Australian Government

Department of Health and Ageing

SCHEDULE OF PHARMACEUTICAL BENEFITS

SUMMARY OF CHANGES

EFFECTIVE 1 JULY 2009

PHARMACEUTICAL BENEFITS

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 July 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 July 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	$1.03
	Extemporaneously-prepared	$1.39
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 items where a restriction and/or a note applies)

9438R **Amino acid formula with vitamins and minerals without lysine and low in tryptophan**, Sachets 20 g, 30 (*GA gel*)

9437Q **Arginine with carbohydrate**, Sachets 4 g containing 500 mg arginine, 30 (*Arginine Amino Acid Supplement*)

9439T **Atovaquone with proguanil hydrochloride**, Tablet 250 mg-100 mg (*Malarone*)

9442Y **Bevacizumab**, Solution for I.V. infusion 100 mg in 4 mL (*Avastin*)

9443B **Bevacizumab**, Solution for I.V. infusion 400 mg in 16 mL (*Avastin*)

9432K **Escitalopram oxalate**, Tablet 10 mg (base) (*Esipram, Esitalo, Lexapro*)

9433L **Escitalopram oxalate**, Tablet 20 mg (base) (*Esipram, Esitalo, Lexapro*)

5557L **Framycetin sulfate**, Eye and ear drops 5 mg per mL (0.5%), 8 mL (*Soframycin*) **(Optometrical)**

9436P **Isoleucine with carbohydrate**, Sachets 4 g containing 1 g isoleucine, 30 (*Isoleucine 1000 Amino Acid Supplement*)

9435N **Metformin hydrochloride**, Tablets 500 mg (extended release), 120 (*Diabex XR*)

9440W **Mupirocin**, Nasal ointment 20 mg (as calcium) per g (2%), 3 g (*Bactroban*)

9441X **Ondansetron**, Syrup 4 mg per 5 mL, 50 mL (*Zofran syrup 50 mL*)

9391G **Risedronate sodium**, Tablet 150 mg (*Actonel Once-a-Month*)

9434M **Valine with carbohydrate**, Sachets 4 g containing 1 g valine, 30 (*Valine 1000 Amino Acid Supplement*)

Additions — Brands

9183H *Dronalen Plus, GM* — **Alendronate sodium with colecalciferol**, Tablet equivalent to 70 mg alendronic acid with 140 micrograms colecalciferol

8700X *APO-Escitalopram, TX; Chem mart Escitalopram, CH; Terry White Chemists Escitalopram, TW* — **Escitalopram oxalate**, Tablet 10 mg (base)

8701Y *APO-Escitalopram , TX; Chem mart Escitalopram , CH; Terry White Chemists Escitalopram , TW* — **Escitalopram oxalate**, Tablet 20 mg (base)

1434L *Fluoxetine generichealth, GQ* — **Fluoxetine hydrochloride**, Capsule 20 mg (base)

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

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

8212F *Humalog Pen, KP* — **Insulin lispro**, Injections (human analogue) 100 units per mL, 3 mL, 5

8390N *Humalog Mix25 Pen, KP* — **Insulin lispro—insulin lispro protamine suspension**, Injections (human analogue) 100 units (25 units-75 units) per mL, 3 mL, 5

8874C *Humalog Mix50 Pen, KP* — **Insulin lispro—insulin lispro protamine suspension**, Injections (human analogue) 100 units (50 units-50 units) per mL, 3 mL, 5

8414W *Irinotecan Actavis, GQ* — **Irinotecan hydrochloride trihydrate**, I.V. injection 40 mg in 2 mL

8415X *Irinotecan Actavis, GQ* — **Irinotecan hydrochloride trihydrate**, I.V. injection 100 mg in 5 mL

2458J *Lisinopril-GA, GN* — **Lisinopril**, Tablet 20 mg

8539K *Oxaliplatin Actavis, GQ* — **Oxaliplatin**, Powder for I.V. infusion 50 mg

8540L *Oxaliplatin Actavis, GQ* — **Oxaliplatin**, Powder for I.V. infusion 100 mg

3050M *Ozapace, RA* — **Perindopril**, Tablet containing 2 mg perindopril erbumine

3051N *Ozapace, RA* — **Perindopril**, Tablet containing 4 mg perindopril erbumine

