Australian Government

Department of Health and Ageing

SCHEDULE OF PHARMACEUTICAL BENEFITS FOR APPROVED PHARMACISTS AND MEDICAL PRACTITIONERS

SUMMARY OF CHANGES

EFFECTIVE 1 JULY 2007

PHARMACEUTICAL BENEFITS

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 July 2007. The Schedule is updated on the first day of each month and is available on the Internet at www.pbs.gov.au.

Fees, Patient Contributions and Safety Net Thresholds

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

Dispensing Fees:	Ready-prepared	$5.32
	Dangerous drug fee	$2.71
	Extemporaneously-prepared	$7.36
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

As a measure of PBS Reform, new streamlined authority arrangements will commence on 1 July 2007. These arrangements provide an alternative method for prescribing approximately 200 of the 450 PBS Authority required items. These items are called **Authority required (STREAMLINED)** and are listed below.

Authority required (STREAMLINED) items do not require prior approval from Medicare Australia or the Department of Veterans' Affairs (DVA) to be prescribed (except where increased quantities and/or repeats are required). Instead, prescribers are required to record a four digit 'streamlined authority code' on the authority prescription.

'Streamlined authority codes' are listed with the corresponding restriction of each **Authority required (STREAMLINED)** item.

Streamlined authority arrangements only apply to items listed in the General Pharmaceutical Benefits Schedule.

For information on how to prescribe **Authority required (STREAMLINED)** items, refer to the Explanatory Notes, Schedule of Pharmaceutical Benefits at www.pbs.gov.au or phone Medicare Australia on 132 290.

For further information on streamlined authority arrangements or PBS Reform, visit the Department of Health and Ageing website www.health.gov.au/pbsreform.

Authority required (STREAMLINED) items

8048N	**Abciximab**, I.V. injection 10 mg in 5 mL (*ReoPro*)
8357W	**Acamprosate calcium**, Tablet 333 mg (enteric coated) (*Campral*)
2019G	**Acitretin**, Capsule 10 mg (*Neotigason*)
2020H	**Acitretin**, Capsule 25 mg (*Neotigason*)
8503M	**Albendazole**, Tablet 200 mg (*Zentel*)
9047E	**Albendazole**, Tablet 200 mg (*Zentel*) **(Diff.Max.Qty)**
8459F	**Albendazole**, Tablet 400 mg (*Eskazole)*
8511Y	**Alendronate sodium**, Tablet equivalent to 70 mg alendronic acid (*Alendro Once Weekly, Fosamax Once Weekly*)
8090T	**Alendronate sodium**, Tablet equivalent to 40 mg alendronic acid (*Fosamax 40 mg*)
9012H	**Alendronate sodium with colecalciferol**, Tablet equivalent to 70 mg alendronic acid with 70 micrograms colecalciferol (*Fosamax Plus*)
8594H	**Amisulpride**, Tablet 100 mg (*Solian 100*)
8595J	**Amisulpride**, Tablet 200 mg (*Solian 200*)
8596K	**Amisulpride**, Tablet 400 mg (*Solian 400*)
8736T	**Amisulpride**, Oral solution 100 mg per mL, 60 mL (*Solian Solution*)
8717T	**Aripiprazole**, Tablet 10 mg (*Abilify*)
8718W	**Aripiprazole**, Tablet 15 mg (*Abilify*)
8719X	**Aripiprazole**, Tablet 20 mg (*Abilify*)
8720Y	**Aripiprazole**, Tablet 30 mg (*Abilify*)
8300W	**Atovaquone**, Oral suspension 750 mg per 5 mL, 210 mL (*Wellvone*)
8845M	**Balsalazide sodium**, Capsule 750 mg (*Colazide*)
8066M	**Bifonazole**, Cream 10 mg per g (1%), 15 g (*Mycospor*)
8604W	**Bisoprolol fumarate**, Tablet 2.5 mg (*Bicor*)
8605X	**Bisoprolol fumarate**, Tablet 5 mg (*Bicor*)
8606Y	**Bisoprolol fumarate**, Tablet 10 mg (*Bicor*)
8844L	**Bivalirudin trifluoroacetate**, Powder for I.V. injection 250 mg (base) (*Angiomax*)
2065Q	**Budesonide**, Nebuliser suspension single dose units 500 micrograms in 2 mL, 30 (*Pulmicort Respules*)
2066R	**Budesonide**, Nebuliser suspension single dose units 1 mg in 2 mL, 30 (*Pulmicort Respules*)
8114C	**Cabergoline**, Tablet 500 micrograms (*Dostinex*)

