July 2006 PBAC Outcomes – Positive Recommendations

Drug and Form	Drug Use and Type	Listing Requested by Sponsor	PBAC Recommendation
Albendazole, tablet, 200 mg, Zentel® GlaxoSmithKline Australia Pty Ltd Minor submission	Anthelmintic	Authority Required listing for the treatment of whipworm in an Aboriginal or a Torres Strait Islander person.	The PBAC recommended listing as an Authority Required benefit under the arrangements made for the 2004-05 Budget measure "Improving the capacity of the PBS to meet the needs of Indigenous Australians" for this patient group.
Alendronate, tablet, 70 mg, Fosamax Once weekly®, Merck Sharp & Dohme (Australia) Pty Ltd; Alendro Once Weekly®, Arrow Pharmaceuticals Limited Alendronate sodium with colecalciferol (vitamin D3), tablet, 70 mg-70 micrograms (2800 i.u.), Fosamax® Plus, Merck Sharp & Dohme (Australia) Pty Ltd Major submission	Treatment of bone resorptive diseases	Amend Authority Required listing to allow treatment of osteoporosis for patients at high risk of fracture.	The PBAC recommended extending the listing on the basis of acceptable cost-effectiveness for the initial and continuing treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in patients aged 70 years of age or older and with a BMD T-score of -3.0 or less. The initial authority application must state the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement.

Amlodipine besylate with atorvastatin calcium, tablets, 5 mg/10 mg, 10 mg/10 mg, 5 mg/20 mg, 10 mg/20 mg, 5 mg/40 mg, 10 mg/40 mg, 5 mg/80 mg, and 10 mg/80 mg Caduet® Pfizer Australia Pty Ltd Major submission	Combination product to lower lipid levels and treat hypertension and/or angina	Restricted Benefit listing for use in patients who have hypertension and/or angina and who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and: (a) who are currently receiving treatment with a dihydropyridine calcium channel blocker; OR (b) whose blood pressure and/or angina is inadequately controlled with other classes of antihypertensive and/or anti-anginal agent, and in whom adjunctive therapy with a dihydropyridine calcium channel blocker would be appropriate; OR (c) who are intolerant of the side effects of other classes of antihypertensive and/or anti-anginal agent, and in whom replacement therapy with a dihydropyridine calcium channel blocker would be appropriate.	The PBAC recommended listing as requested on a cost-minimisation basis compared with the corresponding strengths of the amlodipine and atorvastatin constituents.

Anticholinesterases: Donepezil hydrochoride, tablets, 5 mg, 10 mg, Aricept®, Pfizer Pty Ltd Galantamine hydrochloride, prolonged release capsules 8 mg (base), 16 mg (base), 24 mg (base), Reminyl®, Janssen-Cilag Pty Ltd Rivastigmine hydrogen tartrate, capsules, 1.5 mg (base), 3 mg (base), 4.5 mg (base), 6 mg (base), oral solution 2 mg (base) per mL, 120 mL, Exelon®, Novartis Pharmaceuticals Minor submission	Anti-dementia drugs	Request to amend restrictions: (1) to allow continuing treatment in patients whose baseline Mini Mental State Examination (MMSE) is greater than 24 points to meet the criteria for continuing treatment either by demonstrating a decrease of at least 4 points from baseline on the Alzheimer's Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) as currently, OR by demonstrating a 2 point improvement on the MMSE; and (2) to allow assessment by the Standardised Mini-Mental State Examination (SMMSE) and the Rowland Universal Dementia Assessment Scale (RUDAS).	The PBAC agreed with the requests to allow: (1) patients with MMSE greater than 24 points to be assessed by an improvement in MMSE of 2 points, or by improvement in the ADAS-COG of 4 points; and (2) patients to be assessed using the SMMSE. However the PBAC did not agree to the use of RUDAS as the Committee considered that the characteristics of the RUDAS as a scale to measure change have not yet been validated, although this work is on-going.
Benzathine penicillin, powder for injection, 900 mg (1,200,000i.u.) Pan Benzathine Benzylpenicillin®, Aspen Australia Minor submission	Antibiotic	Unrestricted listing with a maximum quantity of one and Restricted Benefit listing for syphilis with a maximum quantity of 2.	The PBAC had no objection to the Secretariat listing.
Ciprofloxacin, ear drops, 0.3% Ciloxan® Alcon Laboratories (Australia) Pty Ltd Major submission	Antibiotic	Authority Required listing for the treatment of chronic suppurative otitis media in adults and children one year and over.	The PBAC recommended listing on clinical and cost-effectiveness grounds for use in chronic suppurative otitis media in an Aboriginal and Torres Strait Islander person.
Darbepoetin alfa, injection pre-filled syringes, 20 micrograms in 0.5 mL and 50 micrograms in 0.5 mL, Aranesp SureClick®, Amgen Australia Pty Ltd	Treatment for severe anaemia	Section 100 Highly Specialised Drug listing for treatment of anaemia requiring transfusion, defined as a haemoglobin level	The PBAC had no objection to the Secretariat listing of these new presentations.