8704D *Ozapace, RA* — **Perindopril**, Tablet containing 8 mg perindopril erbumine

8787L *Ozidal, RA* — **Risperidone**, Tablet 0.5 mg

8869T *Ozidal, RA* — **Risperidone**, Tablet 0.5 mg **(Diff. Max. Rpts)**

8789N *Ozidal, RA* — **Risperidone**, Tablet 1 mg

3169T *Ozidal, RA* — **Risperidone**, Tablet 1 mg **(Diff. Max. Rpts)**
9079W *Ozidal, RA* — **Risperidone**, Tablet 2 mg
3170W *Ozidal, RA* — **Risperidone**, Tablet 2 mg **(Diff. Max. Rpts)**
3171X *Ozidal, RA* — **Risperidone**, Tablet 3 mg
3172Y *Ozidal, RA* — **Risperidone**, Tablet 4 mg
8523N *APO-Tramadol SR, TX; Chem mart Tramadol SR, CH; Terry White Chemists Tramadol SR, TW* — **Tramadol hydrochloride**, Tablet 100 mg (twice daily sustained release)
5234L *APO-Tramadol SR, TX; Chem mart Tramadol SR, CH; Terry White Chemists Tramadol SR, TW* — **Tramadol hydrochloride**, Tablet 100 mg (twice daily sustained release) **(Dental)**
8524P *APO-Tramadol SR, TX; Chem mart Tramadol SR, CH; Terry White Chemists Tramadol SR, TW* — **Tramadol hydrochloride**, Tablet 150 mg (twice daily sustained release)
5235M *APO-Tramadol SR, TX; Chem mart Tramadol SR, CH; Terry White Chemists Tramadol SR, TW* — **Tramadol hydrochloride**, Tablet 150 mg (twice daily sustained release) **(Dental)**
8525Q *APO-Tramadol SR, TX; Chem mart Tramadol SR, CH; Terry White Chemists Tramadol SR, TW* — **Tramadol hydrochloride**, Tablet 200 mg (twice daily sustained release)
5236N *APO-Tramadol SR, TX; Chem mart Tramadol SR, CH; Terry White Chemists Tramadol SR, TW* — **Tramadol hydrochloride**, Tablet 200 mg (twice daily sustained release) **(Dental)**
2791X *Trandolapril generichealth, GQ* — **Trandolapril**, Capsule 500 micrograms
2792Y *Trandolapril generichealth, GQ* — **Trandolapril**, Capsule 1 mg
2793B *Trandolapril generichealth, GQ* — **Trandolapril**, Capsule 2 mg
8758Y *Trandolapril generichealth, GQ* — **Trandolapril**, Capsule 4 mg

Additions—Notes

(see under 'NOTES' below for full details)

8780D **Risperidone**, Powder for I.M. injection 25 mg (modified release) with 2 mL diluent in pre-filled syringe (*Risperdal Consta*)
8781E **Risperidone**, Powder for I.M. injection 37.5 mg (modified release) with 2 mL diluent in pre-filled syringe (*Risperdal Consta*)
8782F **Risperidone**, Powder for I.M. injection 50 mg (modified release) with 2 mL diluent in pre-filled syringe (*Risperdal Consta*)

Additions—Bioequivalence Indicator

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

9183H *Fosamax Plus 70 mg/140 mcg, MK* — **Alendronate sodium with colecalciferol**, Tablet equivalent to 70 mg alendronic acid with 140 micrograms colecalciferol

DELETIONS

Deletions—Items

2514H **Anecortave acetate**, Suspension for injection 15 mg in 0.5 mL *(Retaane)*
1764W **Oestradiol and oestradiol with norethisterone acetate**, Pack containing 12 tablets oestradiol 2 mg, 10 tablets oestradiol 2 mg with norethisterone acetate 1 mg and 6 tablets oestradiol 1 mg (*Trisequens*)
8353P **Oestradiol with norethisterone acetate**, Tablets 1 mg-500 micrograms, 28 (*Kliovance*)
8081H **Oestradiol with norethisterone acetate**, Tablets 2 mg-1 mg, 28 (*Kliogest*)