2502Q **Calcitriol**, Capsule 0.25 microgram (*Calcitriol-DP, Citrihexal, GenRx Calcitriol, Kosteo, Rocaltrol, Sical, Sitriol*)
8560M **Calcium**, Tablet 250 mg (as citrate) (*Citracal*)
3116B **Calcium**, Tablet (chewable) 500 mg (as carbonate) (*Cal-Sup*)
3117C **Calcium**, Tablet 600 mg (as carbonate) (*Caltrate*)
8514D **Carbomer 974**, Ocular lubricating gel 3 mg per g (0.3%), single dose units 0.5 g, 30 (*Poly Gel*)
8578L **Carbomer 980**, Eye drops 2 mg per g (0.2%), single dose units 0.6 mL, 30 (*Viscotears*)
8823J **Carmellose sodium**, Eye drops 2.5 mg per mL (0.25%), single dose units 0.6 mL, 24 (*TheraTears*)
2338C **Carmellose sodium**, Eye drops 5 mg per mL (0.5%), single dose units 0.4 mL, 30 (*Cellufresh*)
2324H **Carmellose sodium**, Eye drops 10 mg per mL (1%), single dose units 0.4 mL, 30 (*Celluvisc*)
8824K **Carmellose sodium**, Ocular lubricating gel 10 mg per mL (1%), single dose units 0.6 mL, 28 (*TheraTears*)
8255L **Carvedilol**, Tablet 3.125 mg (*Chem mart Carvedilol 3.125 mg, Dilatrend 3.125, GenRx Carvedilol, Kredex, Terry White Chemists Carvedilol 3.125 mg*)
8256M **Carvedilol**, Tablet 6.25 mg (*Chem mart Carvedilol 6.25 mg, Dilatrend 6.25, GenRx Carvedilol, Kredex, Terry White Chemists Carvedilol 6.25 mg*)
8257N **Carvedilol**, Tablet 12.5 mg (*Chem mart Carvedilol 12.5 mg, Dilatrend 12.5, GenRx Carvedilol, Kredex, Terry White Chemists Carvedilol 12.5 mg*)
8258P **Carvedilol**, Tablet 25 mg (*Chem mart Carvedilol 25 mg, Dilatrend 25, GenRx Carvedilol, Kredex, Terry White Chemists Carvedilol 25 mg*)
8358X **Clopidogrel hydrogen sulfate**, Tablet 75 mg (base) (*Iscover, Plavix*)
1027C **Clotrimazole**, Lotion 10 mg per mL (1%), 20 mL (*Canesten*)
8019C **Cyproterone acetate**, Tablet 100 mg (*Cyprohexal, Cyprostat-100, GenRx Cyproterone Acetate, Procur 100, Androcur-100*)
1269T **Cyproterone acetate**, Tablet 50 mg (*Cyprohexal, Cyprone, Cyprostat, GenRx Cyproterone Acetate, Procur, Androcur*)
1270W **Cyproterone acetate**, Tablet 50 mg (*Cyprohexal, Cyprone, Cyprostat, GenRx Cyproterone Acetate, Procur, Androcur*) **(Diff. Max. Qty)**
1285P **Danazol**, Capsule 100 mg (*Azol 100*)
1287R **Danazol**, Capsule 200 mg (*Azol 200*)
8663Y **Desmopressin acetate**, Tablet 200 micrograms *(Minirin)*
8662X **Desmopressin acetate**, Tablet 200 micrograms (*Minirin*) **(Diff.Max.Qty)**
2129C **Desmopressin acetate**, Intranasal solution 100 micrograms per mL, 2.5 mL (*Minirin*)
8711L **Desmopressin acetate**, Nasal spray (pump pack) 10 micrograms per actuation, 60 actuations, 6 mL (*Minirin Nasal Spray*)
8712M **Desmopressin acetate**, Nasal spray (pump pack) 10 micrograms per actuation, 60 actuations, 6 mL (*Minirin Nasal Spray*) **(Diff.Max.Qty)**
2920Q **Disodium etidronate**, Tablet 200 mg (*Didronel*)
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*)
8461H **Disodium pamidronate**, Concentrated injection 15 mg in 5 mL (*Pamisol*)
8208B **Disodium pamidronate**, Injection set containing 4 vials powder for I.V. infusion 15 mg and 4 ampoules solvent 5 mL (*Aredia 15 mg*)
8462J **Disodium pamidronate**, Concentrated injection 30 mg in 10 mL (*Pamisol*)
8463K **Disodium pamidronate**, Concentrated injection 60 mg in 10 mL (*Pamisol*)
8209C **Disodium pamidronate**, Injection set containing 2 vials powder for I.V. infusion 30 mg and 2 ampoules solvent 10 mL (*Aredia 30 mg*)
8367J **Entacapone**, Tablet 200 mg (*Comtan*)
8879H **Eplerenone**, Tablet 25 mg (*Inspra*)
8880J **Eplerenone**, Tablet 50 mg (*Inspra*)
8683B **Eptifibatide acetate**, Solution for I.V. injection 20 mg (base) in 10 mL (*Integrilin*)
8684C **Eptifibatide acetate**, Solution for I.V. infusion 75 mg (base) in 100 mL (*Integrilin*)
8757X **Ezetimibe**, Tablet 10 mg (*Ezetrol*)

8881K **Ezetimibe with simvastatin**, Tablet 10 mg-40 mg (*Vytorin*)
8882L **Ezetimibe with simvastatin**, Tablet 10 mg-80 mg (*Vytorin*)
8775W **Fondaparinux sodium**, Injection 2.5 mg in 0.5 mL single dose pre-filled syringe (*Arixtra*)
8505P **Gabapentin**, Capsule 100 mg (*DBL Gabapentin, Gantin, Neurontin, Nupentin 100*)
1834M **Gabapentin**, Capsule 300 mg (*DBL Gabapentin, Douglas Gabapentin 300mg, Gabahexal 300mg, Gabapentin 300, Gantin, GenRx Gabapentin, Neurontin, Nupentin 300, Pendine 300*)
1835N **Gabapentin**, Capsule 400 mg (*DBL Gabapentin, Douglas Gabapentin 400mg, Gabahexal 400mg, Gabapentin 400, Gantin, GenRx Gabapentin, Neurontin, Nupentin 400, Pendine 400*)
8559L **Gabapentin**, Tablet 600 mg (*Neurontin*)
8389M **Gabapentin**, Tablet 800 mg (*Gantin, Neurontin, Pendine 800*)
8634K **Glucose indicator—blood**, Electrode strips, 50 (*Ascensia Elite*)
2926B **Glucose indicator—blood**, Electrode strips, 100 (*Precision Plus*)
8299T **Hypromellose with dextran**, Eye drops 3 mg-1 mg per mL (0.3%-0.1%), single dose units 0.4 mL, 28 (*Bion Tears*)
8807M **Iron sucrose**, Concentrate for solution for infusion 2.7 g (equivalent to 100 mg iron (III)) in 5 mL (*Venofer*)
2591J **Isotretinoin**, Capsule 10 mg (*GenRx Isotretinoin, Oratane, Roaccutane*)
2592K **Isotretinoin**, Capsule 20 mg (*Chem mart Isotretinoin, GenRx Isotretinoin, Isohexal, Oratane, Terry White Chemists Isotretinoin, Roaccutane*)
2549E **Isotretinoin**, Capsule 40 mg (*Oratane*)
8359Y **Ivermectin**, Tablet 3 mg (*Stromectol*)
9024Y **Ketoconazole**, Cream 20 mg per g (2%), 30 g (*Nizoral 2% Cream*)
9025B **Ketoconazole**, Shampoo 10 mg per g (1%), 100 mL (*Nizoral 1%*)
1574W **Ketoconazole**, Shampoo 20 mg per g (2%), 60 mL (*Nizoral 2%*)
8063J **Lamotrigine**, Tablet 5 mg (*Elmendos, Lamitrin, Lamogine, Seaze 5, Lamictal*)
2848X **Lamotrigine**, Tablet 25 mg (*Elmendos, GenRx Lamotrigine, Lamidus, Lamitrin, Lamogine, Lamotrigine-DP, Seaze 25, Lamictal*)
2849Y **Lamotrigine**, Tablet 50 mg (*Elmendos, GenRx Lamotrigine, Lamidus, Lamitrin, Lamogine, Lamotrigine-DP, Seaze 50, Lamictal*)
2850B **Lamotrigine**, Tablet 100 mg (*Elmendos, GenRx Lamotrigine, Lamidus, Lamitrin, Lamogine, Lamotrigine-DP, Seaze 100, Lamictal*)
2851C **Lamotrigine**, Tablet 200 mg (*Elmendos, GenRx Lamotrigine, Lamidus, Lamitrin, Lamogine, Lamotrigine-DP, Seaze 200, Lamictal*)
8373Q **Leflunomide**, Pack containing 3 tablets leflunomide 100 mg and 30 tablets leflunomide 20 mg (*Arava*)
8374R **Leflunomide**, Tablet 10 mg (*Arabloc, Arava*)
8375T **Leflunomide**, Tablet 20 mg (*Arabloc, Arava*)
1255C **Levodopa with carbidopa**, Tablet 200 mg-50 mg (modified release) (*Sinemet CR*)
8797B **Levodopa with carbidopa and entacapone**, Tablet 50 mg-12.5 mg-200 mg (*Stalevo 50/12.5/200mg*)
8798C **Levodopa with carbidopa and entacapone**, Tablet 100 mg-25 mg-200 mg (*Stalevo 100/25/200mg*)
8799D **Levodopa with carbidopa and entacapone**, Tablet 150 mg-37.5 mg-200 mg (*Stalevo 150/37.5/200mg*)
2318B **Liothyronine sodium**, Tablet 20 micrograms (*Tertroxin*)
1611T **Mesalazine**, Tablet 250 mg (enteric coated) (*Mesasal*)
8731M **Mesalazine**, Tablet 500 mg (enteric coated) (*Salofalk*)
8598M **Mesalazine**, Sachet containing granules, 500 mg per sachet (*Salofalk*)
8599N **Mesalazine**, Sachet containing granules, 1 g per sachet (*Salofalk*)
8753Q **Mesalazine**, Enemas 1 g in 100 mL, 7 (*Pentasa*)
8616L **Mesalazine**, Enemas 2 g in 60 mL, 7 (*Salofalk*)
8617M **Mesalazine**, Enemas 4 g in 60 mL, 7 (*Salofalk*)
8768L **Mesalazine**, Rectal foam 1 g per applicatorful, 14 applications, aerosol 80 g (*Salofalk*)
8818D **Metoprolol succinate**, Pack containing 15 tablets 23.75 mg (controlled release), 15 tablets 47.5 mg (controlled release) and 15 tablets 95 mg (controlled release) (*Toprol-XL Titration Pack*)
8732N **Metoprolol succinate**, Tablet 23.75 mg (controlled release) (*Toprol-XL 23.75*)
8733P **Metoprolol succinate**, Tablet 47.5 mg (controlled release) (*Toprol-XL 47.5*)

