Australian Government

Department of Health and Ageing

SCHEDULE OF PHARMACEUTICAL BENEFITS

SUMMARY OF CHANGES

EFFECTIVE 1 DECEMBER 2008

PHARMACEUTICAL BENEFITS

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 December 2008. 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 December 2008 and are included, where applicable, in prices published in the Schedule—

Dispensing Fees:	Ready-prepared	$5.99
	Dangerous drug fee	$2.71
	Extemporaneously-prepared	$8.03
	Allowable additional patient charge*	$3.63
Additional Fees (for safety net prices):	Ready-prepared	$1.03
	Extemporaneously-prepared	$1.39
Patient Co-payments:	General	$31.30
	Concessional	$5.00
Safety Net Thresholds:	General	$1141.80
	Concessional	$290.00
Safety Net Card Issue Fee:		$7.86

*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 'NOTES' and 'RESTRICTIONS' below for full details)

9289X **Atomoxetine hydrochloride**, Capsule 80 mg (base) (*Strattera*)

9290Y **Atomoxetine hydrochloride**, Capsule 100 mg (base) (*Strattera*)

9230T **Atorvastatin calcium**, Tablet 10 mg (atorvastatin) (*Lipitor*)

9231W **Atorvastatin calcium**, Tablet 20 mg (atorvastatin) (*Lipitor*)

9232X **Atorvastatin calcium**, Tablet 40 mg (atorvastatin) (*Lipitor*)

9233Y **Atorvastatin calcium**, Tablet 80 mg (atorvastatin) (*Lipitor*)

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)**

9249T **Cholestyramine**, Sachets 4.7 g (equivalent to 4 g cholestyramine), 50 (*Questran Lite*)

9250W **Colestipol hydrochloride**, Sachets 5 g, 120 (*Colestid*)

9291B **Docetaxel**, Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL and 1 single use use vial solvent 1.5 mL (*Taxotere*)

9246P **Fenofibrate**, Tablet 48 mg (*Lipidil*)

9247Q **Fenofibrate**, Tablet 145 mg (*Lipidil*)

9207N **Fludarabine phosphate**, Solution for I.V. injection 50 mg in 2 mL (*Fludarabine Ebewe*)

9234B **Fluvastatin sodium**, Capsule 20 mg (fluvastatin) (*Lescol, Vastin*)

9235C **Fluvastatin sodium**, Capsule 40 mg (fluvastatin) (*Lescol, Vastin*)

9236D **Fluvastatin sodium**, Tablet 80 mg (fluvastatin) (prolonged release) (*Lescol XL*)

9248R **Gemfibrozil**, Tablet 600 mg (*Ausgem, Chem mart Gemfibrozil, Gemhexal, GenRx Gemfibrozil, Jezil, Lipazil 600 mg, Pharmacor Gemfibrozil 600, Terry White Chemists Gemfibrozil, Lopid*)

9292C **Levodopa with carbidopa and entacapone**, Tablet 200 mg-50 mg-200 mg (*Stalevo 200/50/200mg*)

5419F **Macrogol 3350**, Sachets containing powder for solution 6.563 g with electrolytes, 30 (*Movicol-Half*) **(Palliative Care)**

5420G **Macrogol 3350**, Sachets containing powder for solution 6.563 g with electrolytes, 30 (*Movicol-Half*) **(Palliative Care) (Diff. Max. Rpts)**

9198D **Nicotine**, Transdermal patch releasing approximately 15 mg per 16 hours (*Nicorette Patch*)

9225M **Pancreatic extract**, Capsule (containing enteric coated minimicrospheres) providing not less than 5,000 BP units of lipase activity (*Creon 5000*)

9226N **Pancreatic extract**, Capsule (containing enteric coated minimicrospheres) providing not less than 10,000 BP units of lipase activity (*Creon 10,000*)

9227P **Pancreatic extract**, Capsule (containing enteric coated minimicrospheres) providing not less than 25,000 BP units of lipase activity (*Creon 25,000*)

9228Q **Pancrelipase**, Capsule (containing enteric coated microspheres) providing not less than 10,000 BP units of lipase activity (*Cotazym-S Forte*)

9229R **Pancrelipase**, Capsule (containing enteric coated microtablets) providing not less than 25,000 BP units of lipase activity (*Panzytrat 25000*)

9286R **Phenoxybenzamine hydrochloride**, Capsules 10 mg, 100 (*Dibenzyline*) **(Effective 14 October 2008)**

9237E **Pravastatin sodium**, Tablet 10 mg (*Chem mart Pravastatin, Cholstat 10, GenRx Pravastatin, Lipostat 10, Liprachol, Pravastatin 10, Pravastatin-DP, Pravastatin-GA 10, Pravastatin generichealth, Pravastatin Winthrop, Terry White Chemists Pravastatin, Pravachol*)

9238F **Pravastatin sodium**, Tablet 20 mg (*Chem mart Pravastatin, Cholstat 20, GenRx Pravastatin, Lipostat 20, Liprachol, Pravastatin 20, Pravastatin-DP, Pravastatin-GA 20, Pravastatin generichealth, Pravastatin Winthrop, Terry White Chemists Pravastatin, Vastoran, Pravachol*)

9239G **Pravastatin sodium**, Tablet 40 mg (*Chem mart Pravastatin, Cholstat 40, GenRx Pravastatin, Lipostat 40, Liprachol, Pravastatin 40, Pravastatin-DP, Pravastatin-GA 40, Pravastatin generichealth, Pravastatin Winthrop, Terry White Chemists Pravastatin, Vastoran, Pravachol*)