Deletions—Brands

1889K *Amohexal, HX* — **Amoxycillin**, Capsule 500 mg
3300Q *Amohexal, HX* — **Amoxycillin**, Capsule 500 mg **(Dental)**
1887H *Amohexal, HX* — **Amoxycillin**, Powder for syrup 250 mg per 5 mL, 100 mL
3393N *Amohexal, HX* — **Amoxycillin**, Powder for syrup 250 mg per 5 mL, 100 mL **(Dental)**

1368B *Amprace 10, FR* — **Enalapril maleate**, Tablet 10 mg
1369C *Amprace 20, FR* — **Enalapril maleate**, Tablet 20 mg
1694E *Nypine 10, AW* — **Nifedipine**, Tablet 10 mg
1695F *Nypine 20, AW* — **Nifedipine**, Tablet 20 mg
8539K *Winthrop Oxaliplatin, WA* — **Oxaliplatin**, Powder for I.V. infusion 50 mg
1746X *Parahexal, HX* — **Paracetamol**, Tablet 500 mg
8784H *Parahexal, HX* — **Paracetamol**, Tablet 500 mg **(Diff. Max. Qty and Rpts)**
5196L *Parahexal, HX* — **Paracetamol**, Tablet 500 mg **(Dental)**
5224Y *Parahexal, HX* — **Paracetamol**, Tablet 500 mg **(Dental) (Diff. Max. Qty)**

Deletions—Bioequivalence Indicators

The bioequivalence indicator (b) has been removed from the following brands:

1746X *Parmol, SI* — **Paracetamol**, Tablet 500 mg
8784H *Parmol, SI* — **Paracetamol**, Tablet 500 mg **(Diff. Max. Qty and Rpts)**
5196L *Parmol, SI* — **Paracetamol**, Tablet 500 mg **(Dental)**
5224Y *Parmol, SI* — **Paracetamol**, Tablet 500 mg **(Dental) (Diff. Max. Qty)**

ALTERATIONS

Alterations—Restrictions

(see under 'RESTRICTIONS' below for full details)

1256D **Cephazolin**, Powder for injection 500 mg (*HH*)
1257E **Cephazolin**, Powder for injection 1 g (*Cefazolin Sandoz, Kefzol, HH*)
9123E **Imatinib**, Tablet 100 mg (as mesylate) (*Glivec*)
9124F **Imatinib**, Tablet 400 mg (as mesylate) (*Glivec*)
8895E **Latanoprost with timolol maleate**, Eye drops 50 micrograms-5 mg (base) per mL (0.005%-0.5%), 2.5 mL (*Xalacom*)
5553G **Latanoprost with timolol maleate**, Eye drops 50 micrograms-5 mg (base) per mL (0.005%-0.5%), 2.5 mL (*Xalacom*) **(Optometrical)**
8816B **Modafinil**, Tablet 100 mg (*Modavigil*)
9057Q **Travoprost with timolol maleate**, Eye drops 40 micrograms-5 mg (base) per mL (0.004%-0.5%), 2.5 mL (*Duotrav*)
5555J **Travoprost with timolol maleate**, Eye drops 40 micrograms-5 mg (base) per mL (0.004%-0.5%), 2.5 mL (*Duotrav*) **(Optometrical)**

SECTION 100

HIGHLY SPECIALISED DRUGS PROGRAM

ADDITIONS

Additions—Item

(see under 'RESTRICTIONS' below for full details)

9639H **Etravirine**, Tablet 100 mg (*Intelence*)

BOTULINUM TOXIN PROGRAM

ALTERATIONS

Alterations—Restrictions

(see under 'RESTRICTIONS' below for full details)

6103F **Botulinum toxin type A purified neurotoxin complex**, Lyophilised powder for I.M. injection 100 units (*Botox*)

6293F **Clostridium botulinum type A toxin—haemagglutinin complex**, Lyophilised powder for I.M. injection 500 units (*Dysport*)

HUMAN GROWTH HORMONE PROGRAM
ALTERATIONS

Alterations—Restrictions

The preamble for the Human Growth Hormone Program has been amended (see the entry for Somatropin under 'RESTRICTIONS' below for full details).