Minor submission		of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia.	
Deferasirox, tablets, 125 mg , 250 mg and 500 mg, Exjade® Novartis Pharmaceuticals Australia Pty Limited Major submission	Iron chelator	Section 100 Highly Specialised Drug listing for: Chronic iron overload in adults, adolescents and children 6 years and older associated with disorders of erythropoiesis; Chronic iron overload in paediatric patients age 2 to 5 years, associated with disorders of erythropoiesis, who are intolerant to desferrioxamine or in whom desferrioxamine has proven ineffective.	The PBAC recommended listing with a restriction consistent with the TGA-approved indication on a cost effectiveness basis versus the comparator, desferrioxamine, noting however that the incremental cost-effectiveness ratio is somewhat uncertain and is likely to be high.
Entecavir, tablet, 500 microgram Baraclude®, Bristol-Myers Squibb Pharmaceuticals Major submission	Chronic hepatitis B	Section 100 Highly Specialised Drug listing for patients aged 16 years or older with chronic hepatitis B who satisfy all of the following criteria: (i) histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy); (ii) abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection (HBe antigen positive and/or HBV DNA positive); (iii) female patients of child-bearing age are not pregnant,	The PBAC recommended the listing of entecavir 500 microgram tablet for the treatment of chronic hepatitis B infection in nucleos(t)ide naïve patients on the basis of acceptable cost-effectiveness compared with lamivudine 100 mg.

		not breast-feeding, and are using an effective form of contraception.	
Entecavir, tablet, 1 mg, Baraclude®, Bristol-Myers Squibb Pharmaceuticals Major submission	Chronic hepatitis B	Section 100 Highly Specialised Drug listing for patients aged 16 years or older with chronic hepatitis B who have failed lamivudine therapy and satisfy all of the following criteria: (i) Repeatedly elevated (> 1.2 ULN) serum ALT levels while on concurrent antihepadnaviral therapy of ≥ 6 months duration in conjunction with documented chronic hepatitis B infection (HBe antigen positive and/or serum HBV DNA positive); (ii) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.	The PBAC recommended the listing of entecavir 1 mg tablet for the treatment of chronic hepatitis B infection in lamivudine resistant patients on a cost minimisation basis compared to adefovir with entecavir 1 mg for 48 weeks considered of equivalent effectiveness to adefovir 10 mg for 48 weeks.
Epirubicin hydrochloride, injection, 50 mg (freeze dried), Mayne Pharma Limited Minor submission	Cytotoxic agent	Unrestricted listing	The PBAC had no objection to the Secretariat listing of this new strength.

