



Australian Government

Department of Health and Ageing

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

SUMMARY OF CHANGES

EFFECTIVE 1 APRIL 2007 — 30 APRIL 2007

PHARMACEUTICAL BENEFITS

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

Internet

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

Fees, Patient Contributions and Safety Net Thresholds

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

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

SUMMARY OF CHANGES

ADDITIONS

Additions — Items

2514H	Anecortave Acetate , suspension for injection 15 mg in 0.5 mL (<i>Retaane</i>)
2549E	Isotretinoin , capsule 40 mg (<i>Oratane</i>)
2387P	Methylphenidate Hydrochloride , tablet 18 mg (extended release) (<i>Concerta</i>)
2388Q	Methylphenidate Hydrochloride , tablet 36 mg (extended release) (<i>Concerta</i>)
2432B	Methylphenidate Hydrochloride , tablet 54 mg (extended release) (<i>Concerta</i>)
9079W	Risperidone , tablet 2 mg (<i>Risperdal</i>) (Diff. Max. Rpts)
9080X	Risperidone , tablet 2 mg (orally disintegrating) (<i>Risperdal Quicklet</i>) (Diff. Max. Rpts)
3036T	Strontium Ranelate , sachet containing granules for oral suspension 2 g (<i>Protos 2 g</i>)
9070J	Ziprasidone Hydrochloride , capsule 20 mg (base) (<i>Zeldox</i>)
9071K	Ziprasidone Hydrochloride , capsule 40 mg (base) (<i>Zeldox</i>)
9072L	Ziprasidone Hydrochloride , capsule 60 mg (base) (<i>Zeldox</i>)
9073M	Ziprasidone Hydrochloride , capsule 80 mg (base) (<i>Zeldox</i>)

Additions — PBS Authority Required Special Patient Contribution Exemption Codes

A special patient contribution now applies to **Naratriptan Hydrochloride**, tablet 2.5 mg (base), and **Zolmitriptan**, tablet 2.5 mg (see Special Pharmaceutical Benefits section in the Schedule). The following codes have been established to provide for cases where an authority has been obtained that grants exemption from the special patient contribution:

9734H **Naratriptan Hydrochloride**, tablet 2.5 mg (base) (*Naramig*)
9736K **Zolmitriptan**, tablet 2.5 mg (*Zomig*)

Additions — Brands

8255L *Chem mart Carvedilol 3.125 mg, CH; Terry White Chemists Carvedilol 3.125 mg, TW — Carvedilol*, tablet 3.125 mg
8256M *Chem mart Carvedilol 6.25 mg, CH; Terry White Chemists Carvedilol 6.25 mg, TW — Carvedilol*, tablet 6.25 mg
8257N *Chem mart Carvedilol 12.5 mg, CH; Terry White Chemists Carvedilol 12.5 mg, TW — Carvedilol*, tablet 12.5 mg
8258P *Chem mart Carvedilol 25 mg, CH; Terry White Chemists Carvedilol 25 mg, TW — Carvedilol*, tablet 25 mg
8883M *Mirtazapine Sandoz, SZ — Mirtazapine*, tablet 45 mg
8539K *Oxalatin, ZP — Oxaliplatin*, powder for I.V. infusion 50 mg
8540L *Oxalatin, ZP — Oxaliplatin*, powder for I.V. infusion 100 mg
3050M *Perindo, AF — Perindopril*, tablet containing 2 mg perindopril erbumine
3051N *Perindo, AF — Perindopril*, tablet containing 4 mg perindopril erbumine
8704D *Perindo, AF — Perindopril*, tablet containing 8 mg perindopril erbumine
8144P *Sumatab, AF — Sumatriptan Succinate*, tablet 50 mg (base)

RETENTION OF ITEM

Contrary to previous advice, the following item will continue to be available as a pharmaceutical benefit from 1 April 2007:

1508J **Hydroxocobalamin**, injection 1 mg in 1 mL (*Neo-Cytamen*)