8734Q **Metoprolol succinate**, Tablet 95 mg (controlled release) (*Toprol-XL 95*)
8735R **Metoprolol succinate**, Tablet 190 mg (controlled release) (*Toprol-XL 190*)
9031H **Miconazole**, Tincture 20 mg per mL (2%), 30 mL (*Daktarin*)
9026C **Miconazole nitrate**, Cream 20 mg per g (2%), 15 g (*Daktarin*)
9027D **Miconazole nitrate**, Cream 20 mg per g (2%), 30 g (*Daktarin*)
9028E **Miconazole nitrate**, Cream 20 mg per g (2%), 70 g (*Daktarin*)
9029F **Miconazole nitrate**, Powder 20 mg per g (2%), 30 g (*Daktarin*)
9030G **Miconazole nitrate**, Lotion 20 mg per mL (2%), 30 g (*Daktarin*)
2313R **Minoxidil**, Tablet 10 mg (*Loniten*)
1648R **Misoprostol**, Tablet 200 micrograms (*Cytotec*)
8627C **Montelukast sodium**, Chewable tablet 4 mg (base) (*Singulair*)
8628D **Montelukast sodium**, Chewable tablet 5 mg (base) (*Singulair*)
1658G **Naproxen**, Oral suspension 125 mg per 5 mL, 474 mL (*Naprosyn*)
1698J **Nystatin**, Cream 100,000 units per g, 15 g (*Mycostatin*)
8170B **Olanzapine**, Tablet 2.5 mg (*Zyprexa*)
8185T **Olanzapine**, Tablet 5 mg (*Zyprexa*)
8186W **Olanzapine**, Tablet 7.5 mg (*Zyprexa*)
8187X **Olanzapine**, Tablet 10 mg (*Zyprexa*)
8433W **Olanzapine**, Wafer 5 mg (*Zyprexa Zydis*)
8434X **Olanzapine**, Wafer 10 mg (*Zyprexa Zydis*)
1728Y **Olsalazine sodium**, Capsule 250 mg (*Dipentum*)
8086N **Olsalazine sodium**, Tablet 500 mg (*Dipentum*)
8584T **Oxcarbazepine**, Tablet 150 mg (*Trileptal*)
8585W **Oxcarbazepine**, Tablet 300 mg (*Trileptal*)
8586X **Oxcarbazepine**, Tablet 600 mg (*Trileptal*)
8588B **Oxcarbazepine**, Oral suspension 60 mg per mL, 250 mL (*Trileptal*)
1822X **Perhexiline maleate**, Tablet 100 mg (*Pexsig*)
8694N **Pioglitazone hydrochloride**, Tablet 15 mg (base) (*Actos*)
8695P **Pioglitazone hydrochloride**, Tablet 30 mg (base) (*Actos*)
8696Q **Pioglitazone hydrochloride**, Tablet 45 mg (base) (*Actos*)
8456C **Quetiapine fumarate**, Tablet 25 mg (base) (*Seroquel*)
8457D **Quetiapine fumarate**, Tablet 100 mg (base) (*Seroquel*)
8458E **Quetiapine fumarate**, Tablet 200 mg (base) (*Seroquel*)
8580N **Quetiapine fumarate**, Tablet 300 mg (base) (*Seroquel*)
8860H **Quinagolide hydrochloride**, Pack containing 3 tablets 25 micrograms (base) and 3 tablets 50 micrograms (base) (*Norprolac*)
8822H **Quinagolide hydrochloride**, Tablet 75 micrograms (base) (*Norprolac*)
1972T **Quinine bisulfate**, Tablet 300 mg (*Quinbisul*)
1975Y **Quinine sulfate**, Tablet 300 mg (*Quinsul, Quinate*)
8363E **Raloxifene hydrochloride**, Tablet 60 mg (*Evista*)
8481J **Risedronate sodium**, Tablet 5 mg (*Actonel*)
8621R **Risedronate sodium**, Tablet 35 mg (*Actonel Once-a-Week*)
8482K **Risedronate sodium**, Tablet 30 mg (*Actonel*)
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*)
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*)
8869T **Risperidone**, Tablet 0.5 mg (*Risperdal*) **(Diff.Max.Qty)**
8870W **Risperidone**, Tablet 0.5 mg (orally disintegrating) (*Risperdal Quicklet*) **(Diff.Max.Qty)**
3169T **Risperidone**, Tablet 1 mg (*Risperdal*) **(Diff.Max.Qty)**