9240H **Pravastatin sodium**, Tablet 80 mg (*Lipostat 80, Pravastatin-GA 80, Pravastatin generichealth, Pravachol*)

9293D **Risperidone**, Oral solution 1 mg per mL, 100 mL (*Risperdal*)

9241J **Simvastatin**, Tablet 5 mg (*Simvabell, Simvahexal, Simvasyn, Zimstat, Zocor*)

9242K **Simvastatin**, Tablet 10 mg (*Chem mart Simvastatin, GenRx Simvastatin, Ransim, Simvabell, Simvahexal, Simvar 10, Simvastatin-DP, Simvastatin generichealth, Simvastatin Winthrop, Simvasyn, Terry White Chemists Simvastatin, Zimstat, GN, Lipex 10, Zocor*)

9243L **Simvastatin**, Tablet 20 mg (*Chem mart Simvastatin, GenRx Simvastatin, Ransim, Simvabell, Simvahexal, Simvar 20, Simvastatin-DP, Simvastatin generichealth, Simvastatin Winthrop, Simvasyn, Terry White Chemists Simvastatin, Zimstat, GN, Lipex 20, Zocor*)

9244M **Simvastatin**, Tablet 40 mg (*Chem mart Simvastatin, GenRx Simvastatin, Ransim, Simvabell, Simvahexal, Simvar 40, Simvastatin-DP, Simvastatin generichealth, Simvastatin Winthrop, Simvasyn, Terry White Chemists Simvastatin, Zimstat, GN, Lipex 40, Zocor*)

9245N **Simvastatin**, Tablet 80 mg (*Chem mart Simvastatin, GenRx Simvastatin, Ransim, Simvabell, Simvahexal, Simvar 80, Simvastatin-DP, Simvastatin generichealth, Simvastatin Winthrop, Simvasyn, Terry White Chemists Simvastatin, Zimstat, GN, Lipex 80, Zocor*)

9287T **Thyroxine sodium**, Tablet equivalent to 75 micrograms anhydrous thyroxine sodium (*Eutroxsig, Oroxine*)

9288W **Zoledronic acid**, Solution for I.V. infusion 5 mg (as monohydrate) in 100 mL (*Aclasta*)

Additions — Brands

(see under 'NOTES' and 'RESTRICTIONS' below for full details)

1886G *Amoxycillin Sandoz, SZ* — **Amoxycillin**, Powder for syrup 125 mg per 5 mL, 100 mL

3302T *Amoxycillin Sandoz, SZ* — **Amoxycillin**, Powder for syrup 125 mg per 5 mL, 100 mL **(Dental)**

1081X *Atenolol-GA, GN* — **Atenolol**, Tablet 50 mg

3119E *Cefalexin Sandoz, SZ* — **Cephalexin**, Capsule 500 mg

3318P *Cefalexin Sandoz, SZ* — **Cephalexin**, Capsule 500 mg **(Dental)**

8374R *APO-Leflunomide, TX* — **Leflunomide**, Tablet 10 mg

8375T *APO-Leflunomide, TX* — **Leflunomide**, Tablet 20 mg

2456G *Lisinopril generichealth, GQ* — **Lisinopril**, Tablet 5 mg

2457H *Lisinopril generichealth, GQ* — **Lisinopril**, Tablet 10 mg

8331L *Chem mart Omeprazole, CH; Terry White Chemists Omeprazole, TW* — **Omeprazole**, Tablet 20 mg

8333N *Chem mart Omeprazole, CH; Terry White Chemists Omeprazole, TW* — **Omeprazole**, Tablet 20 mg **(Diff. Max. Rpts)**

8787L *APO-Risperidone, TX; Rispa, SI; Risperidone-GA, GM; Rixadone, AF* — **Risperidone**, Tablet 0.5 mg

8869T *APO-Risperidone, TX; Rispa, SI; Risperidone-GA, GM; Rixadone, AF* — **Risperidone**, Tablet 0.5 mg **(Diff. Max. Rpts)**

8789N *APO-Risperidone, TX; Rispa, SI; Risperidone generichealth, GQ; Risperidone-GA, GM; Rixadone, AF* — **Risperidone**, Tablet 1 mg

3169T *APO-Risperidone, TX; Rispa, SI; Risperidone generichealth, GQ; Risperidone-GA, GM; Rixadone, AF* — **Risperidone**, Tablet 1 mg **(Diff. Max. Rpts)**

9079W *APO-Risperidone, TX; Rispa, SI; Risperidone generichealth, GQ; Risperidone-GA, GM; Rixadone, AF* — **Risperidone**, Tablet 2 mg

3170W *APO-Risperidone, TX; Rispa, SI; Risperidone generichealth, GQ; Risperidone-GA, GM; Rixadone, AF* — **Risperidone**, Tablet 2 mg **(Diff. Max. Rpts)**

3171X *APO-Risperidone, TX; Rispa, SI; Risperidone generichealth, GQ; Risperidone-GA, GM; Rixadone, AF* — **Risperidone**, Tablet 3 mg

3172Y *APO-Risperidone, TX; Rispa, SI; Risperidone generichealth, GQ; Risperidone-GA, GM; Rixadone, AF* — **Risperidone**, Tablet 4 mg

Additions — Bioequivalence Indicator

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

9185K **Fludarabine phosphate**, Powder for I.V. injection 50 mg (*Fludara*)