ADVANCE NOTICES

Advance Notice—Deletion of Items

The following items will be deleted from the Schedule of Pharmaceutical Benefits on 1 September 2009:

Deletions requested by the manufacturer—

8861J **Etanercept**, Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*)

8862K **Etanercept**, Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*) **(Diff. Max. Rpts)**

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

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

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

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

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

9430H **Etanercept**, Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*) **(Diff. Max. Rpts)**

The following item will be deleted from the Schedule of Pharmaceutical Benefits on 1 October 2009:

Deletion requested by the manufacturer—

6393L **Ribavirin and peginterferon alfa-2a**, Pack containing 84 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 180 micrograms (*Pegasys RBV*)

Retention of Brands

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

8784H **Paracetamol**, Tablet 500 mg (*Dymadon P*)

5196L **Paracetamol**, Tablet 500 mg (*Dymadon P*) **(Dental)**

5224Y **Paracetamol**, Tablet 500 mg (*Dymadon P*) **(Dental) (Diff. Max. Qty)**

RESTRICTIONS

The text of restrictions mentioned above:

9438R **Amino acid formula with vitamins and minerals without lysine and low in tryptophan**, Sachets 20 g, 30 (*GA gel*)

Restricted benefit

A child aged from 6 months up to 10 years with proven glutaric aciduria type 1

9437Q **Arginine with carbohydrate**, Sachets 4 g containing 500 mg arginine, 30 (*Arginine Amino Acid Supplement*)

Restricted benefit

Urea cycle disorders

NOTE:

Arginine with carbohydrate is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism.

9439T **Atovaquone with proguanil hydrochloride**, Tablet 250 mg-100 mg (*Malarone*)

Authority required

Treatment of suspected or confirmed Plasmodium falciparum malaria in a patient aged 3 years or older where quinine containing regimens are inappropriate

NOTE:

Atovaquone with proguanil hydrochloride is not PBS-subsidised for the prophylaxis of malaria.

9442Y **Bevacizumab**, Solution for I.V. infusion 100 mg in 4 mL (*Avastin*)
9443B **Bevacizumab**, Solution for I.V. infusion 400 mg in 16 mL (*Avastin*)

Authority required

Initial PBS-subsidised treatment, in combination with first-line chemotherapy, of a patient with previously untreated metastatic colorectal cancer with a WHO performance status of 0 or 1

Authority required

Continuing PBS-subsidised treatment, in combination with first-line chemotherapy, of a patient with metastatic colorectal cancer who has previously been issued with an authority prescription for bevacizumab and who does not have progressive disease and who remains on first-line chemotherapy

NOTE:

Not for use as monotherapy.

NOTE:

Special Pricing Arrangements apply.

6103F **Botulinum toxin type A purified neurotoxin complex**, Lyophilised powder for I.M. injection 100 units (*Botox*)

NOTE:

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

Criteria for availability

Treatment of blepharospasm associated with dystonia, including benign blepharospasm and VIIth nerve disorders (hemifacial spasm) in patients 12 years and older

Criteria for availability

Treatment of dynamic equinus foot deformity due to spasticity in an ambulant paediatric cerebral palsy patient aged from 2 to 17 years inclusive

Criteria for availability

Continuing PBS-subsidised treatment of dynamic equinus foot deformity due to spasticity in an ambulant cerebral palsy patient 18 years of age or older who was commenced on PBS-subsidised treatment with botulinum toxin type A purified neurotoxin complex as a paediatric patient

Criteria for availability

Treatment of spasmodic torticollis, either as monotherapy or as adjunctive therapy to current standard care

Criteria for availability

Treatment of moderate to severe spasticity of the upper limb in a cerebral palsy patient aged from 2 to 17 years inclusive

Criteria for availability

Continuing PBS-subsidised treatment of moderate to severe spasticity of the upper limb in a cerebral palsy patient 18 years of age or older who was commenced on PBS-subsidised treatment with botulinum toxin type A purified neurotoxin complex as a paediatric patient

NOTE:

Contact Medicare Australia before commencing PBS-subsidised treatment in cerebral palsy patients who have been treated for moderate to severe spasticity of the upper limb with non-PBS-subsidised botulinum toxin prior to the age of 18.

Criteria for availability

Treatment of moderate to severe spasticity [defined as MAS greater than or equal to 3 using modified Ashworth scale] of the upper limb in adults following a stroke, as second line therapy when standard management has failed (e.g. physiotherapy and/or oral spasticity agents) or as an adjunct to physical therapy.

