating physician and an additional independent member of the cystic fibrosis treatment team to establish agreement that dornase alfa treatment is continuing to produce worthwhile benefit. Treatment with dornase alfa should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use. Further reassessments are to be undertaken and documented yearly

Private hospital authority required

Grandfather — continuing for patients five years or older
Continuation of treatment of cystic fibrosis in a patient 5 years of age or older, who initiated treatment with dornase alfa at an age of less than 5 years and for whom a comprehensive assessment, involving the patient's family, the treating physician and an additional independent member of the cystic fibrosis treatment team, documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit. Further reassessments are to be undertaken and documented yearly. Treatment with dornase alfa should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use

Private hospital authority required

Grandfather — for patients less than five years of age who initiated dornase alfa prior to listing
Treatment of cystic fibrosis in a patient less than 5 years of age who initiated treatment with dornase alfa prior to 1 November 2009 and for whom a comprehensive assessment, involving the patient's family, the treating physician and an additional independent member of the cystic fibrosis treatment team, documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit. Further reassessments are to be undertaken and documented yearly. Treatment with dornase alfa should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use

NOTE:

It is highly desirable that all patients be included in the national cystic fibrosis patient data-base.

ETANERCEPT

NOTE:

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

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

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

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

6367D **Etanercept**, Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*)

Public and private hospital authority required

Initial treatment by a paediatric rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of patients under 18 years who have severe active polyarticular course juvenile chronic arthritis; AND

(a) whose parent or authorised guardian has signed a patient agreement form indicating that they understand and acknowledge that PBS-subsidised treatment will cease if the predetermined response criteria do not support continuation of PBS-subsidised treatment; AND
(b) who have demonstrated either:
(i) severe intolerance of, or toxicity due to, methotrexate (see below for definition of severe intolerance and toxicity); or
(ii) failure to achieve an adequate response to 1 or more of the following treatment regimens:
— oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or
— oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other DMARD, alone or in combination with corticosteroids, for a minimum of 3 months. (Note: use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.)

Severe intolerance is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant NSAIDs on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

The following criteria must be met in order to demonstrate failure to achieve an adequate response to either of the above treatment regimens:
(a) an active joint count of at least 20 active (swollen and tender) joints; OR
(b) at least 4 active joints from the following list:
(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).

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, or intolerance develops during the period of use such that permanent withdrawal is necessary and a suitably effective treatment regimen cannot be implemented, this exempts the requirement to demonstrate an inadequate response within the time period specified above for these agents.

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

Only 16 weeks of treatment will be approved. The assessment of the patient's response to initial treatment should be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated

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 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

9483D **Ezetimibe with simvastatin**, Tablet 10 mg-10 mg (*Vytorin*)
9484E **Ezetimibe with simvastatin**, Tablet 10 mg-20 mg (*Vytorin*)

Authority required (STREAMLINED)

2431

Patients with homozygous familial hypercholesterolaemia who are eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs)

Authority required (STREAMLINED)

3194

Patients eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs) where treatment with an HMG CoA reductase inhibitor (statin) must be reduced to a dose of 20 mg or less per day, because the patient developed a clinically important product-related adverse event during treatment with a statin.A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without CK elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important CK elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin

LENALIDOMIDE

NOTE:

Any queries concerning the arrangements to prescribe lenalidomide 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.

Any queries concerning patients who are enrolled on the Lenalidomide Compassionate program may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

These patients must demonstrate they met initial criteria prior to commencing treatment on the compassionate program and also demonstrate they do not have progressive disease. Baseline and current pathology reports must be submitted with the initial application.

Applications for authority to prescribe lenalidomide should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

9643M **Lenalidomide**, Capsule 10 mg (*Revlimid*)
9644N **Lenalidomide**, Capsule 15 mg (*Revlimid*)
9645P **Lenalidomide**, Capsule 25 mg (*Revlimid*)

9642L **Lenalidomide**, Capsule 5 mg (*Revlimid*)

Public and private hospital authority required

Initial PBS-subsidised treatment, as monotherapy or in combination with dexamethasone, of multiple myeloma in a patient 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.

Any queries concerning additional details about treatment failure may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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 4 drug-related dermatological reactions, such as Stevens-Johnson Syndrome, or other Grade 3 or 4 toxicity.

Lenalidomide will only be subsidised for patients with multiple myeloma who are not receiving concomitant PBS-subsidised bortezomib.

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; details of thalidomide treatment failure; and details of the basis of the diagnosis of progressive disease.

To enable confirmation by Medicare Australia of eligibility, 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.

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). 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

Public and private hospital authority required

Continuing PBS-subsidised treatment, as monotherapy or in combination with dexamethasone, of multiple myeloma in a patient who has previously been issued with an authority prescription for lenalidomide and who does not have progressive disease.

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).

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)

NOTE:

Patients receiving lenalidomide via the PBS must be registered in the RevAccess program.

NOTE:

Special Pricing Arrangements apply.

2700D **Thyrotropin alfa**, Powder for injection 0.9 mg, 2 (*Thyrogen*)

Authority required (STREAMLINED)

3193

Ablation of thyroid remnant tissue, in combination with radioactive iodine, in a post thyroidectomy patient without known metastatic disease

9480Y **Tobramycin sulfate**, Injection 500 mg (base) in 5 mL (without preservative) (*Tobra-Day*)

Restricted Benefit

Systemic treatment of Pseudomonas aeruginosa infection in a patient with cystic fibrosis

9481B **Valsartan with hydrochlorothiazide**, Tablet 320 mg-12.5 mg (*Co-Diovan 320/12.5*)

9482C **Valsartan with hydrochlorothiazide**, Tablet 320 mg-25 mg (*Co-Diovan 320/25*)

Restricted Benefit

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

NOTE:

No applications for increased maximum quantities and/or repeats will be authorised for the tablets containing 320 mg valsartan

NOTES

The text of notes mentioned above:

Carmellose sodium with glycerin

The in-use shelf life of Optive is 6 months from the date of opening.

REPATRIATION PHARMACEUTICAL BENEFITS

The change to the Repatriation Pharmaceutical Benefits Schedule is effective from 1 November 2009. The Schedule is updated on the first day of each month and is available on the Internet at www.pbs.gov.au.

SUMMARY OF CHANGES

DELETION

Deletion — Item

4458P **Sodium bicarbonate**, Capsule 840 mg (*Sodibic*)