DELETIONS

Deletions — Items

1125F **Docusate Sodium with Bisacodyl**, suppositories 100 mg-10 mg, 5 (*Coloxyl*)
5309K **Docusate Sodium with Bisacodyl**, suppositories 100 mg-10 mg, 5 (*Coloxyl*) (**Palliative Care**)
5310L **Docusate Sodium with Bisacodyl**, suppositories 100 mg-10 mg, 5 (*Coloxyl*) (**Palliative Care**)
(**Diff. Max. Rpts**)
2545Y **Oxandrolone**, tablet 2.5 mg (*Oxandrin*)
1829G **Pethidine Hydrochloride**, injection 100 mg in 2 mL (*MX*)
5200Q **Pethidine Hydrochloride**, injection 100 mg in 2 mL (*MX*) (**Dental**)

Deletions — PBS Therapeutic Group Premium Exemption Codes

8948Y **Ramipril**, pack containing 7 tablets 2.5 mg, 21 tablets 5 mg and 10 capsules 10 mg (*Tritace Titration Pack*)

Deletions — Brands

1884E *Moxacin, CS* — **Amoxycillin**, capsule 250 mg
3301R *Moxacin, CS* — **Amoxycillin**, capsule 250 mg (**Dental**)
1886G *Moxacin, CS* — **Amoxycillin**, powder for syrup 125 mg per 5 mL, 100 mL
3302T *Moxacin, CS* — **Amoxycillin**, powder for syrup 125 mg per 5 mL, 100 mL (**Dental**)
1929M *Novantrone, SI* — **Mitozantrone Hydrochloride**, injection 20 mg (base) in 10 mL
1930N *Novantrone, SI* — **Mitozantrone Hydrochloride**, injection 25 mg (base) in 12.5 mL

ALTERATIONS

Restriction Changes (see under 'RESTRICTIONS' below for full details)

8511Y **Alendronate Sodium**, tablet equivalent to 70 mg alendronic acid (*Alendronate Once Weekly, Fosamax Once Weekly*)
9012H **Alendronate Sodium with Colecalciferol**, tablet equivalent to 70 mg alendronic acid with 70 micrograms colecalciferol (*Fosamax Plus*)
8574G **Amino Acids — Synthetic, Formula**, compound powder 400 g (*EleCare*)
8443J **Amino Acids — Synthetic, Formula**, compound powder 400 g (*Neocate*)
8754R **Amino Acids — Synthetic, Formula**, compound powder 400 g (*Neocate Advance*)
8575H **Amino Acids — Synthetic, Formula**, compound powder 400 g (*EleCare*)
3066J **Amino Acids — Synthetic, Formula**, compound powder 400 g (*Neocate*)
8755T **Amino Acids — Synthetic, Formula**, compound powder 400 g (*Neocate Advance*)
8757X **Ezetemibe**, tablet 10 mg (*Ezetrol*)
8881K **Ezetemibe with Simvastatin**, tablet 10 mg-40 mg (*Vytorin*)
8882L **Ezetemibe with Simvastatin**, tablet 10 mg-80 mg (*Vytorin*)
8896F **Famciclovir**, tablet 500 mg (*Famvir*) (**Diff. Max. Qty and Rpts**)
2676W **Protein Hydrolysate Formula with Medium Chain Triglycerides**, compound powder 400 g (*Alfaré*)
8259Q **Protein Hydrolysate Formula with Medium Chain Triglycerides**, compound powder 450 g (*Pepti-Junior*)
8787L **Risperidone**, tablet 0.5 mg (*Risperdal*)
8788M **Risperidone**, tablet 0.5 mg (orally disintegrating) (*Risperdal Quicklet*)
8789N **Risperidone**, tablet 1 mg (*Risperdal*)
8790P **Risperidone**, tablet 1 mg (orally disintegrating) (*Risperdal Quicklet*)
8791Q **Risperidone**, oral solution 1 mg per mL, 30 mL (*Risperdal*)

Alterations — Notes

Notes have been amended in respect of the following:

**Diphtheria and Tetanus Vaccine, Adsorbed, Diluted for Adult Use
Famciclovir**

Notes have been deleted in respect of the following:

Isotretinoin

Alterations — Item Description

From:
1611T **Mesalazine**, tablet 250 mg (*Mesasal*)
To:
1611T **Mesalazine**, tablet 250 mg (enteric coated) (*Mesasal*)