8792R **Risperidone**, Tablet 1 mg (orally disintegrating) (*Risperdal Quicklet*) **(Diff.Max.Qty)**
3170W **Risperidone**, Tablet 2 mg (*Risperdal*)
8794W **Risperidone**, Tablet 2 mg (orally disintegrating) (*Risperdal Quicklet*)
3171X **Risperidone**, Tablet 3 mg (*Risperdal*)
3172Y **Risperidone**, Tablet 4 mg (*Risperdal*)
8100H **Risperidone**, Oral solution 1 mg per mL, 100 mL (*Risperdal*)
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*)
9075P **Risperidone**, Tablet 3 mg (orally disintegrating) (*Risperdal Quicklet*)
9076Q **Risperidone**, Tablet 4 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)**
8690J **Rosiglitazone maleate**, Tablet 8 mg (base) (*Avandia*)
8689H **Rosiglitazone maleate**, Tablet 4 mg (base) (*Avandia*)
9060W **Rosiglitazone maleate with metformin hydrochloride**, Tablet 2 mg (base)-1 g (*Avandamet*)
9059T **Rosiglitazone maleate with metformin hydrochloride**, Tablet 2 mg (base)-500 mg (*Avandamet*)
9062Y **Rosiglitazone maleate with metformin hydrochloride**, Tablet 4 mg (base)-1 g (*Avandamet*)
9061X **Rosiglitazone maleate with metformin hydrochloride**, Tablet 4 mg (base)-500 mg (*Avandamet*)
2995P **Salcatonin**, Injection 50 i.u. in 1 mL (*Miacalcic 50*)
2997R **Salcatonin**, Injection 100 i.u. in 1 mL (*Miacalcic 100*)
2946C **Sodium acid phosphate**, Compound effervescent tablet containing elemental phosphorus 500 mg, sodium 469 mg (20.4 mmol), potassium 123 mg (3.1 mmol) (*Phosphate Sandoz*)
3036T **Strontium ranelate**, Sachet containing granules for oral suspension 2 g (*Protos 2 g*)
8341B **Sumatriptan**, Nasal spray 20 mg in 0.1 mL single dose unit (*Imigran*)
8144P **Sumatriptan succinate**, Tablet 50 mg (base) (*Sumatab, Suvalan 50, Imigran*)
8885P **Sumatriptan succinate**, Tablet 50 mg (base) (fast disintegrating) (*Imigran FDT*)
1330B **Tetrabenazine**, Tablet 25 mg (*OA*)
1070H **Thiamine hydrochloride**, Tablet 100 mg (*Betamin*)
2163W **Thioridazine hydrochloride**, Tablet 10 mg (*Aldazine 10*)
2359E **Thioridazine hydrochloride**, Tablet 25 mg (*Aldazine 25*)
2164X **Thioridazine hydrochloride**, Tablet 50 mg (*Aldazine 50*)
2165Y **Thioridazine hydrochloride**, Tablet 100 mg (*Aldazine 100*)
8221Q **Tiagabine hydrochloride**, Tablet 5 mg (base) (*Gabitril*)
8222R **Tiagabine hydrochloride**, Tablet 10 mg (base) (*Gabitril*)
8223T **Tiagabine hydrochloride**, Tablet 15 mg (base) (*Gabitril*)
2095G **Ticlopidine hydrochloride**, Tablet 250 mg (*Ticlopidine Hexal, Tilodene, Ticlid*)
8267D **Tiludronate disodium**, Tablet equivalent to 200 mg tiludronic acid (*Skelid*)
8350L **Tirofiban hydrochloride**, Solution concentrate for I.V. infusion 12.5 mg (base) in 50 mL (*Aggrastat*)
8448P **Ursodeoxycholic acid**, Capsule 250 mg (*Ursofalk*)
2667J **Vigabatrin**, Tablet 500 mg (*Sabril*)
2668K **Vigabatrin**, Oral powder, sachet 500 mg (*Sabril*)
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*)

ADDITIONS

Additions - Items

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

2382J **Amino acid formula with vitamins and minerals without phenylalanine**, Oral liquid 87 mL, 30 (*PKU Cooler 10*)

2474F **Amino acid formula with vitamins and minerals without phenylalanine**, Oral liquid 174 mL, 30 (*PKU Cooler 20*)

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

9092M **Atomoxetine hydrochloride**, Capsule 10 mg (base) (*Strattera*)

9093N **Atomoxetine hydrochloride**, Capsule 18 mg (base) (*Strattera*)

9094P **Atomoxetine hydrochloride**, Capsule 25 mg (base) (*Strattera*)

9095Q **Atomoxetine hydrochloride**, Capsule 40 mg (base) (*Strattera*)

9096R **Atomoxetine hydrochloride**, Capsule 60 mg (base) (*Strattera*)

2080L **Calcipotriol**, Cream 50 micrograms per g (0.005%), 30 g (*Daivonex*)

1921D **Insulin glulisine**, Injections (human analogue) 100 units per mL, 3 mL, 5 (*Apidra*)

Additions - Brands

1182F *Fosinopril Sandoz, SZ* — **Fosinopril sodium**, Tablet 10 mg

1183G *Fosinopril Sandoz, SZ* — **Fosinopril sodium**, Tablet 20 mg

1834M *Gabapentin 300, CR* — **Gabapentin**, Capsule 300 mg

9040T *Levemir Penfill, NO* — **Insulin detemir**, Injections (human analogue) 100 units per mL, 3 mL, 5

2456G *Lisinopril 5, CR* — **Lisinopril**, Tablet 5 mg

2457H *Lisinopril 10, CR* — **Lisinopril**, Tablet 10 mg

2458J *Lisinopril 20, CR* — **Lisinopril**, Tablet 20 mg

2430X *Metformin 500, CR* — **Metformin hydrochloride**, Tablet 500 mg

1801T *Metformin 850, CR* — **Metformin hydrochloride**, Tablet 850 mg

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

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

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

2236Q *Sertraline 50, CR* — **Sertraline hydrochloride**, Tablet 50 mg (base)

2237R *Sertraline 100, CR* — **Sertraline hydrochloride**, Tablet 100 mg (base)

DELETIONS

Deletion - Section 4, Drug Tariff

Pholcodine Citrate Syrup BPC 1959

ALTERATIONS

Alterations - Restrictions

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

8511Y **Alendronate sodium**, Tablet equivalent to 70 mg alendronic acid (*Alendro Once Weekly, Fosamax Once Weekly*)

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

2502Q **Calcitriol**, Capsule 0.25 microgram (*Calcitriol-DP, Citrihexal, GenRx Calcitriol, Kosteo, Rocaltrol, Sical, Sitriol*)

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

1285P **Danazol**, Capsule 100 mg (*Azol 100*)

1287R **Danazol**, Capsule 200 mg (*Azol 200*)

8712M **Desmopressin acetate**, Nasal spray (pump pack) 10 micrograms per actuation, 60 actuations, 6 mL (*Minirin Nasal Spray*)

8663Y **Desmopressin acetate**, Tablet 200 micrograms (*Minirin*)

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*)

8495D **Donepezil hydrochloride**, Tablet 5 mg (*Aricept*)

8496E **Donepezil hydrochloride**, Tablet 10 mg (*Aricept*)

8879H **Eplerenone**, Tablet 25 mg (*Inspra*)

8880J **Eplerenone**, Tablet 50 mg (*Inspra*)

8757X **Ezetimibe**, Tablet 10 mg (*Ezetrol*)

8881K **Ezetimibe with simvastatin**, Tablet 10 mg-40 mg (*Vytorin*)

8882L **Ezetimibe with simvastatin**, Tablet 10 mg-80 mg (*Vytorin*)

8770N **Galantamine hydrobromide**, Capsule 8 mg (base) (prolonged release) (*Reminyl*)

8771P **Galantamine hydrobromide**, Capsule 16 mg (base) (prolonged release) (*Reminyl*)