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

8787L *Risperdal, JC* — **Risperidone**, Tablet 0.5 mg

8869T *Risperdal, JC* — **Risperidone**, Tablet 0.5 mg **(Diff. Max. Rpts)**

8789N *Risperdal, JC* — **Risperidone**, Tablet 1 mg

3169T *Risperdal, JC* — **Risperidone**, Tablet 1 mg **(Diff. Max. Rpts)**

9079W *Risperdal, JC* — **Risperidone**, Tablet 2 mg

3170W *Risperdal, JC* — **Risperidone**, Tablet 2 mg **(Diff. Max. Rpts)**

3171X *Risperdal, JC* — **Risperidone**, Tablet 3 mg

3172Y *Risperdal, JC* — **Risperidone**, Tablet 4 mg

Additions — Restrictions

(see under 'RESTRICTIONS' below for full details)

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

9146J **Macrogol 3350**, Sachets containing powder for solution 6.563 g with electrolytes, 30 (*Movicol-Half*)

8612G **Macrogol 3350**, Sachets containing powder for solution 13.125 g with electrolytes, 30 (*Movicol*)

Additions — Note

(see under 'NOTES' below for full details)

Fludarabine phosphate

DELETIONS

Deletions — Items

2978R **Cholestyramine**, Sachets 9.4 g (equivalent to 8 g cholestyramine), 50 (*Questran Lite*)

9046D **Glucose indicator—blood**, Electrode strips, 50 (*Touch-In Plus*)

1819R **Levobunolol hydrochloride**, Eye drops 2.5 mg per mL (0.25%), 5 mL (*Betagan*)

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

Deletions — Brands

1147J *Capoten, BQ* — **Captopril**, Tablet 12.5 mg

2791X *Odrik, KN* — **Trandolapril**, Capsule 500 micrograms

Alterations — Manufacturer's Code

		From	*To*
1609Q	**Methadone hydrochloride**, Tablet 10 mg (*Physeptone*)	GK	SI
1606M	**Methadone hydrochloride**, Injection 10 mg in 1 mL (*Physeptone*)	GK	SI
5399E	**Methadone hydrochloride**, Oral liquid 25 mg per 5 mL, 200 mL (*SI*) **(Palliative Care)**	GK	SI
5400F	**Methadone hydrochloride**, Oral liquid 25 mg per 5 mL, 200 mL (*SI*) **(Palliative Care) (Diff. Max. Rpts)**	GK	SI

Alterations — Restrictions

(see under 'RESTRICTIONS' below for full details)

8191D **Dolasetron mesylate**, Tablet 200 mg (*Anzemet*)

8192E **Dolasetron mesylate**, I.V. injection 100 mg in 5 mL (*Anzemet*)
8728J **Granisetron hydrochloride**, Tablet 2 mg (base) (*Kytril*)
8729K **Granisetron hydrochloride**, Concentrated injection 3 mg (base) in 3 mL (*Kytril*)
8224W **Ondansetron**, Tablet 4 mg (*Ondansetron-RL, Ondaz, Onsetron 4, Zofran*)
8225X **Ondansetron**, Tablet 8 mg (*Ondansetron-RL, Ondaz, Onsetron 8, Zofran*)
8410P **Ondansetron**, Wafer 4 mg (*Ondansetron-RL Zydis, Ondaz Zydis, Zofran Zydis*)
8411Q **Ondansetron**, Wafer 8 mg (*Ondansetron-RL Zydis, Ondaz Zydis, Zofran Zydis*)
8226Y **Ondansetron**, I.V. injection 4 mg in 2 mL (*Ondansetron-RL, Ondaz, Onsetron, PF, Zofran*)
8227B **Ondansetron**, I.V. injection 8 mg in 4 mL (*Ondansetron-RL, Ondaz, Onsetron, PF, Zofran*)
2745L **Tropisetron hydrochloride**, Capsule 5 mg (base) (*Navoban*)

2746M **Tropisetron hydrochloride**, I.V. injection 5 mg (base) in 5 mL (*Navoban*)

Alterations — Notes

(see under 'NOTES' below for full details)

8511Y **Alendronate sodium**, Tablet equivalent to 70 mg alendronic acid (*Adronat, Alendrobell 70mg, Alendronate Sandoz, Alendro Once Weekly, APO-Alendronate, Chem mart Alendronate 70mg, Ossmax 70mg, Terry White Chemists Alendronate 70mg, Fosamax Once Weekly*)

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

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

8056B **Disodium etidronate and calcium carbonate**, Pack containing 28 tablets disodium etidronate 200 mg and 76 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium) (*Didrocal*)

8363E **Raloxifene hydrochloride**, Tablet 60 mg (*Evista*)
8481J **Risedronate sodium**, Tablet 5 mg (*Actonel*)
8621R **Risedronate sodium**, Tablet 35 mg (*Actonel Once-a-Week*)

8899J **Risedronate sodium and calcium carbonate**, Pack containing 4 tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium) (*Actonel Combi*)

9147K **Risedronate sodium and calcium carbonate with colecalciferol**, Pack containing 4 tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms (*Actonel Combi D*)

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

SECTION 100 — HIGHLY SPECIALISED DRUGS PROGRAM

ADDITIONS

Additions — Items

(see under 'RESTRICTIONS' below for full details)

9633B **Lopinavir with ritonavir**, Tablet 100 mg-25 mg (*Kaletra*)

9634C **Ribavirin and peginterferon alfa-2b**, Pack containing 196 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 150 micrograms with diluent (*Pegatron*)

Additions — Restrictions

(see under 'RESTRICTIONS' below for full details)