Etanercept, powder for injection, 25 mg Enbrel® Wyeth Australia Pty Ltd Minor submission	Ankylosing spondylitis	Request the removal of HLA-B27 status from eligibility criteria for ankylosing spondylitis.	The PBAC agreed to the request recalling that it had initially recommended inclusion of this requirement in the restriction because HLA-B27 status represents an objective diagnostic criterion for ankylosing spondylitis. The PBAC considered that the current sacro-iliac x-ray criteria will provide an adequate level of certainty of the diagnosis of ankylosing spondylitis for the purposes of the PBS listing restriction.
Exemestane, tablet, 25 mg, Aromasin® Pfizer Australia Pty Ltd Major submission	Breast cancer	Extend Restricted Benefit listing to include treatment of hormone-dependent early breast cancer in post-menopausal women following a minimum of 2 years treatment with tamoxifen citrate.	The PBAC recommended listing on a cost-effectiveness basis against tamoxifen for the adjuvant hormonal treatment of early breast cancer. The total duration of PBS-subsidised adjuvant hormonal treatment (tamoxifen + aromatase inhibitors) should not exceed 5 years.
Fenofibrate, tablets, 48 mg and 145 mg, Lipidil®, Laboratoires Fournier S.A. Pty Ltd Minor submission	Lipid-lowering drug	List on the PBS use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs.	The PBAC had no objection to the Secretariat listing of this new formulation and strengths of fenofibrate.
Fluorouracil, injection, 1 g in 20 mL, Fluorouracil Ebewe®, InterPharma Pty Ltd Minor submission	Antineoplastic agent	Unrestricted listing	The PBAC had no objection to the Secretariat listing of this new strength of an already listed drug
Glucose indicator – blood, electrode strips, 50, Glucogard 01®, Diacare International Pty Ltd Minor submission	Diabetic testing strips	Unrestricted listing	The PBAC agreed to list this new brand of testing strips.

Hydroxocobalamin, injection, 1 mg in 1 mL, 3 ampoules, Mayne Pharma Limited Minor submission	Treatment of vitamin B12 deficiencies	Increase maximum quantity from 2 to 3.	The PBAC had no objection to increasing the maximum quantity due to an extension of the expiry date following from an improvement in the manufacturing process.
Ibuprofen, tablet, 400 mg, Brufen®, Abbott Australasia Pty Ltd Minor submission	Non-steroidal antiinflammatory drug	Increase maximum quantity for unrestricted listing from 20 to 30.	The PBAC had no objection to the Secretariat listing to the proposed change in pack size.
Imiquimod, cream, 5%, Aldara® 3M Health Care Pty Ltd Major submission	Treatment of basal cell skin cancer	Authority Required listing for treatment of biopsy confirmed primary (previously untreated) superficial basal cell carcinoma (sBCC) in immunocompetent patients who cannot have surgical excision, cryotherapy, nor curettage with diathermy and require drug therapy under certain specified conditions.	The PBAC recommended listing as an authority required benefit for treatment of biopsy confirmed primary (previously untreated) superficial basal cell carcinoma (sBCC) in immunocompetent patients who cannot have surgical excision, cryotherapy, or curettage with diathermy, on the basis of acceptable cost-effectiveness compared to placebo for patients who cannot have surgical excision, cryotherapy or curettage.
Infliximab, powder for injection, 100 mg Remicade® Schering-Plough Pty Ltd Minor submission	Ankylosing spondylitis	Request the removal of HLA-B27 status from eligibility criteria for ankylosing spondylitis.	The PBAC agreed to the request recalling that it had initially recommended inclusion of this requirement in the restriction because HLA-B27 status represents an objective diagnostic criterion for ankylosing spondylitis. The PBAC considered that the current sacro-iliac x-ray criteria will provide an adequate level of certainty of the diagnosis of ankylosing spondylitis for the purposes of the PBS listing restriction.

