

November 2006 PBAC Outcomes – Positive Recommendations

Drug and Form	Drug Use and Type	Listing Requested by Sponsor	PBAC Recommendation
Adalimumab, prefilled syringe, 40mg in 0.8 mL, Humira [®] , Abbott Australasia Pty Ltd Major Submission	Ankylosing spondylitis	Authority required for adults with ankylosing spondylitis who meet certain criteria.	The PBAC agreed to extend the authority required listing to include the treatment of ankylosing spondylitis on a cost minimisation basis with etanercept.
Adefovir dipivoxil, tablet, 10 mg, Hepsera [®] , Gilead Sciences Pty Ltd Minor Submission	Chronic hepatitis B.	Section 100 (Highly Specialised Drug) Change current PBS restriction wording to include patients who have failed antihepadnaviral therapy instead of only patients who have failed lamivudine therapy.	The PBAC agreed to the sponsor's request, noting that cross resistance between the two antihepadnavirals, lamivudine and entecavir had been documented, and thus it was appropriate for patients who had failed either therapy to have access to adefovir.
Amino acid formula without lysine and low in tryptophan, powder 400 g, XLYS Low Try Analog [®] , Scientific Hospital Supplies Australia Minor Submission	Nutritional supplement	Restricted benefit listing for dietary management of infants (birth to 1 year) with Glutaric Aciduria Type 1.	The PBAC recommended listing on a cost effectiveness basis against no treatment for the dietary management of infants and young children with Glutaric Aciduria Type 1.
Amino acid formula without lysine and low in tryptophan, powder 400 g, XLYS Low Try Maxamaid [®] , Scientific Hospital Supplies Australia Minor Submission	Nutritional supplement	Restricted benefit listing for dietary management of children aged 1-8 years with Glutaric Aciduria Type 1.	The PBAC recommended listing on a cost effectiveness basis against no treatment for the dietary management of infants and children aged less than 7 with Glutaric Aciduria Type 1. The PBAC accepted the advice of the Nutritional Products Working Party that children under 7 years of age benefited most from this treatment and thus 7 and 8 year olds were excluded from the restriction.
Amino acids – synthetic formula, compound powder 400 g, Elecare [®] , Abbott Australasia Pty Ltd; Neocate [®] and Neocate Advance [®] , Scientific Hospital Supplies Australia Minor submission	Nutritional supplement	Removal of requirement to demonstrate soy intolerance.	The PBAC accepted the advice of the Nutritional Products Working Party that the requirement to demonstrate intolerance to soy protein prior to treatment be removed from the restriction for these products. Soy protein is no longer recommended for use in intolerance.

<p>Amino acids- synthetic formula, 400 g, Neocate Advance Tropical Flavour[®], Scientific Hospital Supplies Australia Minor Submission</p>	<p>Nutritional supplement</p>	<p>Addition of a new tropical flavour formulation to the current listing for Neocate Advance for the same indications.</p>	<p>The PBAC recommended listing on a cost-minimisation basis compared with Neocate Advance. The PBAC further accepted the advice of the Nutritional Products Working Party that the requirement to demonstrate intolerance to soy protein prior to treatment be removed from the restriction of this product.</p>
<p>Amino acids – synthetic formula supplemented with long chain polyunsaturated fatty acids, compound powder, Neocate LCP[®], Scientific Hospital Supplies Australia Minor Submission</p>	<p>Nutritional supplement</p>	<p>Authority required listing for the management of combined intolerance (not colic) to cows' milk and protein hydrolysate formulas; Authority required listing for the management of severe intestinal malabsorption including short bowel syndrome.</p>	<p>The PBAC recommended listing with a small premium over Neocate without long chain polyunsaturated fatty acids (LCPs), noting that there is a theoretical basis for a benefit of LCP supplementation in infants under 12 months with food allergies. The Committee further noted that the sponsor has agreed to review the premium if future clinical evidence does not support this benefit.</p>
<p>Anecortave acetate, suspension depot, 15 mg in 0.5mL, Retaane[®], Alcon Laboratories (Australia) Pty Ltd Major submission</p>	<p>Subfoveal choroidal neovascularisation (CNV)</p>	<p>Section 100 for the treatment of subfoveal choroidal neovascularisation (CNV) due to exudative age related macular degeneration (AMD) where the CNV is composed predominantly ($\geq 50\%$) of classic lesions. Treatment can only be undertaken by designated trained specialist ophthalmologists. Anecortave and PDT with verteporfin are not subsidised for adjunctive use.</p>	<p>The PBAC recommended listing as monotherapy for subfoveal CNV due to exudative AMD where the CNV is composed predominantly ($\geq 50\%$) of classic lesions in a patient with a baseline visual acuity equal to or better than 6/60 (20/200), on the basis of acceptable cost-effectiveness compared with verteporfin (i.e. anecortave is less effective and less costly).</p> <p>The PBAC requested that a number of other issues with the listing wording be resolved by the Restriction Working Group in consultation with the sponsor and other stakeholders.</p>