6399T **Ribavirin and peginterferon alfa-2b**, Pack containing 84 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 50 micrograms with diluent (*Pegatron*)

6400W **Ribavirin and peginterferon alfa-2b**, Pack containing 112 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 50 micrograms with diluent (*Pegatron*)

6401X **Ribavirin and peginterferon alfa-2b**, Pack containing 84 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 80 micrograms with diluent (*Pegatron*)

6402Y **Ribavirin and peginterferon alfa-2b**, Pack containing 140 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 80 micrograms with diluent (*Pegatron*)

6403B **Ribavirin and peginterferon alfa-2b**, Pack containing 168 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 80 micrograms with diluent (*Pegatron*)

6404C **Ribavirin and peginterferon alfa-2b**, Pack containing 84 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 100 micrograms with diluent (*Pegatron*)

6405D **Ribavirin and peginterferon alfa-2b**, Pack containing 112 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 100 micrograms with diluent (*Pegatron*)

6406E **Ribavirin and peginterferon alfa-2b**, Pack containing 84 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 120 micrograms with diluent (*Pegatron*)

6407F **Ribavirin and peginterferon alfa-2b**, Pack containing 140 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 120 micrograms with diluent (*Pegatron*)

6408G **Ribavirin and peginterferon alfa-2b**, Pack containing 84 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 150 micrograms with diluent (*Pegatron*)

6409H **Ribavirin and peginterferon alfa-2b**, Pack containing 140 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 150 micrograms with diluent (*Pegatron*)

6410J **Ribavirin and peginterferon alfa-2b**, Pack containing 168 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 150 micrograms with diluent (*Pegatron*)

DELETION

Deletion — Item

6331F **Nelfinavir Mesylate**, Tablet 250 mg (base) *(Viracept)*

ALTERATION

Alteration — Restriction

(see under 'RESTRICTIONS' below for full details)

9630W **Telbivudine**, Tablet 600 mg (*Sebivo*)

SECTION 100 — 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*)

SECTION 100 — OPIATE DEPENDENCE TREATMENT PROGRAM

ALTERATIONS

Alterations — Manufacturer's Code

		From	*To*
6171T	**Methadone hydrochloride**, Oral liquid 25 mg per 5 mL, 200 mL (*SI*)	GK	SI
6172W	**Methadone hydrochloride**, Oral liquid 25 mg per 5 mL, 1 L (*SI*)	GK	SI

ADVANCE NOTICES

Advance Notices - Deletions

The following brands will be deleted from the Schedule of Pharmaceutical Benefits on 1 January 2009:

Brands discontinued by the manufacturer —

1891M *Clavulin Duo, ME* — **Amoxycillin with clavulanic acid**, Tablet 500 mg-125 mg

5008N *Clavulin Duo, ME* — **Amoxycillin with clavulanic acid**, Tablet 500 mg-125 mg **(Dental)**

8254K *Clavulin Duo Forte, ME* — **Amoxycillin with clavulanic acid**, Tablet 875 mg-125 mg

5006L *Clavulin Duo Forte, ME* — **Amoxycillin with clavulanic acid**, Tablet 875 mg-125 mg **(Dental)**

1892N *Clavulin, ME* — **Amoxycillin with clavulanic acid**, Powder for syrup 125 mg-31.25 mg per 5 mL, 75 mL

5009P *Clavulin, ME* — **Amoxycillin with clavulanic acid**, Powder for syrup 125 mg-31.25 mg per 5 mL, 75 mL **(Dental)**

8319W *Clavulin Duo 400, ME* — **Amoxycillin with clavulanic acid**, Powder for syrup 400 mg-57 mg per 5 mL, 60 mL

5011R *Clavulin Duo 400, ME* — **Amoxycillin with clavulanic acid**, Powder for syrup 400 mg-57 mg per 5 mL, 60 mL **(Dental)**

8465M *Bupropion-RL, RE* — **Bupropion hydrochloride**, Tablet 150 mg (sustained release)

8710K *Bupropion-RL, RE* — **Bupropion hydrochloride**, Tablet 150 mg (sustained release) **(Diff. Max. Qty)**

8063J *Elmendos, ME* — **Lamotrigine**, Tablet 5 mg

2848X *Elmendos, ME* — **Lamotrigine**, Tablet 25 mg

2849Y *Elmendos, ME* — **Lamotrigine**, Tablet 50 mg

2850B *Elmendos, ME* — **Lamotrigine**, Tablet 100 mg

2851C *Elmendos, ME* — **Lamotrigine**, Tablet 200 mg

8144P *Suvalan 50, ME* — **Sumatriptan succinate**, Tablet 50 mg (base)

2109B *Nolvadex, AP* — **Tamoxifen citrate**, Tablet 10 mg (base)

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

Items discontinued by the manufacturer —

1036M **Aminoglutethimide**, Tablet 250 mg (*Cytadren 250*)

1777M **Piperazine oestrone sulfate**, Tablet 730 micrograms (equivalent to 625 micrograms sodium oestrone sulfate) (*Genoral 0.625*, *Ogen .625*)

1778N **Piperazine oestrone sulfate**, Tablet 1.46 mg (equivalent to 1.25 mg sodium oestrone sulfate) (*Genoral 1.25*, *Ogen 1.25*)

The following brands will be deleted from the Schedule of Pharmaceutical Benefits on 1 February 2009:

Brands discontinued by the manufacturer —

1081X *Anselol 50 mg, GM* — **Atenolol**, Tablet 50 mg

2792Y *Odrik, KN* — **Trandolapril**, Capsule 1 mg

2793B *Odrik, KN* — **Trandolapril**, Capsule 2 mg

RESTRICTIONS

The text of restrictions mentioned above:

9290Y **Atomoxetine hydrochloride**, Capsule 100 mg (base) (*Strattera*)

9289X **Atomoxetine hydrochloride**, Capsule 80 mg (base) (*Strattera*)

Authority required

Initial sole PBS-subsidised treatment of attention-deficit hyperactivity disorder (ADHD) diagnosed between the ages of 6 and 18 years inclusive, by a paediatrician or psychiatrist according to the DSM-IV criteria, where

treatment with dexamphetamine sulfate or methylphenidate hydrochloride poses an unacceptable medical risk due to the following contraindications as specified in the TGA-approved product information:

(1) The patient has a history of substance abuse or misuse (other than alcohol); and/or

(2) The patient has comorbid motor tics or Tourette's Syndrome; and/or

(3) The patient has comorbid severe anxiety diagnosed according to the DSM-IV

Authority required

Initial sole PBS-subsidised treatment of attention-deficit hyperactivity disorder (ADHD) diagnosed between the ages of 6 and 18 years inclusive, by a paediatrician or psychiatrist according to the DSM-IV criteria, where

treatment with dexamphetamine sulfate or methylphenidate hydrochloride has resulted in the development or worsening of a comorbid mood disorder (diagnosed according to the DSM-IV criteria i.e. anxiety disorder, obsessive compulsive disorder, depressive disorder) of a severity necessitating permanent stimulant treatment withdrawal; or where the combination of stimulant treatment with another agent would pose an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal

Authority required

Initial sole PBS-subsidised treatment of attention-deficit hyperactivity disorder (ADHD) diagnosed between the ages of 6 and 18 years inclusive, by a paediatrician or psychiatrist according to the DSM-IV criteria, where

treatment with dexamphetamine sulfate AND methylphenidate hydrochloride has resulted in the development of adverse reactions of a severity necessitating permanent treatment withdrawal:

(1) Adverse effects on growth and weight; and/or

(2) Adverse effects on sleep including insomnia; and/or

(3) Adverse effects on appetite including anorexia

Authority required

Continuing sole PBS-subsidised treatment where the patient has previously been issued with an authority prescription for this drug

NOTE:

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

9230T **Atorvastatin calcium**, Tablet 10 mg (atorvastatin) (*Lipitor*)

9231W **Atorvastatin calcium**, Tablet 20 mg (atorvastatin) (*Lipitor*)

9232X **Atorvastatin calcium**, Tablet 40 mg (atorvastatin) (*Lipitor*)

9233Y **Atorvastatin calcium**, Tablet 80 mg (atorvastatin) (*Lipitor*)

9234B **Fluvastatin sodium**, Capsule 20 mg (fluvastatin) (*Lescol, Vastin*)

9235C **Fluvastatin sodium**, Capsule 40 mg (fluvastatin) (*Lescol, Vastin*)

9236D **Fluvastatin sodium**, Tablet 80 mg (fluvastatin) (prolonged release) (*Lescol XL*)

9237E **Pravastatin sodium**, Tablet 10 mg (*Chem mart Pravastatin, Cholstat 10, GenRx Pravastatin, Lipostat 10, Liprachol, Pravastatin 10, Pravastatin-DP, Pravastatin-GA 10, Pravastatin generichealth, Pravastatin Winthrop, Terry White Chemists Pravastatin, Pravachol*)

9238F **Pravastatin sodium**, Tablet 20 mg (*Chem mart Pravastatin, Cholstat 20, GenRx Pravastatin, Lipostat 20, Liprachol, Pravastatin 20, Pravastatin-DP, Pravastatin-GA 20, Pravastatin generichealth, Pravastatin Winthrop, Terry White Chemists Pravastatin, Vastoran, Pravachol*)

9239G **Pravastatin sodium**, Tablet 40 mg (*Chem mart Pravastatin, Cholstat 40, GenRx Pravastatin, Lipostat 40, Liprachol, Pravastatin 40, Pravastatin-DP, Pravastatin-GA 40, Pravastatin generichealth, Pravastatin Winthrop, Terry White Chemists Pravastatin, Vastoran, Pravachol*)

9240H **Pravastatin sodium**, Tablet 80 mg (*Lipostat 80, Pravastatin-GA 80, Pravastatin generichealth, Pravachol*)

9242K **Simvastatin**, Tablet 10 mg (*Chem mart Simvastatin, GenRx Simvastatin, Ransim, Simvabell, Simvahexal, Simvar 10, Simvastatin-DP, Simvastatin generichealth, Simvastatin Winthrop, Simvasyn, Terry White Chemists Simvastatin, Zimstat, GN, Lipex 10, Zocor*)

9243L **Simvastatin**, Tablet 20 mg (*Chem mart Simvastatin, GenRx Simvastatin, Ransim, Simvabell, Simvahexal, Simvar 20, Simvastatin-DP, Simvastatin generichealth, Simvastatin Winthrop, Simvasyn, Terry White Chemists Simvastatin, Zimstat, GN, Lipex 20, Zocor*)

9244M **Simvastatin**, Tablet 40 mg (*Chem mart Simvastatin, GenRx Simvastatin, Ransim, Simvabell, Simvahexal, Simvar 40, Simvastatin-DP, Simvastatin generichealth, Simvastatin Winthrop, Simvasyn, Terry White Chemists Simvastatin, Zimstat, GN, Lipex 40, Zocor*)