Infliximab, powder for injection, 100 mg Remicade® Schering-Plough Pty Ltd Major submission	Severe plaque psoriasis	Section 100 Highly Specialised Drug listing for the treatment of adult patients with severe plaque psoriasis for whom phototherapy or conventional systemic therapy have been inadequate or are inappropriate.	The PBAC recommended listing for the treatment of severe chronic plaque psoriasis in patients who meet certain criteria on a cost-minimisation basis with efalizumab. The equi-effective doses are infliximab 5mg/kg for 7.25 infusions for 1 year and efalizumab 1 mg/kg/week for 1 year. Restriction to be finalised
Letrozole, tablet, 2.5 mg, Femara® Novartis Pharmaceuticals Australia Pty Limited Major submission	Breast cancer	Extend Restricted Benefit listing to include the treatment of hormone-dependent early breast cancer in post-menopausal women.	The PBAC recommended listing on a cost-minimisation basis with anastrozole. The equi-effective doses are letrozole 2.5 mg and anastrozole 1 mg. The total duration of PBS-subsidised adjuvant hormonal treatment (tamoxifen + aromatase inhibitors) should not exceed 5 years.
Lopinavir with ritonavir, tablet, 200 mg-50 mg, Kaletra® Abbott Australasia Pty Ltd Minor submission	Treatment for HIV/AIDS	Section 100 Highly Specialised Drug listing as for other presentations of the same combination.	The PBAC had no objection to the Secretariat listing to add a new formulation of an already listed product to the current Section 100 listing.
Morphine hydrochloride, oral solution, 1 mg per mL, 500 mL, M.O.S 1®, 5 mg per mL, 250 mL, M.O.S 5®, 5 mg per mL, 500 mL, M.O.S 5®, 10 mg per mL, 250 mL, M.O.S 10® , Valeant Pharmaceuticals Australasia. Minor submission	Opioid analgesic	List as per the already listed morphine hydrochloride solution.	The PBAC had no objection to the Secretariat listing of the additional brands of morphine hydrochloride oral solution, noting that this was a temporary measure to ensure the ongoing availability of oral morphine solution under the PBS, following the recall of the current PBS-listed brand of morphine hydrochloride oral solution.

Pimecrolimus, cream, 1% 15 g, Elidel® Novartis Pharmaceuticals Australia Pty Ltd Major submission	Treatment of atopic dermatitis	Extend Authority Required listing to include patients aged over 18 years.	The PBAC recommended listing on the basis of acceptable comparative efficacy and cost- effectiveness over topical corticosteroids (TCS) and vehicle cream in the requested populations.
Posaconazole, oral suspension, 40 mg per mL, Noxafil® Schering-Plough Pty Ltd Major submission	Anti-fungal agent	Authority Required listing for the treatment of invasive aspergillosis in patients in patients 13 years or older intolerant to, or with disease refractory to alternative therapy. Treatment of fusariosis, zygomycosis, coccidioidomycosis, chromoblastomycosis and mycetoma in patients 13 years or older intolerant to, or with disease refractory to alternative therapy.	The PBAC recommended the listing of posaconazole on the grounds of high but acceptable cost-effectiveness compared to a suite of salvage therapies.
Risperidone, orally disintegrating tablets, 3 mg and 4 mg, Risperdal® Quicklet®, Janssen-Cilag Pty Ltd Minor submission	Treatment for schizophrenia and bipolar 1 disorder	List as for the 3 mg and 4 mg regular tablets.	The PBAC had no objection to the Secretariat listing to add these higher strength formulations for the treatment of schizophrenia and bipolar I disorder.
Ritonavir, oral solution, 600 mg per 7.5 mL (80 mg per mL), 90 mL, Norvir®, Abbott Australasia Pty Ltd Minor submission	Treatment for HIV/AIDS	List as for other presentations of this drug.	The PBAC had no objection to the Secretariat listing to add a new volume of the same concentration to the current Section 100 listing.

