

November 2008 PBAC OUTCOMES – Positive Recommendations

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
Amino acid formula with vitamins and minerals without phenylalanine, oral liquid 62.5 mL, 60, (Lophlex LQ 10[®]) Nutricia Australia Pty Ltd Minor submission	Medicinal food	Phenylketonuria.	Recommended.
Amino acid formula without phenylalanine and vitamins and minerals, sachets 18.2 g, 60, (ADD-INS[®]) Nutricia Australia Pty Ltd Minor submission	Medicinal food	To request a change in existing formulation and presentation.	Recommended.
Amino acid formula, excluding phenylalanine and tyrosine, with fat, carbohydrate, vitamins, minerals and trace elements, sachets 29 g, 30, (TYR Anamix Junior[®]) Nutricia Australia Pty Ltd Minor submission	Medicinal food	Tyrosinaemia.	Recommended.

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Amino acid formula, excluding phenylalanine, with fat, carbohydrate, vitamins, minerals and trace elements and supplemented with DHA, oral liquid 125 mL, 36, (PKU Anamix Junior LQ[®]) Nutricia Australia Pty Ltd Minor submission	Medicinal food	Phenylketonuria.	Recommended.
Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids, 400 g, (Neocate LCP[®]) Nutricia Australia Pty Ltd Minor submission	Medicinal food	To request a change in the listed formulation, resulting in an increase in calcium and phosphorus.	Recommended.
Bivalirudin trifluoroacetate, powder for I.V. injection, 250 mg (base), (Angiomax[®]) CSL Biotherapies Minor submission	Anticoagulant	Extend current listing to allow use in patients undergoing emergency percutaneous coronary intervention (PCI).	Recommended.
Blood glucose indicator, electrode strips, 50, (Freestyle[®]) Abbott Australasia Pty Ltd Minor submission	Test strip to monitor blood in diabetes	Listing of Freestyle [®] blood glucose electrode test strips.	Recommended.

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Botulinum toxin type A, lyophilised powder for IM injection, 100 units vial, (Botox®) Allergan Australia Pty Ltd Major submission	Spasticity of the upper limbs of children with cerebral palsy	Extend the current Section 100 listing to include the treatment of moderate to severe spasticity of the upper limbs of children (2 years of age or older) with cerebral palsy.	Recommended on the basis of acceptable cost-effectiveness in the context of a condition where large utility gains are probable in responders and where non-responders are unlikely to continue treatment.
Capecitabine, tablet, 150 mg, 500 mg, (Xeloda®) Roche Products Pty Ltd Major submission	Anti-cancer drug	Extend the listing of oxaliplatin to include use in combination with capecitabine for the treatment of patients with metastatic colorectal cancer.	Recommended a change to the listing of oxaliplatin to allow use with capecitabine on a cost-minimisation basis compared with the chemotherapy regimen, modified FOLFOX-6.
Clopidogrel 75 mg with aspirin 100 mg, tablet, (CoPlavix®, DuoCover®) Sanofi-Aventis Australia Pty Ltd Bristol-Myers Squibb Pharmaceuticals Minor submission	Anticoagulant combination	List the combination product for the treatment of acute coronary syndrome.	Recommended listing on a cost minimisation basis compared to clopidogrel alone for acute coronary syndrome and prevention of stroke, myocardial infarction or angina in patients who have had one of these events when on aspirin alone.
Desvenlafaxine, tablet extended release, 50 mg, 100 mg, (Pristiq®) Wyeth Australia Pty Ltd Major submission	Antidepressant	Major depressive disorders.	Recommended for listing on a cost minimisation basis compared with venlafaxine. The equi-effective doses are desvenlafaxine 50 mg and venlafaxine 75 mg.

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Efalizumab, injection set containing 4 vials powder for injection 125 mg and 4 pre-filled syringes diluent, 1.3mL, (Raptiva[®]) Merck Serono Australia Pty Ltd Major submission	Psoriasis	To extend initial treatment phase for chronic plaque psoriasis from 12 to 24 weeks.	PBAC recommended that patients who achieve between a 50% and 75% reduction in their PASI score by week 12 be allowed to continue PBS subsidised treatment with efalizumab for a further 12 weeks, with the first 12 weeks of treatment counted as a failure for the purposes of administering the PBS chronic plaque psoriasis biological agent interchangeability rules.
Escitalopram, oral solution, 10 mg (base) per mL, (Lexapro[®]) Lundbeck Australia Pty Ltd Minor submission	Mood disorders	Extend the listing of this formulation to include moderate to severe generalised anxiety disorder (GAD) and moderate to severe social anxiety disorder (SAD).	Recommended.
Esomeprazole, sachet containing granules for oral suspension, 10 mg per sachet, (Nexium[®]) AstraZeneca Pty Ltd Minor submission	Ulcer/reflux	To list a new form and strength for use in children aged 1 to 11 years, inclusive.	Recommended with a small premium over the capsule formulations of the same medicine.
Essential amino acids formula with vitamins and minerals, Sachets 12.5 g, 50, (EAA Supplement[®]) Vitaflo Australia Pty Ltd Minor submission	Medicinal food	For use in the dietary management of urea cycle disorders and other very rare conditions that require a very low protein diet.	Recommended.