8772Q **Galantamine hydrobromide**, Capsule 24 mg (base) (prolonged release) (*Reminyl*)

8373Q **Leflunomide**, Pack containing 3 tablets leflunomide 100 mg and 30 tablets leflunomide 20 mg (*Arava*)

8374R **Leflunomide**, Tablet 10 mg (*Arabloc, Arava*)

8375T **Leflunomide**, Tablet 20 mg (*Arabloc, Arava*)

1648R **Misoprostol**, Tablet 200 micrograms (*Cytotec*)

8627C **Montelukast sodium**, Chewable tablet 4 mg (base) (*Singulair*)

8628D **Montelukast sodium**, Chewable tablet 5 mg (base) (*Singulair*)

8694N **Pioglitazone hydrochloride**, Tablet 15 mg (base) (*Actos*)

8695P **Pioglitazone hydrochloride**, Tablet 30 mg (base) (*Actos*)

8696Q **Pioglitazone hydrochloride**, Tablet 45 mg (base) (*Actos*)

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*)

8497F **Rivastigmine hydrogen tartrate**, Capsule 1.5 mg (base) (*Exelon*)

8498G **Rivastigmine hydrogen tartrate**, Capsule 3 mg (base) (*Exelon*)

8499H **Rivastigmine hydrogen tartrate**, Capsule 4.5 mg (base) (*Exelon*)

8500J **Rivastigmine hydrogen tartrate**, Capsule 6 mg (base) (*Exelon*)

8563Q **Rivastigmine hydrogen tartrate**, Oral solution 2 mg (base) per mL, 120 mL (*Exelon*)

8690J **Rosiglitazone maleate**, Tablet 8 mg (base) (*Avandia*)

8689H **Rosiglitazone maleate**, Tablet 4 mg (base) (*Avandia*)

9060W **Rosiglitazone maleate with metformin hydrochloride**, Tablet 2 mg (base)-1 g (*Avandamet*)

9059T **Rosiglitazone maleate with metformin hydrochloride**, Tablet 2 mg (base)-500 mg (*Avandamet*)

9062Y **Rosiglitazone maleate with metformin hydrochloride**, Tablet 4 mg (base)-1 g (*Avandamet*)

9061X **Rosiglitazone maleate with metformin hydrochloride**, Tablet 4 mg (base)-500 mg (*Avandamet*)

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

Alterations - Notes

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

Notes have been deleted in respect of the following:

8879H **Eplerenone**, Tablet 25 mg *(Inspra)*

8880J **Eplerenone**, Tablet 50 mg *(Inspra)*

Notes have been amended in respect of the following:

8511Y **Alendronate sodium**, Tablet equivalent to 70 mg alendronic acid *(Alendro Once Weekly, Fosamax Once Weekly)*

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

8808N **Aprepitant**, Pack containing 1 capsule 125 mg and 2 capsules 80 mg (*Emend*)

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)*

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

Alterations - Proprietary Name

		From	*To*
8846N	**Amino acid formula with vitamins and minerals without phenylalanine**, Oral liquid 130 mL, 30	PKU Express Liquid	PKU Cooler 15

Alterations - Manufacturer's Code

		From	*To*
9013J	**Glucose indicator—blood**, Electrode strips, 50 (*Glucocard 01 Sensor*)	DR	OZ
8749L	**Glucose indicator—blood**, Electrode strips, 50 (*GlucoCare*)	DR	OZ
8766J	**Glucose indicator—blood**, Electrode strips, 50 (*GlucoCare Super Sensor*)	DR	OZ
3113W	**Vancomycin**, Capsule 125 mg (125,000 i.u.) vancomycin activity (*Vancocin*)	LY	AS
3114X	**Vancomycin**, Capsule 250 mg (250,000 i.u.) vancomycin activity (*Vancocin*)	LY	AS

SECTION 100 - HIGHLY SPECIALISED DRUGS PROGRAM
ALTERATIONS

Alterations - Restrictions

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

6332G	**Lanreotide acetate**, Powder for suspension for injection 30 mg (base) with diluent ampoule (*Somatuline LA*)
6423C	**Lanreotide acetate**, Injection 60 mg (base) in single dose pre-filled syringe (*Somatuline Autogel*)
6424D	**Lanreotide acetate**, Injection 90 mg (base) in single dose pre-filled syringe (*Somatuline Autogel*)
6425E	**Lanreotide acetate**, Injection 120 mg (base) in single dose pre-filled syringe *(Somatuline Autogel)*
6227R	**Octreotide acetate**, Injection 50 micrograms (base) in 1 mL (*Sandostatin 0.05*)
6228T	**Octreotide acetate**, Injection 100 micrograms (base) in 1 mL (*Sandostatin 0.1*)
6229W	**Octreotide acetate**, Injection 500 micrograms (base) in 1 mL (*Sandostatin 0.5*)
6426F	**Octreotide acetate**, Injection (modified release) 10 mg (base) vial and diluent syringe (*Sandostatin LAR*)
6427G	**Octreotide acetate**, Injection (modified release) 20 mg (base) vial and diluent syringe (*Sandostatin LAR*)
6428H	**Octreotide acetate**, Injection (modified release) 30 mg (base) vial and diluent syringe (*Sandostatin LAR*)

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)**, Injections (human) 100 units (20 units-80 units) per mL, 3 mL, 5 (*Mixtard 20/80 Penfill 3 mL*)

Advance Notices - Deletion of Brands

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

Brand discontinued by the manufacturer -

2913H *Microval 28, WY* — **Levonorgestrel**, Tablets 30 micrograms, 28

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

The text of restrictions mentioned above:

8511Y **Alendronate sodium**, Tablet equivalent to 70 mg alendronic acid (*Alendro Once Weekly, Fosamax Once Weekly*)

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

Authority required (STREAMLINED)

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)

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.

2382J **Amino acid formula with vitamins and minerals without phenylalanine**, Oral liquid 87 mL, 30 (*PKU Cooler 10*)

2474F **Amino acid formula with vitamins and minerals without phenylalanine**, Oral liquid 174 mL, 30 (*PKU Cooler 20*)

Restricted benefit

Phenylketonuria

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

Restricted benefit

Maple syrup urine disease

9092M **Atomoxetine hydrochloride**, Capsule 10 mg (base) (*Strattera*)

9093N **Atomoxetine hydrochloride**, Capsule 18 mg (base) (*Strattera*)

9094P **Atomoxetine hydrochloride**, Capsule 25 mg (base) (*Strattera*)

9095Q **Atomoxetine hydrochloride**, Capsule 40 mg (base) (*Strattera*)

9096R **Atomoxetine hydrochloride**, Capsule 60 mg (base) (*Strattera*)

Authority required

Initial 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 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 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 treatment where the patient has previously been issued with an authority prescription for this drug

2080L **Calcipotriol**, Cream 50 micrograms per g (0.005%), 30 g (*Daivonex*)

Restricted benefit

Chronic stable plaque type psoriasis vulgaris

2502Q **Calcitriol**, Capsule 0.25 microgram (*Calcitriol-DP, Citrihexal, GenRx Calcitriol, Kosteo, Rocaltrol, Sical, Sitriol*)

Authority required (STREAMLINED)

Hypocalcaemia due to renal disease

Authority required (STREAMLINED)

Hypoparathyroidism

Authority required (STREAMLINED)

Hypophosphataemic rickets

Authority required (STREAMLINED)

Vitamin D-resistant rickets

Authority required (STREAMLINED)

Treatment 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.