Rosiglitazone with metformin, tablets, 2 mg/500 mg, 2 mg/1 g, 4 mg/500 mg, and 4 mg/1 g, Avandamet® GlaxoSmithKline Australia Pty Ltd Major submission	Oral hypoglycaemics	Authority Required listing: Initiation of therapy, in type 2 diabetic patients who are eligible to treatment with rosiglitazone and metformin.	The PBAC recommended listing of rosiglitazone with metformin fixed dose combination tablets on the grounds the combination tablets are no worse than concomitant rosiglitazone and metformin. The equi-effective doses in the context of cost-minimisation were rosiglitazone 4 mg plus metformin 500 mg fixed dose combination tablet compared to rosiglitazone 4 mg and metformin 500 mg. The PBAC agreed that the combination tablet should be available to the same patient population as had access to individual components.
Rosuvastatin, tablets 5 mg, 10 mg, 20 mg, and 40 mg, Crestor® AstraZeneca Pty Ltd Major submission	Lipid lowering drug	Restricted Benefit listing for use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs.	The PBAC recommended listing on a cost-minimisation basis with atorvastatin, with the ratio of equi-effective doses being rosuvastatin to atorvastatin 1:3.
Saquinavir mesylate, tablet, 500 mg, Invirase®, Roche Products Pty Ltd Minor submission	Treatment for HIV/AIDS	Section 100 Highly Specialised Drug listing	The PBAC had no objection to the Secretariat listing to add a new strength to the current Section 100 listings.
Sodium cromoglycate**,** eye drops, 20 mg per mL (2%), 10mL, Cromolux®, AFT Pharmaceuticals Pty Ltd; Opticrom®, Aventis Pharma Prty Ltd Minor submission	Antiallergic eye drops		The PBAC recommended that sodium cromoglycate eye drops could be transferred from an 'Authority Required' to 'Restricted Benefit' listing. The Committee further requested the DUSC monitor usage.

Sodium valproate, crushable tablet 100mg, tablets (enteric coated) 200 mg and 500mg, oral liquid 200 mg per 5 mL, 300mL, and syrup, 200 mg per 5 mL, 300 mL, Epilim®, Sanofi-Synthelabo Australia Pty Ltd; Valpro®, Alphapharm Pty Ltd Minor submission	Treatment for epilepsy	Amend CAUTION to: There are reports of fatal hepatotoxicity, particularly in children: there is increasing evidence of dose related teratogenesis from this drug.	The PBAC recommended the caution for sodium valproate be amended to replace the current note regarding spina bifida with the new note suggested by the Australian Association of Neurologists. This reflected the finding that with increased experience it has become apparent that spina bifida is not the only teratogenic effect of sodium valproate.
Somatropin, 5 mg in 1.5 mL, injection cartridges, Omnitrope®, Sandoz Pty Ltd Minor submission	Human growth hormone	List under the Human Growth Hormone Program	The PBAC had no objection to the Secretariat listing to add a new brand to the current Section 100 listings
Tramadol, sustained release tablet, 50 mg, Tramal®, CSL Limited Minor submission	Opioid analgesic	Listing as a Restricted Benefit for pain where aspirin and/or paracetamol alone are inappropriate or have failed.	The PBAC had no objection to the Secretariat listing to add a new strength to the current listings for this restriction.
Trastuzumab, powder for infusion, 150 mg (Herceptin®) Roche Products Pty Ltd Major submission	Breast cancer	Authority Required benefit for adjuvant treatment of patients with HER2-positive early breast cancer.	The PBAC recommended listing for treatment for HER2 positive early breast cancer commencing concurrently with adjuvant chemotherapy following surgery on a cost-effectiveness basis over no treatment. Restriction to be finalised.

Travoprost with timolol eye drops, 40 µg-5 mg (base) (0.004%-0.5%) Extravan® Alcon Laboratories (Australia) Pty Ltd Major submisson	Ocular hypertension (glaucoma)	Restricted Benefit listing for the reduction of elevated intra-ocular pressure (IOP) in patients with ocular hypertension, who are not adequately controlled with timolol maleate 5 mg (base) per mL eye drops or who are insufficiently responsive to prostaglandins or other intraocular pressure lowering medications.	The PBAC recommended listing on a cost minimisation basis with Xalacom® (latanoprost with timolol). The equi-effective doses are the fixed dose combination of travoprost 40 µg/mL with timolol 5 mg/mL, one drop instilled once daily and the fixed dose combination of latanoprost 50 µg/mL and timolol 5 mg/mL, one drop instilled once daily. A minor change to the restriction requested was recommended, substituting the words “prostaglandins or other IOP lowering medications” with “travaprost”.