Alterations — Maximum Quantity

		<i>From</i>	<i>To</i>
8783G	Diphtheria and Tetanus Vaccine, Adsorbed, Diluted for Adult Use , injection 0.5 mL in pre-filled syringe (<i>ADT Booster</i>)	3	5
1377L	Epirubicin Hydrochloride , solution for injection 50 mg in 25 mL (<i>Epirubicin Ebewe, Pharmorubicin Solution</i>)	3	4
9018P	Epirubicin Hydrochloride , powder for injection 50 mg (<i>MX</i>)	3	4

Alterations — Proprietary Name

3463G	Diphtheria and Tetanus Vaccine, Adsorbed, Diluted for Adult Use , injection 0.5 mL in pre-filled syringe (Doctor's Bag)	<i>From:</i>	ADT
		<i>To:</i>	ADT Booster
8783G	Diphtheria and Tetanus Vaccine, Adsorbed, Diluted for Adult Use , injection 0.5 mL in pre-filled syringe	<i>From:</i>	ADT
		<i>To:</i>	ADT Booster

Alterations — Manufacturer's Code

		<i>From</i>	<i>To</i>
2593L	Iron Polymaltose Complex , injection 100 mg (iron) in 2 mL (<i>Ferrum H</i>)	BX	AS
8807M	Iron Sucrose , concentrate for solution for infusion 2.7 g (equivalent to 100 mg iron (III)) in 5 mL (<i>Venofer</i>)	BX	AS
8399C	Pantoprazole Sodium Sesquihydrate , tablet (enteric coated), equivalent to 20 mg pantoprazole (<i>Somac</i>)	PH	AH
8007K	Pantoprazole Sodium Sesquihydrate , tablet (enteric coated), equivalent to 40 mg pantoprazole (<i>Somac</i>)	PH	AH
8008L	Pantoprazole Sodium Sesquihydrate , tablet (enteric coated), equivalent to 40 mg pantoprazole (<i>Somac</i>) (Diff. Max. Rpts)	PH	AH

SECTION 100 — HIGHLY SPECIALISED DRUGS PROGRAM

DELETIONS

Deletions — Items

6333H **Amprenavir**, capsule 150 mg (*Agenerase*)
6334J **Amprenavir**, oral solution 15 mg per mL, 240 mL (*Agenerase*)

ALTERATIONS

Restriction Changes (see under 'RESTRICTIONS' below for full details)

- 6450L **Adefovir Dipivoxil**, tablet 10 mg (*Hepsera*)
6363X **Pegfilgrastim**, injection 6 mg in 0.6 mL single use pre-filled syringe (*Neulasta*)

SECTION 100 — IVF/GIFT PROGRAM

ADDITIONS

Additions — Items

- 9606N **Choriogonadotropin Alfa**, powder for injection 250 micrograms with solvent (*Ovidrel*)

SECTION 100 — SPECIAL AUTHORITY PROGRAM

ALTERATIONS

Restriction Changes (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 **October** 2007:

Items discontinued by the manufacturer —

- 1425B **Insulin Neutral — Insulin Isophane (N.P.H.), (Mixed) (Biphasic Isophane)**, injection (human)
100 units (50 units-50 units) per mL, 10 mL (*Mixtard 50/50*)
8006J **Insulin Neutral — Insulin Isophane (N.P.H.), (Mixed) (Biphasic Isophane)**, injection (human)
100 units (20 units-80 units) per mL, 10 mL (*Mixtard 20/80 Penfill 3 mL*)

Advance Notices — Deletion of Brand

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

Brand discontinued by the manufacturer —

- 1426C *Mixtard 30/70, NO* — **Insulin Neutral — Insulin Isophane (N.P.H.), (Mixed) (Biphasic Isophane)**, injection (human) 100 units (30 units-70 units) per mL, 10 mL

RESTRICTIONS

Details of restriction text for new items and restriction alterations as noted above:

6450L **Adefovir Dipivoxil**, tablet 10 mg (*Hepsera*)

Private hospital authority required

Chronic hepatitis B in a patient who has failed antihepadnaviral therapy and who satisfies all of the following criteria:

(1) Repeatedly elevated (greater than 1.2 times the upper limit of normal) serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection (HBe antigen positive and/or serum HBV DNA positive);

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

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

NOTE:

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

Patients may receive treatment in combination with lamivudine for the initial 3 months only of PBS-subsidised adefovir dipivoxil therapy. Patients who are immunocompromised may receive treatment in combination with lamivudine for the initial 12 months of PBS-subsidised adefovir dipivoxil therapy. Thereafter, PBS-subsidised adefovir dipivoxil must be used as monotherapy.