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

Authority required

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

1285P **Danazol**, Capsule 100 mg (*Azol 100*)

1287R **Danazol**, Capsule 200 mg (*Azol 200*)

Caution:

Pregnancy must be excluded prior to administration of this drug.

Authority required (STREAMLINED)

Endometriosis, visually proven.

Authority required (STREAMLINED)

Hereditary angio-oedema.

Authority required (STREAMLINED)

Short-term treatment (up to 6 months) of intractable primary menorrhagia (Treatment of this indication is limited to 6 months. See Australian Product Information).

Authority required (STREAMLINED)

Short-term treatment (up to 6 months) of severe benign (fibrocystic) breast disease or mastalgia associated with severe symptomatic benign breast disease in patients refractory to other treatments (Treatment of this indication is limited to 6 months. See Australian Product Information).

8712M **Desmopressin acetate**, Nasal spray (pump pack) 10 micrograms per actuation, 60 actuations, 6 mL (*Minirin Nasal Spray*)

Authority required (STREAMLINED)

Primary nocturnal enuresis in patients aged 6 years or older who are refractory to an enuresis alarm.

Authority required (STREAMLINED)

Primary nocturnal enuresis in patients aged 6 years or older for whom an enuresis alarm is contraindicated. The reason that an alarm is contraindicated must be documented in the patient's medical records when treatment is initiated.

Note:

Not to be used in preference to enuresis alarms.

8663Y **Desmopressin acetate**, Tablet 200 micrograms (*Minirin*)

Note:

Only one application per six months with no more than twice the maximum quantity will be authorised for the tablets.

Authority required (STREAMLINED)

Primary nocturnal enuresis in patients aged 6 years or older who are refractory to an enuresis alarm.

Authority required (STREAMLINED)

Primary nocturnal enuresis in patients aged 6 years or older for whom an enuresis alarm is contraindicated. The reason that an alarm is contraindicated must be documented in the patient's medical records when treatment is initiated.

Note:

Not to be used in preference to enuresis alarms.

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*)

Authority required (STREAMLINED)

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:

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

8496E **Donepezil hydrochloride**, Tablet 10 mg (*Aricept*)

8495D **Donepezil hydrochloride**, Tablet 5 mg (*Aricept*)
8771P **Galantamine hydrobromide**, Capsule 16 mg (base) (prolonged release) (*Reminyl*)
8772Q **Galantamine hydrobromide**, Capsule 24 mg (base) (prolonged release) (*Reminyl*)
8770N **Galantamine hydrobromide**, Capsule 8 mg (base) (prolonged release) (*Reminyl*)
8497F **Rivastigmine hydrogen tartrate**, Capsule 1.5 mg (base) (*Exelon*)
8498G **Rivastigmine hydrogen tartrate**, Capsule 3 mg (base) (*Exelon*)
8499H **Rivastigmine hydrogen tartrate**, Capsule 4.5 mg (base) (*Exelon*)
8500J **Rivastigmine hydrogen tartrate**, Capsule 6 mg (base) (*Exelon*)

8563Q **Rivastigmine hydrogen tartrate**, Oral solution 2 mg (base) per mL, 120 mL (*Exelon*)

Authority required

INITIAL APPLICATION FOR THE TREATMENT OF MILD TO MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients with an (S)MMSE of 10 or more.Initial treatment of mild to moderately severe Alzheimer's disease. Confirmation of this diagnosis must be made by a specialist/consultant physician (including a psychiatrist).

The authority application must include the result of the baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE). This baseline (S)MMSE must be a score of 10 or more. If this score is 25 - 30 points, the result of a baseline Alzheimer's Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

If an ADAS-Cog score is not supplied with the initial application, this scale cannot be used for the purpose of fulfilling the criteria for continued PBS supply.

This application must be made in writing, but initial supply may be sought by telephone.For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised

Authority required

CONTINUING TREATMENT — (S)MMSE or ADAS-Cog improvement.Continuing treatment, following initial PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease in patients with demonstrated improvement in cognitive function as measured by:(a) for patients with a baseline (S)MMSE score of 10 or more and less than 25, an increase of at least 2 points from baseline on the Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE);(b) for patients with a baseline (S)MMSE score of at least 25 points, a decrease of at least 4 points from baseline on the Alzheimer's Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) or an increase of at least 2 points from baseline on the Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE).

The initial authority application for continuing treatment must include the relevant result from the (S)MMSE or the ADAS-Cog and must be in writing.

Subsequent applications for continuing treatment can be made by telephone

Authority required

INITIAL APPLICATION FOR THE TREATMENT OF MILD TO MODERATELY SEVERE ALZHEIMER'S DISEASE — Patients with an (S)MMSE of 9 or less who require a clinician's assessment.Initial treatment of mild to moderately severe Alzheimer's disease of patients with a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, who are unable to register a score of 10 or more for reasons other than their Alzheimer's disease, as specified below. Confirmation of this diagnosis must be made by a specialist/consultant physician (including a psychiatrist).

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

This application must be made in writing, but initial supply may be sought by telephone.For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

Patients who qualify under this criterion are from 1 or more of the following groups:(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment

Authority required

CONTINUING TREATMENT — Clinician assessed improvement.Continuing treatment, following initial PBS-subsidised therapy, of mild to moderately severe Alzheimer's disease in patients with demonstrated improvement in function, based on a rating of "very much improved" or "much improved" on the Clinicians Interview Based Impression of Change (CIBIC) scale, which must be assessed by the same clinician who initiated treatment.

The initial authority application for continuing treatment must state the improvement achieved on the CIBIC scale and must be in writing.

Subsequent applications for continuing treatment can be made by telephone

8879H **Eplerenone**, Tablet 25 mg (*Inspra*)

8880J **Eplerenone**, Tablet 50 mg (*Inspra*)

Caution:

Serum electrolytes should be checked regularly.

Authority required (STREAMLINED)

Heart failure with a left ventricular ejection fraction of 40% or less occurring within 3 to 14 days following an acute myocardial infarction. Treatment with eplerenone must be commenced within 14 days of an acute myocardial infarction.

The date of the acute myocardial infarction and the date of initiation of eplerenone treatment must be documented in the patient's medical records when PBS-subsidised treatment is initiated.

8757X **Ezetimibe**, Tablet 10 mg (*Ezetrol*)

Authority required (STREAMLINED)

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.

(c) peripheral vascular disease.

(d) heterozygous familial hypercholesterolaemia.