Maximum number of treatments to be authorised is 4 (total Botox and Dysport) per upper limb per lifetime. Treatment should not be initiated until 3 months post-stroke in patients who do not have established severe contracture. Treatment should be discontinued if the patient does not respond (decrease of MAS greater than 1 in at least one joint) after two treatments.

The date of the stroke must be provided.

Contraindications to treatment include established severe contracture, known sensitivity to botulinum toxin.

NOTE:

The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

1257E **Cephazolin**, Powder for injection 1 g (*Cefazolin Sandoz*, *Kefzol*, *HH*)

1256D **Cephazolin**, Powder for injection 500 mg (*HH*)

Restricted benefit

Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

Restricted benefit

Septicaemia, suspected

Restricted benefit

Septicaemia, proven

Restricted benefit

Cellulitis

6293F **Clostridium botulinum type A toxin—haemagglutinin complex**, Lyophilised powder for I.M. injection 500 units (*Dysport*)

NOTE:

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

Criteria for availability

Treatment of dynamic equinus foot deformity due to spasticity in an ambulant paediatric cerebral palsy patient aged from 2 to 17 years inclusive

Criteria for availability

Continuing PBS-subsidised treatment of dynamic equinus foot deformity due to spasticity in an ambulant cerebral palsy patient 18 years of age or older who was commenced on PBS-subsidised treatment with clostridium botulinum type A toxin-haemagglutinin complex as a paediatric patient

Criteria for availability

Treatment of spasmodic torticollis, either as monotherapy or as adjunctive therapy to current standard care

Criteria for availability

Treatment of moderate to severe spasticity [defined as MAS greater than or equal to 3 using modified Ashworth scale] of the upper limb in adults following a stroke, as second line therapy when standard management has failed (e.g. physiotherapy and/or oral spasticity agents) or as an adjunct to physical therapy.

Maximum number of treatments to be authorised is 4 (total Botox and Dysport) per upper limb per lifetime. Treatment should not be initiated until 3 months post-stroke in patients who do not have established severe contracture. Treatment should be discontinued if the patient does not respond (decrease of MAS greater than 1 in at least one joint) after two treatments.

The date of the stroke must be provided.

Contraindications to treatment include established severe contracture, known sensitivity to botulinum toxin.

NOTE:

The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

9432K **Escitalopram oxalate**, Tablet 10 mg (base) (*Esipram*, *Esitalo*, *Lexapro*)
9433L **Escitalopram oxalate**, Tablet 20 mg (base) (*Esipram*, *Esitalo*, *Lexapro*)

Restricted benefit

Moderate to severe generalised anxiety disorder (GAD), as defined by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, in a patient who has not responded to non-pharmacological therapy and

for whom a GP Mental Health Care Plan, as described under item 2710 of the Medicare Benefits Schedule, has been prepared

Restricted benefit

Moderate to severe generalised anxiety disorder (GAD), as defined by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, in a patient who has not responded to non-pharmacological therapy and

who has been assessed by a psychiatrist

Restricted benefit

Continuing PBS-subsidised treatment, for moderate to severe generalised anxiety disorder (GAD), of a patient commenced on escitalopram prior to 1 March 2008

Restricted benefit

Moderate to severe social anxiety disorder (social phobia, SAD), as described by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, in a patient who has not responded to non-pharmacological therapy and

for whom a GP Mental Health Care Plan, as described under item 2710 of the Medicare Benefits Schedule, has been prepared

Restricted benefit

Moderate to severe social anxiety disorder (social phobia, SAD), as described by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, in a patient who has not responded to non-pharmacological therapy and

who has been assessed by a psychiatrist

Restricted benefit

Continuing PBS-subsidised treatment, for moderate to severe social anxiety disorder (social phobia, SAD), of a patient commenced on escitalopram prior to 1 March 2008

9639H **Etravirine**, Tablet 100 mg (*Intelence*)

Private hospital authority required

Treatment, in combination with other antiretroviral agents, of HIV infection in an antiretroviral experienced patient with:

(a) evidence of HIV replication (viral load greater than 10,000 copies per mL); and/or

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

A patient must have failed previous treatment with, or have resistance to, 3 different antiretroviral regimens which have included:

(i) at least 1 non-nucleoside reverse transcriptase inhibitor; and

(ii) at least 1 nucleoside reverse transcriptase inhibitor; and

(iii) at least 1 protease inhibitor

9123E **Imatinib**, Tablet 100 mg (as mesylate) (*Glivec*)
9124F **Imatinib**, Tablet 400 mg (as mesylate) (*Glivec*)

NOTE:

Any queries concerning the arrangements to prescribe imatinib mesylate 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 imatinib mesylate should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

For the following diseases, written authority is required at initiation and for continuation:

Chronic myeloid leukaemia (chronic phase);

Dermatofibrosarcoma protuberans;

Hypereosinophilic syndrome;

Chronic eosinophilic leukaemia;

Myelodysplastic or myeloproliferative disorder;

Aggressive systemic mastocytosis with eosinophilia.