9241J **Simvastatin**, Tablet 5 mg (*Simvabell, Simvahexal, Simvasyn, Zimstat, Zocor*)

9245N **Simvastatin**, Tablet 80 mg (*Chem mart Simvastatin, GenRx Simvastatin, Ransim, Simvabell, Simvahexal, Simvar 80, Simvastatin-DP, Simvastatin generichealth, Simvastatin Winthrop, Simvasyn, Terry White Chemists Simvastatin, Zimstat, GN, Lipex 80, Zocor*)

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare Benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

NOTE:

The risk of serious muscle toxicity is increased if gemfibrozil is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare Benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

NOTE:

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

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

Restricted benefit

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

Restricted benefit

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

Restricted benefit

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

Restricted benefit

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

9355J **Carmellose sodium with glycerin**, Eye drops 5 mg-9 mg per mL (0.5%-0.9%), 15 mL (*Optive*)
5556K **Carmellose sodium with glycerin**, Eye drops 5 mg-9 mg per mL (0.5%-0.9%), 15 mL (*Optive*)

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

NOTE:

The shelf life of Optive is 6 months from the date of opening

9356K **Carmellose sodium with glycerin**, Eye drops 5 mg-9 mg per mL (0.5%-0.9%), 15 mL (*Optive*)

Restricted benefit

For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

NOTE:

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

NOTE:

The shelf life of Optive is 6 months from the date of opening

9249T **Cholestyramine**, Sachets 4.7 g (equivalent to 4 g cholestyramine), 50 (*Questran Lite*)
9250W **Colestipol hydrochloride**, Sachets 5 g, 120 (*Colestid*)

Restricted benefit

For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

NOTE:

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

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

Restricted benefit

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

Restricted benefit

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

Restricted benefit

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

Restricted benefit

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 per upper limb per lifetime. Treatment should not be initiated until 3 to 6 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.
Contraindications to treatment include established severe contracture, known sensitivity to botulinum toxin

9291B **Docetaxel**, Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL and 1 single use use vial solvent 1.5 mL (*Taxotere*)

Authority required

Neoadjuvant treatment of a patient with a WHO performance status of 1 or less, with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx, in combination with cisplatin and fluorouracil

NOTE:

The carcinoma can be considered inoperable for technical or organ preservation reasons

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

Authority required

Neoadjuvant treatment of a patient with a WHO performance status of 1 or less, with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx, in combination with cisplatin and fluorouracil

NOTE:

The carcinoma can be considered inoperable for technical or organ preservation reasons

Authority required

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

Authority required

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

Authority required

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

Authority required

Locally advanced or metastatic non-small cell lung cancer

Authority required

Treatment of HER2 positive early breast cancer in combination with trastuzumab

Authority required

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

8192E **Dolasetron mesylate**, I.V. injection 100 mg in 5 mL (*Anzemet*)
8191D **Dolasetron mesylate**, Tablet 200 mg (*Anzemet*)
8729K **Granisetron hydrochloride**, Concentrated injection 3 mg (base) in 3 mL (*Kytril*)
8728J **Granisetron hydrochloride**, Tablet 2 mg (base) (*Kytril*)

8226Y **Ondansetron**, I.V. injection 4 mg in 2 mL (*Ondansetron-RL, Ondaz, Onsetron, PF, Zofran*)
8227B **Ondansetron**, I.V. injection 8 mg in 4 mL (*Ondansetron-RL, Ondaz, Onsetron, PF, Zofran*)
8224W **Ondansetron**, Tablet 4 mg (*Ondansetron-RL, Ondaz, Onsetron 4, Zofran*)
8225X **Ondansetron**, Tablet 8 mg (*Ondansetron-RL, Ondaz, Onsetron 8, Zofran*)
8410P **Ondansetron**, Wafer 4 mg (*Ondansetron-RL Zydis, Ondaz Zydis, Zofran Zydis*)
8411Q **Ondansetron**, Wafer 8 mg (*Ondansetron-RL Zydis, Ondaz Zydis, Zofran Zydis*)
2745L **Tropisetron hydrochloride**, Capsule 5 mg (base) (*Navoban*)
2746M **Tropisetron hydrochloride**, I.V. injection 5 mg (base) in 5 mL (*Navoban*)

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

9247Q **Fenofibrate**, Tablet 145 mg (*Lipidil*)
9246P **Fenofibrate**, Tablet 48 mg (*Lipidil*)

NOTE:

The risk of serious muscle toxicity is increased if fenofibrate is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare Benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

NOTE:

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

9248R **Gemfibrozil**, Tablet 600 mg (*Ausgem, Chem mart Gemfibrozil, Gemhexal, GenRx Gemfibrozil, Jezil, Lipazil 600 mg, Pharmacor Gemfibrozil 600, Terry White Chemists Gemfibrozil, Lopid*)

NOTE:

The risk of serious muscle toxicity is increased if gemfibrozil is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare Benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

NOTE:

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

9207N **Fludarabine phosphate**, Solution for I.V. injection 50 mg in 2 mL (*Fludarabine Ebewe*)

Authority required

B-cell chronic lymphocytic leukaemia in combination with cyclophosphamide where the patient has advanced disease (Binet Stage B or C) or evidence of progressive Stage A disease.

Stage A progressive disease is defined by at least one of the following: persistent rise in lymphocyte count with doubling time less than 12 months; a downward trend in haemoglobin or platelets, or both; more than 50% increase in the size of liver, spleen, or lymph nodes, or appearance of these signs if not previously present; constitutional symptoms attributable to disease.