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Exenatide, injection, 5 micrograms in 20 microlitres, 10 micrograms in 40 microlitres, (Byetta[®]) Eli Lilly Pty Ltd Major submission	Type 2 Diabetes	Treatment of Type 2 diabetes.	Recommended for listing on a cost minimisation basis compared with insulin glargine, taking into account the higher costs associated with the initiation and titration of insulin glargine. The equi-effective doses are exenatide 9.07 micrograms twice daily and insulin glargine 24.93 international units (IU) per day when these agents are in used in triple combination therapy with metformin and a sulfonylurea; and exenatide 9.35 micrograms twice daily and insulin glargine 27.30 IU per day when these agents are used as part of dual combination therapy with either metformin or a sulfonylurea.
Filgrastim, injection 300 micrograms in 1 mL, 300 micrograms in 0.5 mL, single use pre-filled syringe, 480 micrograms in 1.6 mL, 480 micrograms in 0.5 mL, single use pre-filled syringe (Neupogen[®]) Amgen Australia Pty Ltd Minor submission	Immunostimulant	As primary prophylaxis of neutropenic complications in patients with chronic lymphocytic leukaemia treated with fludarabine and cyclophosphamide.	Recommended for secondary prophylaxis, as the data presented did not support use in primary prophylaxis.
Hydromorphone hydrochloride, tablet prolonged release, 8 mg, 16 mg, 32 mg, 64 mg, (Jurnista[®]) Janssen-Cilag Pty Ltd Major submission	Opioid pain reliever	Chronic severe disabling pain not responding to non-narcotic analgesics.	Recommended for listing in the General and Dental schedules on a cost minimisation basis to oxycodone controlled release tablets. The equi-effective doses are 26.4 mg hydromorphone hydrochloride prolonged release to 74 mg oxycodone hydrochloride controlled release, giving a ratio of 1: 2.8.

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Ibandronic acid, tablet, 50 mg, (Bondronat[®]) Hospira Australia Pty Ltd Major submission	Reduce bone pain and risk of fracture	Treatment of patients with bone metastases from breast cancer.	Recommended on a cost-minimisation basis compared with oral clodronate. The equi-effective doses are ibandronic acid 50 mg daily and clodronate 1600 mg daily.
Lanthanum carbonate, tablet, 500 mg, 750 mg, 1000 mg, (Fosrenol[®]) Shire Australia Pty Ltd Major submission	Phosphate-binder	Hyperphosphataemia (high level of phosphate in blood) in renal failure.	Recommended on a cost minimisation basis compared with sevelamer. The equi-effective average daily doses are 1936 mg lanthanum and 5231 mg sevelamer.
Lenalidomide, capsule, 5 mg, 10 mg, 15 mg, 25 mg, (Revlimid[®]) Celgene Pty Ltd Major submission	Multiple myeloma	Treatment of patients with relapsed/refractory multiple myeloma for whom thalidomide therapy has failed.	Recommended on a cost minimisation basis compared with bortezomib. The equi-effective doses to be based on 6 cycles of bortezomib.
Levetiracetam, tablet, 250 mg, 500 mg, 1000 mg, oral solution 100 mg per mL (Keppra[®]) UCB Australia Pty Ltd Major submission	Anti-epileptic	Extend current indications to include treatment, as add-on therapy, of primary generalised tonic clonic seizures and generalised myoclonic seizures.	Recommended on a cost-minimisation basis with lamotrigine with the equi-effective doses for these indications being levetiracetam 2887 mg and lamotrigine 296 mg.
Levodopa with carbidopa and entacapone, tablet, 200 mg/50 mg/200 mg, Stalevo[®], Novartis Pharmaceuticals Australia Pty Ltd. Minor submission	Parkinson disease	Listing of additional strength.	Recommended.