NOTE:

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

Authority required

Initial treatment in combination with chemotherapy as induction or consolidation of a newly diagnosed patient with acute lymphoblastic leukaemia (ALL) bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL.

The first authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Acute Lymphoblastic Leukaemia Imatinib PBS Authority Application - Supporting Information Form; and

(c) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow. (The date of the relevant pathology report needs to be provided); and

(d) a signed patient acknowledgement

Authority required

Initial treatment of a patient with acute lymphoblastic leukaemia bearing the Philadelphia chromosome or expressing the transcript BCR-ABL who was previously treated with imatinib mesylate under the Imatinib Compassionate Program and who meets all the PBS criteria.

The first authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Acute Lymphoblastic Leukaemia Imatinib PBS Authority Application - Supporting Information Form; and

(c) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow. (The date of the relevant pathology report needs to be provided); and

(d) a signed patient acknowledgement

Authority required

Continuing treatment in combination with chemotherapy as maintenance of first complete remission of patients with acute lymphoblastic leukaemia bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL.

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

Imatinib mesylate is available with a lifetime maximum of 24 months for continuing treatment with imatinib mesylate therapy for patients with acute lymphoblastic leukaemia reimbursed through the PBS.

Any queries concerning the arrangements to prescribe imatinib mesylate beyond 24 months may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

NOTE:

Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

NOTE:

No applications for increased repeats will be authorised.

9436P **Isoleucine with carbohydrate**, Sachets 4 g containing 1 g isoleucine, 30 (*Isoleucine 1000 Amino Acid Supplement*)

9434M **Valine with carbohydrate**, Sachets 4 g containing 1 g valine, 30 (*Valine 1000 Amino Acid Supplement*)

Restricted benefit

Maple syrup urine disease

8895E **Latanoprost with timolol maleate**, Eye drops 50 micrograms-5 mg (base) per mL (0.005%-0.5%), 2.5 mL (*Xalacom*)

5553G **Latanoprost with timolol maleate**, Eye drops 50 micrograms-5 mg (base) per mL (0.005%-0.5%), 2.5 mL (*Xalacom*)

9057Q **Travoprost with timolol maleate**, Eye drops 40 micrograms-5 mg (base) per mL (0.004%-0.5%), 2.5 mL (*Duotrav*)

5555J **Travoprost with timolol maleate**, Eye drops 40 micrograms-5 mg (base) per mL (0.004%-0.5%), 2.5 mL (*Duotrav*)

Restricted benefit

Reduction of elevated intra-ocular pressure in patients with open-angle glaucoma who are not adequately controlled with timolol maleate 5 mg (base) per mL (0.5%) eye drops or prostaglandin or prostamide analogue monotherapies

Restricted benefit

Reduction of elevated intra-ocular pressure in patients with ocular hypertension who are not adequately controlled with timolol maleate 5 mg (base) per mL (0.5%) eye drops or prostaglandin or prostamide analogue monotherapies

8816B **Modafinil**, Tablet 100 mg (*Modavigil*)

NOTE:

Any queries concerning the arrangements to prescribe modafinil 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 modafinil 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.

NOTE:

Modafinil is not PBS-subsidised when used in combination with PBS-subsidised dexamphetamine sulfate.

Authority required

Initial treatment, by a qualified sleep medicine practitioner or neurologist, of patients with narcolepsy where:

(i) therapy with dexamphetamine sulfate poses an unacceptable medical risk; or

(ii) intolerance to dexamphetamine sulfate of a severity necessitating treatment withdrawal develops.