The diagnosis of chronic lymphocytic leukaemia (CLL) must have been established based on:
(a) a lymphocytosis, with more than 5,000 million lymphocytes per L in the peripheral blood; and
(b) a clonal population of B-cells (CD5/CD19) documented by flow cytometry

9292C **Levodopa with carbidopa and entacapone**, Tablet 200 mg-50 mg-200 mg (*Stalevo 200/50/200mg*)

Authority required (STREAMLINED)

2059

Parkinson's disease in patients being treated with levodopa—decarboxylase inhibitor combinations who are experiencing fluctuations in motor function due to end-of-dose effect

Authority required (STREAMLINED)

2060

Parkinson's disease in patients stabilised on concomitant treatment with levodopa—decarboxylase inhibitor combinations and entacapone

9633B **Lopinavir with ritonavir**, Tablet 100 mg-25 mg (*Kaletra*)

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

5419F **Macrogol 3350**, Sachets containing powder for solution 6.563 g with electrolytes, 30 (*Movicol-Half*)

Authority required

Initial supply (for up to 4 months) for palliative care patients where constipation is a problem

Authority required

Continuing supply for palliative care patients where constipation is a problem, and where consultation with a palliative care specialist or service has occurred

NOTE:

No applications for increased repeats will be authorised

5420G **Macrogol 3350**, Sachets containing powder for solution 6.563 g with electrolytes, 30 (*Movicol-Half*)

Authority required

Continuing supply for palliative care patients where constipation is a problem

NOTE:

No applications for increased repeats will be authorised

8612G **Macrogol 3350**, Sachets containing powder for solution 13.125 g with electrolytes, 30 (*Movicol*)
9146J **Macrogol 3350**, Sachets containing powder for solution 6.563 g with electrolytes, 30 (*Movicol-Half*)

Restricted benefit

Constipation in patients with malignant neoplasia

Restricted benefit

Chronic constipation or faecal impaction not adequately controlled with first line interventions such as bulk-forming agents

Restricted benefit

Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function not responding to other oral therapies

Restricted benefit

Patients receiving palliative care

9198D **Nicotine**, Transdermal patch releasing approximately 15 mg per 16 hours (*Nicorette Patch*)

Authority required

Nicotine dependence in an Aboriginal or a Torres Strait Islander person as the sole PBS-subsidised therapy

NOTE:

Only 2 courses of PBS-subsidised nicotine replacement therapy will be authorised per year

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

Benefit is improved if used in conjunction with a comprehensive support and counselling program

9226N **Pancreatic extract**, Capsule (containing enteric coated minimicrospheres) providing not less than 10,000 BP units of lipase activity (*Creon 10,000*)

9227P **Pancreatic extract**, Capsule (containing enteric coated minimicrospheres) providing not less than 25,000 BP units of lipase activity (*Creon 25,000*)

9225M **Pancreatic extract**, Capsule (containing enteric coated minimicrospheres) providing not less than 5,000 BP units of lipase activity (*Creon 5000*)

9228Q **Pancrelipase**, Capsule (containing enteric coated microspheres) providing not less than 10,000 BP units of lipase activity (*Cotazym-S Forte*)

9229R **Pancrelipase**, Capsule (containing enteric coated microtablets) providing not less than 25,000 BP units of lipase activity (*Panzytrat 25000*)

Restricted benefit

For use in patients with cystic fibrosis, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare Benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

NOTE:

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

9286R **Phenoxybenzamine hydrochloride**, Capsules 10 mg, 100 (*Dibenzyline*)

Restricted benefit

Phaeochromocytoma

Restricted benefit

Neurogenic urinary retention

6405D **Ribavirin and peginterferon alfa-2b**, Pack containing 112 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 100 micrograms with diluent (*Pegatron*)

6400W **Ribavirin and peginterferon alfa-2b**, Pack containing 112 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 50 micrograms with diluent (*Pegatron*)

6407F **Ribavirin and peginterferon alfa-2b**, Pack containing 140 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 120 micrograms with diluent (*Pegatron*)

6409H **Ribavirin and peginterferon alfa-2b**, Pack containing 140 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 150 micrograms with diluent (*Pegatron*)

6402Y **Ribavirin and peginterferon alfa-2b**, Pack containing 140 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 80 micrograms with diluent (*Pegatron*)

6410J **Ribavirin and peginterferon alfa-2b**, Pack containing 168 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 150 micrograms with diluent (*Pegatron*)

6403B **Ribavirin and peginterferon alfa-2b**, Pack containing 168 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 80 micrograms with diluent (*Pegatron*)

9634C **Ribavirin and peginterferon alfa-2b**, Pack containing 196 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 150 micrograms with diluent (*Pegatron*)

6404C **Ribavirin and peginterferon alfa-2b**, Pack containing 84 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 100 micrograms with diluent (*Pegatron*)

6406E **Ribavirin and peginterferon alfa-2b**, Pack containing 84 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 120 micrograms with diluent (*Pegatron*)

6408G **Ribavirin and peginterferon alfa-2b**, Pack containing 84 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 150 micrograms with diluent (*Pegatron*)

6399T **Ribavirin and peginterferon alfa-2b**, Pack containing 84 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 50 micrograms with diluent (*Pegatron*)

6401X **Ribavirin and peginterferon alfa-2b**, Pack containing 84 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 80 micrograms with diluent (*Pegatron*)

CAUTION:

Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored

CAUTION:

Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

Private hospital authority required

Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no prior interferon alfa or peginterferon alfa treatment for hepatitis C and who satisfy all of the following criteria:

(1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive);

(2) Female patients of child-bearing age are not pregnant, not breast-feeding, and both patient and their partner are using effective forms of contraception (one for each partner). Male patients and their partners are using effective forms of contraception (one for each partner). Female partners of male patients are not pregnant

For patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis, the treatment course is limited to 24 weeks. For hepatitis C patients with genotype 1, 4, 5 or 6 and those genotype 2 or 3 patients with hepatic cirrhosis or bridging fibrosis, the treatment course is limited to 48 weeks

Patients with genotype 1, 4, 5 or 6 who are eligible for 48 weeks of treatment may only continue treatment after the first 12 weeks if the result of an HCV RNA quantitative assay (performed at the same laboratory using the same test) shows that the plasma HCV RNA has become undetectable or the viral load has

decreased by at least a 2 log drop. (An HCV RNA assay at week 12 is unnecessary for genotype 2 and 3 patients because of the high likelihood of early viral response by week 12)

Patients with genotype 1, 4, 5 or 6 who are viral positive at week 12 but have attained at least a 2 log drop in viral load may only continue treatment after the first 24 weeks of treatment if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 24. Similarly, genotype 2 or 3 patients with hepatic cirrhosis or bridging fibrosis may only continue treatment after the first 24 weeks if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 24. An HCV RNA qualitative assay at week 24 is unnecessary for those patients with genotype 1, 4, 5 or 6 who became viral negative at week 12

NOTE:

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24 hour access by patients to medical advice; and

(c) an established liver clinic; and

(d) facilities for safe liver biopsy

Private hospital authority required

Patients who have failed one prior attempt at interferon based therapies (non-pegylated or pegylated)

Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C and who satisfy all of the following criteria:

(1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive);

(2) Female patients of child-bearing age are not pregnant, not breast-feeding, and both patient and their partner are using effective forms of contraception (one for each partner). Female partners of male patients are not pregnant

The treatment course is limited to 48 weeks. Patients may only continue treatment after the first 12 weeks of treatment if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 12

NOTE:

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24 hour access by patients to medical advice; and

(c) an established liver clinic; and(d) facilities for safe liver biopsy

9293D **Risperidone**, Oral solution 1 mg per mL, 100 mL (*Risperdal*)

Authority required (STREAMLINED)

2061

Behavioural disturbances characterised by psychotic symptoms and aggression in patients with dementia where non-pharmacological methods have been unsuccessful

CAUTION:

In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalities) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo

Authority required (STREAMLINED)

2598

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

9630W **Telbivudine**, Tablet 600 mg (*Sebivo*)

Private hospital authority required

Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B who is nucleoside analogue naive and satisfies all of the following criteria:

(1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy);

(2)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection; or

(b) Elevated HBV DNA levels in conjunction with documented chronic hepatitis B infection;

(3) 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

9288W **Zoledronic acid**, Solution for I.V. infusion 5 mg (as monohydrate) in 100 mL (*Aclasta*)

Authority required

Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in women with fracture due to minimal trauma

Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in men with hip fracture due to minimal trauma

In all cases, 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

Only one treatment each year for three consecutive years per patient will be PBS-subsidised

NOTE:

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

NOTES

The text of notes mentioned above:

8511Y **Alendronate sodium**, Tablet equivalent to 70 mg alendronic acid

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, disodium etidronate, raloxitene hydrochloride, strontium ranelate and zoledronic acid

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

9012H **Alendronate sodium with colecalciferol**, Tablet equivalent to 70 mg alendronic acid with 70 micrograms colecalciferol (*Fosamax Plus 70 mg/140 mcg*)

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

8056B **Disodium etidronate and calcium carbonate**, Pack containing 28 tablets disodium etidronate 200 mg and 76 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium)

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

Fludarabine phosphate

The solution for I.V. injection and powder for I.V. injection (after reconstitution) are bioequivalent

8363E **Raloxifene hydrochloride**, Tablet 60 mg

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

8481J **Risedronate sodium**, Tablet 5 mg
8621R **Risedronate sodium**, Tablet 35 mg

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

8899J **Risedronate sodium and calcium carbonate**, Pack containing 4 tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium)

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

9147K **Risedronate sodium and calcium carbonate with colecalciferol**, Pack containing 4 tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms

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

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

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

The solution for I.V. injection and powder for I.V. injection (after reconstitution) are bioequivalent.

REPATRIATION PHARMACEUTICAL BENEFITS

This Schedule is effective from 1 December 2008 and all previous issues are cancelled.

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

SUMMARY OF CHANGES

DELETIONS

Deletions — Items

4843X **Dressing—non-adherent**, Dressings, self-adhesive, 5 cm x 7.5 cm, 10 (*Telfa 6020C*)

4271T **Hydrolyzed collagen proteins**, Hair conditioner 250 mL (*Ionil Rinse*)

4445Y **Salicylic acid with benzalkonium chloride, alcohol and polyoxyethylene ethers**, Scalp cleanser 20 mg-2 mg-130 mg-216 mg per mL (2%-0.2%-13%-21.6%), 250 mL (*Ionil*)

ALTERATION

Alteration — Proprietary Name

From:
4028B **Docusate sodium with senna**, Tablet 50 mg-8 mg (*DP soflax*)
To:
4028B **Docusate sodium with senna**, Tablet 50 mg-8 mg (*Soflax*)