8511Y **Alendronate Sodium**, tablet equivalent to 70 mg alendronic acid (*Alendronate Once Weekly, Fosamax Once Weekly*)

Authority required

Initial treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in patients aged 70 years of age or older and with a BMD T-score of -3.0 or less.

The initial authority application must state the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement;

Continuing treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in patients aged 70 years of age or older and with a BMD T-score of -3.0 or less, where the patient has previously been issued with an authority prescription for this drug.

Authority required

Initial treatment as the sole PBS-subsidised anti-resorptive agent for established 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 included in the authority application.

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;

Continuing treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma, where the patient has previously been issued with an authority prescription for this drug.

9012H **Alendronate Sodium with Colecalciferol**, tablet equivalent to 70 mg alendronic acid with 70 micrograms colecalciferol (*Fosamax Plus*)

Authority required

Initial treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in patients aged 70 years of age or older and with a BMD T-score of -3.0 or less.

The initial authority application must state the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement;

Continuing treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in patients aged 70 years of age or older and with a BMD T-score of -3.0 or less, where the patient has previously been issued with an authority prescription for this drug.

Authority required

Initial treatment as the sole PBS-subsidised anti-resorptive agent for established 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 included in the authority application.

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;

Continuing treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma, where the patient has previously been issued with an authority prescription for this drug.

8574G **Amino Acids — Synthetic, Formula**, compound powder 400 g (*EleCare*)

8443J **Amino Acids — Synthetic, Formula**, compound powder 400 g (*Neocate*)

8754R **Amino Acids — Synthetic, Formula**, compound powder 400 g (*Neocate Advance*)

Authority required

Initial treatment, for up to 3 months, for combined intolerance (not infant colic) to cows' milk protein and protein hydrolysate formulae in a child aged less than 2 years. Combined intolerance is demonstrated when the child has failed to respond to a strict cows' milk protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula. The date of birth of the patient must be included in the authority application.

NOTE:

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

8575H **Amino Acids — Synthetic, Formula**, compound powder 400 g (*EleCare*)

3066J **Amino Acids — Synthetic, Formula**, compound powder 400 g (*Neocate*)

8755T **Amino Acids — Synthetic, Formula**, compound powder 400 g (*Neocate Advance*)

Authority required

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

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

Severe intestinal malabsorption including short bowel syndrome where protein hydrolysate formulae have failed;
Severe intestinal malabsorption including short bowel syndrome where the patient has been receiving parenteral nutrition.

NOTE:

Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

2514H **Anecortave Acetate**, suspension for injection 15 mg in 0.5 mL (*Retaane*)

Authority required

Initial treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of predominantly (greater than or equal to 50%) classic, subfoveal choroidal neovascularisation (CNV) due to age-related macular degeneration (AMD), as diagnosed by fluorescein angiography, in a patient with a baseline visual acuity equal to or better than 6/60 (20/200).

No more than 10 treatments (1 initial and 9 continuing) per eye will be authorised.

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

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

- (a) a completed authority prescription form; and
- (b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form [www.medicareaustralia.gov.au]; and
- (c) a copy of the fluorescein angiogram demonstrating that the CNV is predominantly classic (greater than or equal to 50%).

Written applications for authority to prescribe anecortave acetate should be forwarded to:

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

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

Authority required

Continuing treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of predominantly (greater than or equal to 50%) classic, subfoveal choroidal neovascularisation (CNV) due to age-related macular degeneration (AMD) where the patient has previously been granted an authority prescription for the same eye.

No more than 10 treatments (1 initial and 9 continuing) per eye will be authorised.

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

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

9606N **Choriogonadotropin Alfa**, powder for injection 250 micrograms with solvent (*Ovidrel*)

Patients who are receiving medical treatment as described in items 13200 or 13203 of the Medicare Benefits Schedule.