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Macrogol 3350, sachets containing powder for solution 6.563 g with electrolytes, 30, (Movicol-Half[®]) Norgine Pty Ltd Minor submission	Laxative	1. To add "Patients receiving palliative care" into the current Section 85 Restricted Benefit listing. (Movicol and Movicol-Half). 2. To request an Authority Required listing in the Palliative Care schedule (Movicol-Half).	Recommended.
Mesalazine, tablet prolonged release, 500 mg, (Pentasa[®]) Ferring Pharmaceuticals Pty Ltd Minor submission	Ulcerative colitis/Crohn's Disease	Increase in the maximum quantity.	Recommended.
Metformin, 500 mg, tablet extended release, (Diabex XR[®]), Alphapharm Pty Ltd Minor submission	Hypoglycaemic agent	Increase the pack size of the current listed product from 90 tablets to 120 tablets.	Recommended.
Mirtazapine, tablet, 15 mg, (Axit 15[®]) Alphapharm Pty Ltd Minor submission	Antidepressant	List a new strength.	Recommended
Modified long chain amylopectin, sachet 60 g providing 50 g of glycosade, 30, (Glycosade[®]) Vitaflo Australia Pty Ltd Minor submission	Medicinal food	For use in the management of glycogen storage disease (GSD).	Recommended.

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Oxaliplatin, solution concentrate for I.V. infusion, 50 mg in 10 mL, 100 mg in 20 mL and 200 mg in 40 mL, (Eloxatin[®]), powder for I.V. infusion, 50 mg and 100 mg, (Oxalatin[®], Oxaliplatin Ebewe[®], Winthrop Oxaliplatin[®], HH[®]) Sanofi-Aventis Australia Pty Ltd, Spirit Pharmaceuticals Pty Ltd, InterPharma Pty Ltd, Winthrop Pharmaceuticals, Hospira Pty Ltd. Major submission	Anti-cancer drug	Extend the listing to include use in combination with capecitabine for the treatment of patients with metastatic colorectal cancer.	Recommended a change to the listing of oxaliplatin to allow use with capecitabine on a cost-minimisation basis compared with the chemotherapy regimen, modified FOLFOX-6.
Oxycodone hydrochloride, tablet controlled release, 15 mg and 30 mg, (OxyContin[®]) Mundipharma Pty Ltd Minor submission	Narcotic analgesic	List two new strengths.	Recommended.
Pancreatic extract, capsule providing not less than 40,000 BP units of lipase activity, (Creon 40,000[®]) Solvay Pharmaceuticals Minor submission	Enzyme replacement	List a new strength.	Recommended.

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Pegfilgrastim, injection, 6 mg in 0.6 mL, single use pre-filled syringe, (Neulasta[®]) Amgen Australia Pty Ltd Minor submission	Immunostimulant	As primary prophylaxis of neutropenic complications in patients with chronic lymphocytic leukaemia treated with fludarabine and cyclophosphamide.	Recommended for secondary prophylaxis, as the data presented did not support use in primary prophylaxis.
Phenoxybenzamine, capsule 10 mg, 100, (Dibenzyl[®]) Goldshield Healthcare Minor submission.	Phaeochromocytoma	To list a new formulation on a temporary basis.	Recommended.
Phenylalanine with carbohydrate, Sachets 4g containing 50 mg phenylalanine, 30, (Phenylalanine Amino Acid Supplement[®]) Vitaflo Australia Pty Ltd Minor submission	Medicinal food	Tyrosinaemia.	Recommended.
Polyethylene glycol 400 with propylene glycol, eye drops 4 mg-3 mg per mL (0.4%-0.3%), single dose units 0.8 mL, 28, (Systane[®]) Alcon Laboratories Australia Pty Ltd Minor submission	Lubricant eye drop	To change the vial size from 0.7 mL (as recommended by PBAC in November 2004) to 0.8 mL.	Recommended.

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Pramipexole, tablet, 0.125 mg, 0.25mg, (Sifrol[®]) Boehringer Ingelheim Pty Ltd Major submission	Alleviates the symptoms of Parkinson disease and of Restless Legs Syndrome	Extend the listed indications to include treatment of severe primary Restless Legs Syndrome.	Recommended on a cost minimisation basis compared with levodopa-benserazide. The equivalent doses for this indication are pramipexole 490 micrograms and levodopa with benserazide 192/48 mg.
Risperidone, oral solution 1 mg per mL, 100 mL, (Risperdal[®]) Janssen-Cilag Pty Ltd Minor submission	Behavioural disturbance	To request that the two restrictions applying to the 30 mL pack be applied to the 100 mL pack, as the sponsor is deleting the former.	Agreed by Delegate.
Tacrolimus, capsules 500 mcg, 1 mg and 5 mg, (Prograf[®]) Janssen-Cilag Pty Ltd Minor submission	Immunosuppressant	Change the current restriction wording so that it does not specify type of transplant.	Recommended.
Telmisartan with hydrochlorothiazide, tablets, 80 mg/25 mg, (Micardis Plus[®]) Boehringer Ingelheim Pty Ltd Minor submission	Hypertension	List a new strength.	Recommended.
Temozolomide, capsule, 140 mg, (Temodal[®]) Schering-Plough Pty Ltd Minor submission	Anti-cancer drug	List a new strength.	Recommended.