The presence of any 1 of the following indicates treatment with dexamphetamine sulfate poses an unacceptable medical risk:

(a) a psychiatric disorder;

(b) a cardiovascular disorder;

(c) a history of substance abuse;

(d) glaucoma;

(e) any other absolute contraindication to dexamphetamine sulfate as specified in the TGA-approved Product Information.

Patients must meet the following definition of narcolepsy:

Excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months and:

(i) a definite history of cataplexy;

or

a mean sleep latency less than or equal to 10 minutes on a Multiple Sleep Latency Test (MSLT). The MSLT must be preceded by nocturnal polysomnography. Sleep prior to the MSLT must be at least 6 hours in duration;

or

an electroencephalographic (EEG) recording showing the pathologically rapid development of REM sleep; and

(ii) absence of any medical or psychiatric disorder that could otherwise account for the hypersomnia.

The authority application must be made in writing and must include the following:

(a) a completed authority prescription form; and

(b) a completed Modafinil (Modavigil) PBS Authority Application for Use in the Treatment of Narcolepsy - Supporting Information Form [www.medicareaustralia.gov.au]; and

(c) details of the contraindication or intolerance to dexamphetamine sulfate; and

(d) either:

(i) the result and date of the polysomnography test and MSLT conducted by, or under the supervision of, a qualified sleep medicine practitioner; or

(ii) the result and date of the EEG, conducted by, or under the supervision of, a neurologist.

The polysomnography, MSLT or EEG test reports must be provided with the authority application

Authority required

Continuing treatment of narcolepsy, where the patient has previously been issued with an authority prescription for this drug

9440W **Mupirocin**, Nasal ointment 20 mg (as calcium) per g (2%), 3 g (*Bactroban*)

Authority required (STREAMLINED)

3136

Nasal colonisation with Staphylococcus aureus in an Aboriginal or a Torres Strait Islander person

NOTE:

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

9441X **Ondansetron**, Syrup 4 mg per 5 mL, 50 mL (*Zofran syrup 50 mL*)

Restricted benefit

Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle

9391G **Risedronate sodium**, Tablet 150 mg (*Actonel Once-a-Month*)

Authority required (STREAMLINED)

3070

Treatment as the sole PBS-subsidised anti-resorptive agent for corticosteroid-induced osteoporosis in a patient currently on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy with a Bone Mineral Density (BMD) T-score of -1.5 or less.

The duration and dose of corticosteroid therapy together with 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)

2645

Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a patient aged 70 years of age 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)

2646

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 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, strontium ranelate and zoledronic acid.

Somatropin (Recombinant human growth hormone)

Criteria for availability

Short stature in accordance with the 'Guidelines for the Availability of Human Growth Hormone (hGH) as a Pharmaceutical Benefit'.

Genotropin branded products (including MiniQuick) are also available for the treatment of Prader-Willi Syndrome in accordance with the 'Guidelines for the Availability of Human Growth Hormone (hGH) as a Pharmaceutical Benefit for the treatment of Prader-Willi Syndrome'.

NOTE:

These guidelines may be obtained from the Department of Health and Ageing's internet site at *http://www.health.gov.au/hGH,* or from:

Growth Hormone Program

Access and Systems Branch

Department of Health and Ageing

GPO Box 9848

CANBERRA ACT 2601

Contact telephone number (02) 6289 7274

NOTES

The text of notes mentioned above:

8780D **Risperidone**, Powder for I.M. injection 25 mg (modified release) with 2 mL diluent in pre-filled syringe (*Risperdal Consta*)

8781E **Risperidone**, Powder for I.M. injection 37.5 mg (modified release) with 2 mL diluent in pre-filled syringe (*Risperdal Consta*)

8782F **Risperidone**, Powder for I.M. injection 50 mg (modified release) with 2 mL diluent in pre-filled syringe (*Risperdal Consta*)

NOTE:

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

REPATRIATION PHARMACEUTICAL BENEFITS

These changes to the Repatriation Pharmaceutical Benefits Schedule are effective from 1 July 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

DELETIONS

Deletions—Items

4020N **Miconazole nitrate**, Pessaries 100 mg, 7 (*Monistat 7*)

4021P **Miconazole nitrate**, Vaginal cream 100 mg per 5 g (2%), 40 g (*Monistat 7*)

Deletions - Brand

4007X *Hexal Konazol 2% Shampoo, HX* — **Ketoconazole**, Shampoo 20 mg per g (2%), 100 mL