(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 dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; 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 dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

Patients eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs) where treatment with an HMG CoA reductase inhibitor (statin) is contraindicated.

Authority required (STREAMLINED)

Patients eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs) where treatment with an HMG CoA reductase inhibitor (statin) 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.

Authority required (STREAMLINED)

Homozygous sitosterolaemia.

Authority required (STREAMLINED)

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), in combination with an HMG CoA reductase inhibitor (statin).

8881K **Ezetimibe with simvastatin**, Tablet 10 mg-40 mg (*Vytorin*)

8882L **Ezetimibe with simvastatin**, Tablet 10 mg-80 mg (*Vytorin*)

Authority required (STREAMLINED)

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.

(c) peripheral vascular disease.

(d) heterozygous familial hypercholesterolaemia.

(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 dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; 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 dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated

Authority required (STREAMLINED)

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).

6423C **Lanreotide acetate**, Injection 60 mg (base) in single dose pre-filled syringe (*Somatuline Autogel*)

6425E **Lanreotide acetate,** Injection 120 mg (base) in single dose pre-filled syringe (*Somatuline Autogel)*

6424D **Lanreotide acetate**, Injection 90 mg (base) in single dose pre-filled syringe (*Somatuline Autogel*)

Private hospital authority required

Active acromegaly in a patient with persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre AND

(a) after failure of other therapy including dopamine agonists; or

(b) as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or

(c) if the patient is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated.

In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose). Lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

Treatment must cease if IGF1 is not lower after 3 months treatment;

Functional carcinoid tumour causing intractable symptoms. The patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of

anti-histamines, anti-serotonin agents and anti-diarrhoea agents, and surgery or antineoplastic therapy must have failed or be inappropriate.

Treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

6332G **Lanreotide acetate**, Powder for suspension for injection 30 mg (base) with diluent ampoule (*Somatuline LA*)

Private hospital authority required

Active acromegaly in a patient with persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre AND

(a) after failure of other therapy including dopamine agonists; or

(b) as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or

(c) if the patient is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated.

In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (6 weeks after the last dose). Lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

Treatment must cease if IGF1 is not lower after 3 months treatment.

8373Q **Leflunomide**, Pack containing 3 tablets leflunomide 100 mg and 30 tablets leflunomide 20 mg (*Arava*)

Caution:

Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

Authority required (STREAMLINED)

Initial treatment of severe active rheumatoid arthritis where other disease modifying anti-rheumatic drugs (including methotrexate) are ineffective and/or inappropriate. Treatment must be initiated by a physician.

Note:

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

8374R **Leflunomide**, Tablet 10 mg (*Arabloc, Arava*)

8375T **Leflunomide**, Tablet 20 mg (*Arabloc, Arava*)

Authority required (STREAMLINED)

Treatment of severe active rheumatoid arthritis where other disease modifying anti-rheumatic drugs (including methotrexate) are ineffective and/or inappropriate. Treatment must be initiated by a physician.

1648R **Misoprostol**, Tablet 200 micrograms (*Cytotec*)

Note:

Caution:

Misoprostol is a prostaglandin analogue. It should not be used in pregnant women.

Authority required (STREAMLINED)

Reduction in the incidence of gastrointestinal complications in patients who have a history of peptic ulcer disease and where NSAID therapy is essential.

Authority required (STREAMLINED)

Duodenal ulcer (including pyloric and stomal ulcers), proven by current or prior x-ray, endoscopy or surgery. The date and the method by which the ulcer was proven must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

Gastric ulcer, proven by x-ray, endoscopy or surgery within the previous 2 years. The date and the method by which the ulcer was proven must be documented in the patient's medical records when treatment is initiated.

8627C **Montelukast sodium**, Chewable tablet 4 mg (base) (*Singulair*)

Authority required (STREAMLINED)

First-line preventer medication, as the single preventer agent for children aged 2 to 5 years with frequent intermittent or mild persistent asthma, as an alternative to sodium cromoglycate or nedocromil sodium.

8628D **Montelukast sodium**, Chewable tablet 5 mg (base) (*Singulair*)

Authority required (STREAMLINED)

First-line preventer medication, as the single preventer agent for children aged 6 to 14 years with frequent intermittent or mild persistent asthma, as an alternative to sodium cromoglycate or nedocromil sodium.

6426F **Octreotide acetate**, Injection (modified release) 10 mg (base) vial and diluent syringe (*Sandostatin LAR*)

6427G **Octreotide acetate**, Injection (modified release) 20 mg (base) vial and diluent syringe (*Sandostatin LAR*)

6428H **Octreotide acetate**, Injection (modified release) 30 mg (base) vial and diluent syringe (*Sandostatin LAR*)

Private hospital authority required

Acromegaly in a patient controlled on Sandostatin subcutaneous injections.

In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose). Octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

Treatment must cease if IGF1 is not lower after 3 months of treatment;

Functional carcinoid tumour or vasoactive intestinal peptide secreting tumour (VIPoma) with symptom control on Sandostatin subcutaneous injections.

Treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with Sandostatin subcutaneous injections. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

6228T **Octreotide acetate**, Injection 100 micrograms (base) in 1 mL (*Sandostatin 0.1*)

6229W **Octreotide acetate**, Injection 500 micrograms (base) in 1 mL (*Sandostatin 0.5*)

6227R **Octreotide acetate**, Injection 50 micrograms (base) in 1 mL (*Sandostatin 0.05*)

Private hospital authority required

Active acromegaly in a patient with persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre AND

(a) after failure of other therapy including dopamine agonists; or

(b) as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or

(c) if the patient is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated.

In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks. Octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

Treatment must cease if IGF1 is not lower after 3 months treatment at a dose of 100 micrograms 3 times daily;

Functional carcinoid tumour or vasoactive intestinal peptide secreting tumour (VIPoma) causing intractable symptoms. The patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, and surgery or antineoplastic therapy must have failed or be inappropriate.

Treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

8694N **Pioglitazone hydrochloride**, Tablet 15 mg (base) (*Actos*)

8695P **Pioglitazone hydrochloride**, Tablet 30 mg (base) (*Actos*)

8696Q **Pioglitazone hydrochloride**, Tablet 45 mg (base) (*Actos*)

Authority required (STREAMLINED)

Dual oral combination therapy with metformin or a sulfonylurea

Type 2 diabetes, in combination with either metformin or a sulfonylurea, in a patient whose HbA1c is greater than 7% prior to initiation of a thiazolidinedione (glitazone) despite treatment with either metformin or a sulfonylurea and where a combination of metformin and a sulfonylurea is contraindicated or not tolerated.

The date and level of the HbA1c must be documented in the patient's medical records at the time glitazone treatment is initiated. The HbA1c must be no more than 4 months old at the time glitazone treatment is initiated.

Note:

Pioglitazone hydrochloride is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy).

Pioglitazone hydrochloride is not PBS-subsidised as monotherapy.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) red cell transfusion within the previous 3 months.

A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of glitazone therapy, must be documented in the patient's medical records.