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Tenofovir disoproxil fumarate, tablet, 300 mg, (Viread[®]) Gilead Sciences Pty Ltd Major submission	Chronic hepatitis B	Adult patients with chronic hepatitis B who are nucleos(t)ide analogue naïve or who have failed prior antihepadnaviral therapy.	Recommended on a cost minimisation basis compared with entecavir for nucleos(t)ide naïve, hepatitis B antigen positive (HBeAg positive) patients. The equi-effective doses in this indication are tenofovir 300 mg per day and entecavir 0.5 mg per day. The Committee rejected the application for listing of tenofovir in HBeAg negative nucleos(t)ide naïve and nucleos(t)ide experienced chronic hepatitis B patients, considering insufficient evidence had been presented to support the claim of non-inferiority to entecavir and adefovir, respectively.
Teriparatide, injection, 250 microgram per mL, (Forteo[®]) Eli Lilly Pty Ltd Major submission	Osteoporosis	Second-line therapy for severe established osteoporosis in patients who meet certain criteria; and glucocorticoid induced osteoporosis in patients with one or more fractures.	Recommended for use in severe established osteoporosis on the basis of acceptable cost effectiveness in the context of a high clinical need. The Committee rejected the application for listing in glucocorticoid induced osteoporosis on the basis of a high and uncertain cost-effectiveness ratio.
Tobramycin, injection, 500 mg in 5 mL, (Tobra-Day[®]) Phebra Pty Ltd Minor submission	Antibiotic	Treatment of <i>Pseudomonas aeruginosa</i> infections in patients with cystic fibrosis.	Recommended for systemic use in the proposed patient group.
Trandolapril 2 mg with verapamil 180 mg, tablet sustained release, (Tarka[®]) Abbott Australasia Minor submission	Hypertension	List a new strength.	Recommended.

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Triglycerides, medium chain, Sachets 16 g containing 10 g MCT fats, 25, (MCT Pro-Cal[®]) Vitaflo Australia Pty Ltd Minor submission	Medicinal food	For use in the dietary management of fat malabsorption, long chain fatty acid oxidation disorders, Type 1 hyperlipidaemia, chylothorax and management of malnutrition.	Recommended as an authority required benefit.
Ursodeoxycholic acid, capsule, 250 mg, (Ursofalk[®]) Orphan Australia Pty Ltd Minor submission	Bile acid preparation	To increase the maximum quantity per prescription from 100 to 200 capsules.	Recommended.
Whey protein formula supplemented with amino acids, vitamins and minerals, and low in protein, phosphate, potassium and lactose. Supplemented with long chain polyunsaturated fatty acids (LCPs), Sachets 100 g, 10, (RenaStart[®]) Vitaflo Australia Pty Ltd Minor submission	Medicinal food	For use in the dietary treatment of infants and children up to the age of 10 years with chronic renal failure and those requiring dialysis.	Recommended.
Ziprasidone, capsule, 20 mg, 40 mg, 60 mg, 80 mg, (Zeldox[®]) Pfizer Pty Ltd Major submission	Bipolar disorder	Extend the current listing to include acute mania and mixed episodes associated with bipolar I disorder.	Recommended on a cost minimisation basis compared with olanzapine. The equi-effective doses are ziprasidone 119.85 mg and olanzapine 15.19 mg daily (risperidone 5.4 mg daily).

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Zoledronic acid, solution for infusion 5 mg in 100 mL, (Aclasta[®]) Novartis Pharmaceuticals Pty Ltd Major submission	Reduces risk of fracture in patients with osteoporosis	To extend the listing to include osteoporosis in women aged 70 years with a bone mineral density (BMD) T-score of -3.0 or less.	Recommended on a cost minimisation basis compared with oral alendronate. The equi-effective doses are alendronate 70 mg weekly for 52 weeks versus zoledronic acid 5 mg once per year, less the cost of infusing zoledronic acid.