NOTE:

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

8757X Ezetemibe, tablet 10 mg (*Ezetrol*)

Authority required

Initial treatment, in conjunction with dietary therapy and exercise, for co-administration with an HMG CoA reductase inhibitor (statin) in patients whose cholesterol levels are inadequately controlled with a statin and who have:

- (a) coronary heart disease; or
- (b) diabetes mellitus; or
- (c) peripheral vascular disease; or
- (d) heterozygous familial hypercholesterolaemia; or
- (e) symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy, a cholesterol level in excess of that threshold after at least 3 months of treatment at a daily dose of 40 mg or greater of a statin, in conjunction with dietary therapy and exercise. The cholesterol level after 3 months of treatment with a statin and the dose of the statin must be provided at the time of application. The cholesterol level results provided must be no more than 2 months old at the time of application; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level, a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a daily dose of 40 mg or greater of a statin, in conjunction with dietary therapy and exercise. The cholesterol level after 3 months of treatment with a statin and the dose of the statin must be provided at the time of application. The cholesterol level results provided must be no more than 2 months old at the time of application;

Continuing treatment for co-administration with HMG CoA reductase inhibitors (statins) in patients with coronary heart disease or diabetes mellitus or peripheral vascular disease or heterozygous familial hypercholesterolaemia or symptomatic cerebrovascular disease whose cholesterol levels were inadequately controlled with a statin, where the patient has previously been issued with an authority prescription for this drug.

Authority required

Patients eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs):

- (a) where treatment with an HMG CoA reductase inhibitor (statin) is contraindicated; or
- (b) where treatment with an HMG CoA reductase inhibitor (statin) is unsuitable because the patient developed a clinically important product-related adverse event during treatment with a statin, and required discontinuation of all statin treatment.

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.

8881K **Ezetemibe with Simvastatin**, tablet 10 mg-40 mg (*Vytorin*)
8882L **Ezetemibe with Simvastatin**, tablet 10 mg-80 mg (*Vytorin*)

Authority required

Initial treatment, in conjunction with dietary therapy and exercise, in patients whose cholesterol levels are inadequately controlled with an HMG CoA reductase inhibitor (statin) and who have:

- (a) coronary heart disease; or
- (b) diabetes mellitus; or
- (c) peripheral vascular disease; or
- (d) heterozygous familial hypercholesterolaemia; or
- (e) cerebrovascular disease which has become symptomatic.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy, a cholesterol level in excess of that threshold after at least 3 months of treatment at a daily dose of 40 mg or greater of a statin, in conjunction with dietary therapy and exercise. The cholesterol level after 3 months of treatment with a statin and the dose of the statin must be provided at the time of application. The cholesterol level results provided must be no more than 2 months old at the time of application; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level, a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a daily dose of 40 mg or greater of a statin, in conjunction with dietary therapy and exercise. The cholesterol level after 3 months of treatment with a statin and the dose of the statin must be provided at the time of application. The cholesterol level results provided must be no more than 2 months old at the time of application;

Continuing treatment in patients with coronary heart disease or diabetes mellitus or peripheral vascular disease or heterozygous familial hypercholesterolaemia or symptomatic cerebrovascular disease whose cholesterol levels were inadequately controlled with a statin, where the patient has previously been issued with an authority prescription for this item or the combination of ezetimibe and 40 mg or greater of a statin;

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).

8896F **Famciclovir**, tablet 500 mg (*Famvir*) (Diff. Max. Qty and Rpts)

Authority required

Suppressive therapy of moderate to severe recurrent oral or labial herpes in a patient with HIV infection and:

- (a) a CD4 cell count of less than 150 million per litre; or
- (b) other opportunistic infections or AIDS defining tumours.

Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment.

2549E **Isotretinoin**, capsule 40 mg (*Oratane*)

Authority required

Severe cystic acne not responsive to other therapy.

2387P **Methylphenidate Hydrochloride**, tablet 18 mg (extended release) (*Concerta*)

2388Q **Methylphenidate Hydrochloride**, tablet 36 mg (extended release) (*Concerta*)

2432B **Methylphenidate Hydrochloride**, tablet 54 mg (extended release) (*Concerta*)

Authority required

Treatment of attention deficit hyperactivity disorder (ADHD) in a child or adolescent aged between 6 to 18 years inclusive, who has demonstrated a response to immediate release methylphenidate hydrochloride with no emergence of serious adverse events, and who requires continuous coverage over 12 hours.