Authority required (STREAMLINED)

Combination therapy with insulin

Type 2 diabetes, in combination with insulin, in a patient whose HbA1c is greater than 7% prior to initiation of a thiazolidinedione (glitazone) despite treatment with insulin and oral anti-diabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the HbA1c must be documented in the patient's medical records at the time glitazone treatment is initiated. The HbA1c must be no more than 4 months old at the time glitazone treatment is initiated.

Note:

Pioglitazone hydrochloride is not PBS-subsidised as monotherapy.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) red cell transfusion within the previous 3 months.

A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of glitazone therapy, must be documented in the patient's medical records.

8363E **Raloxifene hydrochloride**, Tablet 60 mg (*Evista*)

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

Authority required (STREAMLINED)

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

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

8621R **Risedronate sodium**, Tablet 35 mg (*Actonel Once-a-Week*)

8481J **Risedronate sodium**, Tablet 5 mg (*Actonel*)

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*)

Authority required (STREAMLINED)

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.

8689H **Rosiglitazone maleate**, Tablet 4 mg (base) (*Avandia*)

8690J **Rosiglitazone maleate**, Tablet 8 mg (base) (*Avandia*)

Authority required (STREAMLINED)

Dual oral combination therapy with metformin or a sulfonylurea

Type 2 diabetes, in combination with either metformin or a sulfonylurea, in a patient whose HbA1c is greater than 7% prior to initiation of a thiazolidinedione (glitazone) despite treatment with either metformin or a sulfonylurea and where a combination of metformin and a sulfonylurea is contraindicated or not tolerated.

The date and level of the HbA1c must be documented in the patient's medical records at the time glitazone treatment is initiated. The HbA1c must be no more than 4 months old at the time glitazone treatment is initiated.

Note:

Rosiglitazone maleate is not PBS-subsidised for use as monotherapy.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) red cell transfusion within the previous 3 months.

A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of glitazone therapy, must be documented in the patient's medical records.

Authority required (STREAMLINED)

Triple oral combination therapy with metformin and a sulfonylurea

Type 2 diabetes, in combination with metformin and a sulfonylurea, in a patient whose HbA1c is greater than 7% prior to initiation of a thiazolidinedione (glitazone) despite treatment with maximally tolerated doses of metformin and a sulfonylurea.

The date and level of the HbA1c must be documented in the patient's medical records at the time glitazone treatment is initiated. The HbA1c must be no more than 4 months old at the time glitazone treatment is initiated.

Note:

Rosiglitazone maleate is not PBS-subsidised for use as monotherapy.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) red cell transfusion within the previous 3 months.

A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of glitazone therapy, must be documented in the patient's medical records.

Authority required (STREAMLINED)

Combination therapy with insulin

Type 2 diabetes, in combination with insulin, in a patient whose HbA1c is greater than 7% prior to initiation of a thiazolidinedione (glitazone) despite treatment with insulin and oral anti-diabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the HbA1c must be documented in the patient's medical records at the time glitazone treatment is initiated. The HbA1c must be no more than 4 months old at the time glitazone treatment is initiated.

Note:

Rosiglitazone maleate is not PBS-subsidised for use as monotherapy.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) red cell transfusion within the previous 3 months.

A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results

of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of glitazone therapy, must be documented in the patient's medical records.

9060W **Rosiglitazone maleate with metformin hydrochloride**, Tablet 2 mg (base)-1 g (*Avandamet*)

9059T **Rosiglitazone maleate with metformin hydrochloride**, Tablet 2 mg (base)-500 mg (*Avandamet*)

9062Y **Rosiglitazone maleate with metformin hydrochloride**, Tablet 4 mg (base)-1 g (*Avandamet*)

9061X **Rosiglitazone maleate with metformin hydrochloride**, Tablet 4 mg (base)-500 mg (*Avandamet*)

Note:

Rosiglitazone with metformin fixed dose combination tablet is not PBS-subsidised when used in combination with insulin.

Authority required (STREAMLINED)

Type 2 diabetes in a patient whose HbA1c is greater than 7% prior to initiation of a thiazolidinedione (glitazone) despite treatment with metformin and where a sulfonylurea is contraindicated or not tolerated.

The date and level of the HbA1c must be documented in the patient's medical records at the time glitazone treatment is initiated. The HbA1c must be no more than 4 months old at the time glitazone treatment is initiated.

Note:

Blood glucose monitoring as an alternative assessment to HbA1c levels will be accepted in the following circumstances:

(a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) red cell transfusion within the previous 3 months.

A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of glitazone therapy, must be documented in the patient's medical records.

Authority required (STREAMLINED)

Type 2 diabetes, in combination with a sulfonylurea, in a patient whose HbA1c is greater than 7% prior to initiation of a thiazolidinedione (glitazone) despite treatment with maximally tolerated doses of metformin and a sulfonylurea.

The date and level of the HbA1c must be documented in the patient's medical records at the time glitazone treatment is initiated. The HbA1c must be no more than 4 months old at the time glitazone treatment is initiated.

Note:

Blood glucose monitoring as an alternative assessment to HbA1c levels will be accepted in the following circumstances:

(a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) red cell transfusion within the previous 3 months.

A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of glitazone therapy, must be documented in the patient's medical records.

NOTES

The text of notes mentioned above:

8511Y **Alendronate sodium**, Tablet equivalent to 70 mg alendronic acid *(Alendro Once Weekly, Fosamax Once Weekly)*

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

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 *(Actonal)*

8621R **Risedronate sodium**, Tablet 35 mg *(Actonal 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)*

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

Note:

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

8808N **Aprepitant**, Pack containing 1 capsule 125 mg and 2 capsules 80 mg *(Emend)*

Note:

No applications for increased maximum quantities will be authorised. Prescribers should advise Medicare Australia of the number of cycles planned when requesting approval for repeats.

REPATRIATION PHARMACEUTICAL BENEFITS

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

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

SUMMARY OF CHANGES

DELETIONS

Deletions - Item

4283K **Ipratropium bromide with salbutamol sulfate**, Oral pressurised inhalation 20 micrograms (anhydrous)-100 micrograms (base) per dose (200 doses) (*Combivent*)

Deletions - Brands

4922C *Replicare Ultra 66000435, SN* — **Dressing—hydrocolloid (superficial wound—moderate exudate)**, Dressings 15 cm x 15 cm, 5

4842W *Replicare Ultra 66000437, SN* — **Dressing—hydrocolloid (superficial wound—moderate exudate)**, Dressings, sacral, 5

ALTERATIONS

Alterations - Proprietary Name

		From	*To*
4760M	**Bandage—zinc paste**, Bandages 80 cm (stockings), 4	ZipZoc 66051550	ZipZoc 66000747
4599C	**Dressing—hydrogel—amorphous**, Tube 50 g	SoloSite Gel 36361338	SoloSite Gel 36361354
4860T	**Dressing—non-adherent**, Dressings 5 cm x 5 cm, 5	Melolin 36101720	Melolin 36361357