6363X **Pegfilgrastim**, injection 6 mg in 0.6 mL single use pre-filled syringe (*Neulasta*)

Private hospital authority required

For use in patients undergoing induction and consolidation therapy for acute myeloid leukaemia; Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in:

- Acute lymphoblastic leukaemia;
- Breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide);
- Ewing's sarcoma;
- Germ cell tumours;
- Infants and children with CNS tumours;
- Neuroblastoma;
- Non-Hodgkin's lymphoma (intermediate or high grade);
- Osteosarcoma;
- Relapsed Hodgkin's disease;
- Rhabdomyosarcoma;

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

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

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

2676W **Protein Hydrolysate Formula with Medium Chain Triglycerides**, compound powder 400 g (*Alfaré*)

Authority required

Initial treatment, for up to 3 months, for intolerance (not infant colic) to cows' milk protein in a child aged less than 2 years. Intolerance is demonstrated when the child has failed to respond to a strict cows' milk protein free diet. The date of birth of the patient must be included in the authority application;

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

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

- Biliary atresia;
- Chronic liver failure with fat malabsorption;
- Chylous ascites;
- Chylothorax;
- Cystic fibrosis;
- Enterokinase deficiency;
- Proven fat malabsorption;
- Severe diarrhoea of greater than 2 weeks' duration in an infant aged less than 4 months. The date of birth of the patient must be included in the authority application;
- Severe intestinal malabsorption including short bowel syndrome.

8259Q **Protein Hydrolysate Formula with Medium Chain Triglycerides**, compound powder 450 g
(*Pepti-Junior*)

Authority required

Initial treatment, for up to 3 months, for intolerance (not infant colic) to cows' milk protein in a child aged less than 2 years. Intolerance is demonstrated when the child has failed to respond to a strict cows' milk protein free diet. The date of birth of the patient must be included in the authority application;

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

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

Biliary atresia;

Chronic liver failure with fat malabsorption;

Chylous ascites;

Cystic fibrosis;

Enterokinase deficiency;

Proven fat malabsorption;

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

Severe intestinal malabsorption including short bowel syndrome.

8787L **Risperidone**, tablet 0.5 mg (*Risperdal*)

8788M **Risperidone**, tablet 0.5 mg (orally disintegrating) (*Risperdal Quicklet*)

8789N **Risperidone**, tablet 1 mg (*Risperdal*)

8790P **Risperidone**, tablet 1 mg (orally disintegrating) (*Risperdal Quicklet*)

9079W **Risperidone**, tablet 2 mg (*Risperdal*) (**Diff. Max. Qty**)

9080X **Risperidone**, tablet 2 mg (orally disintegrating) (*Risperdal Quicklet*) (**Diff. Max. Qty**)

8791Q **Risperidone**, oral solution 1 mg per mL, 30 mL (*Risperdal*)

Authority required

Treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a child or adolescent aged less than 18 years with autism. Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or ICD-10 international classification of mental and behavioural disorders.

3036T **Strontium Ranelate**, sachet containing granules for oral suspension 2 g (*Protos 2 g*)

Authority required

Initial 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 included in the authority application.

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;

Continuing treatment as the sole PBS-subsidised anti-resorptive agent for established post-menopausal osteoporosis in patients with fracture due to minimal trauma, where the patient has previously been issued with an authority prescription for this drug.

NOTE:

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

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

Section 100 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).

9070J **Ziprasidone Hydrochloride**, capsule 20 mg (base) (*Zeldox*)

9071K **Ziprasidone Hydrochloride**, capsule 40 mg (base) (*Zeldox*)

9072L **Ziprasidone Hydrochloride**, capsule 60 mg (base) (*Zeldox*)

9073M **Ziprasidone Hydrochloride**, capsule 80 mg (base) (*Zeldox*)

Authority required

Schizophrenia.

NOTES

Details of Notes for items mentioned above:

Diphtheria and Tetanus Vaccine, Adsorbed, Diluted for Adult Use

For vaccination of children (greater than or equal to 5 years) and adults who have previously received at least 3 doses of a vaccine for primary immunisation against diphtheria and tetanus. ADT Booster is not intended for primary immunisation against diphtheria and tetanus.

Famciclovir

Famciclovir 500 mg is not PBS-subsidised for chickenpox.

Famciclovir 500 mg is not PBS-subsidised for herpes zoster, genital herpes or other herpes simplex infections in immunocompetent patients.