<p>Atomoxetine, capsule, 10 mg, 18 mg, 25 mg, 40 mg and 60 mg, Strattera[®], Eli Lilly Australia Pty Ltd Minor submission</p>	<p>Attention deficit hyperactivity disorder</p>	<p>Authority Required for the 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:</p> <ul style="list-style-type: none"> · Treatment with dexamphetamine sulfate or methylphenidate poses an unacceptable medical risk due to the following contraindications as specified in the TGA-approved product information: · a history of substance abuse or misuse (other than alcohol); and/or · comorbid motor tics or Tourette's Syndrome; and/or · comorbid severe anxiety diagnosed according to the DSM-IV. <p>OR</p> <p>Treatment with dexamphetamine sulfate or methylphenidate 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.</p> <p>OR</p> <p>Treatment with dexamphetamine sulfate AND methylphenidate has resulted in the development of adverse reactions of a severity necessitating permanent treatment withdrawal:</p> <ul style="list-style-type: none"> · Adverse effects on growth and weight · Adverse effects on sleep including insomnia · Adverse effects on appetite including anorexia <p>Continuing treatment where the patient has previously been issued with an authority prescription for this drug.</p>	<p>The PBAC recommended listing on a cost effectiveness basis over placebo at the new price proposed. The PBAC accepted that there is a clinical need for this product and that the restriction appropriately targets those patients most likely to benefit from treatment.</p>
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Bicalutamide with goserelin acetate, 50 mg tablet x 28 plus subcutaneous (sc) implant in pre-filled injection syringe 3.6 mg (base) x 1; 50 mg tablet x 28 plus sc implant in pre-filled injection syringe (long acting) 10.8 mg (base) x 1; and 50 mg tablet x 84 plus sc implant in pre-filled injection syringe (long acting) 10.8 mg (base) x 1, Zoladex Plus [®] , AstraZeneca Pty Ltd Minor submission	Prostatic carcinoma	Authority required listing for metastatic (equivalent to stage D) prostatic carcinoma in patients for whom a combination of an antiandrogen and a GnRH (LH-RH) agonist is required.	The PBAC recommended listing on a cost-minimisation basis compared with the corresponding strengths of the constituents.
Ceftriaxone, powder for injection 500 mg, Intensive Care Products Pty Ltd Minor submission	Antibiotic	Restricted benefit listing for the treatment of gonorrhoea.	The PBAC had no objection to the Secretariat listing of the 500 mg strength as a restricted benefit for the treatment of gonorrhoea to replace the 250 mg Rocephin [®] product.
Entecavir, oral solution, 0.05 mg/mL, Baraclude [®] , Bristol-Myers Squibb Australia Pty Ltd Minor submission	Chronic hepatitis B	New oral solution presentation.	The PBAC had no objection to the Secretariat listing of an oral solution for the treatment of adult patients with chronic hepatitis B.
Epirubicin, powder for injection, 50 mg, DBL [®] Epirubicin, Mayne Pharma Limited Minor Submission	Cytotoxic agent	Increase PBS maximum quantity from 3 to 4.	The PBAC agreed to an increase in the maximum quantity from 3 to 4.
Etanercept, injection set containing 4 pre-filled syringes for injection 25 mg and injection set containing 4 pre-filled syringes for injection 50 mg, Enbrel [®] , Wyeth Pharmaceuticals Minor submission	Rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, chronic plaque psoriasis.	Additional presentations.	The PBAC had no objection to the Secretariat listing of additional presentations for the same indications are currently listed, where the same strength is currently listed.
Exemestane, tablet, 25 mg, Aromasin [®] , Pfizer Australia Pty Ltd Minor submission	Breast cancer	Increase repeats	The PBAC agreed to increase the number of repeats to five for consistency with the current PBS listing for anastrozole.
Ezetimibe, tablet, 10 mg, Ezetrol [®] , Merck Sharp and Dohme (Australia) Pty Ltd Major submission	Lipid-lowering drug	Extend authority required indication to allow use in patients with hypertension or a family history of coronary heart disease, whose cholesterol levels are inadequately controlled with a HMG-CoA reductase inhibitor (statin), and to allow use in combination with a low dose of statin in patients with high dose statin	The PBAC recommended extending the listing to include the treatment of patients with hypertension or a family history of coronary heart disease in patients whose cholesterol levels are inadequately controlled with a statin according to the current ezetimibe PBS

		intolerance.	<p>restriction definitions of inadequate control, on a cost effectiveness basis against placebo.</p> <p>The PBAC also recommended extending the listing of the single agent ezetimibe product to include treatment of patients who experience a clinically important product-related adverse event to a statin as defined in the current PBS ezetimibe restriction, but who can continue to take a statin at a dose of 20 mg per day or less, on the basis of a demonstrated clinical need in a high risk group of patients, where cost-effectiveness is established. However, the PBAC rejected the sponsor's application to list an ezetimibe with simvastatin 10 mg- 10 mg tablet for this indication, see "First Time Rejections".</p>
Ezetimibe with simvastatin, tablet, 10 mg-40 mg and 10 mg-80 mg, Vytorin [®] , Merck Sharp and Dohme (Australia) Pty Ltd Major submission	Lipid-lowering drug	Extend authority required indication to allow use in patients with hypertension or a family history of coronary heart disease, whose cholesterol levels are inadequately controlled with a HMG-CoA reductase inhibitor (statin).	The PBAC recommended extending the listing to include the treatment of patients with hypertension or a family history of coronary heart disease in patients whose cholesterol levels are inadequately controlled with a statin according to the current ezetimibe PBS restriction definitions of inadequate control, on a cost effectiveness basis against placebo.
Ezetimibe, tablet, 10mg, Ezetrol [®] and ezetimibe with simvastatin, tablet, 10 mg-40 mg and 10 mg-80 mg, Vytorin [®] , Merck Sharp & Dome (Australia) Pty Ltd Minor submission	Lipid-lowering drug	Change current requirement for cholesterol test result to be no more than 1 month old, to no more than 4 months old.	The PBAC agreed to allow the cholesterol test result to be no more than 2 months old at the time of application. The PBAC did not consider it clinically appropriate to allow results up to 4 months old to be provided as requested in the sponsor's application.

Famciclovir, tablet, 500 mg, Famvir [®] , Novartis Pharmaceuticals Australia Pty Ltd Major submission	Antiviral	Extend the authority required listing to include episodic treatment of moderate to severe recurrent orolabial herpes in patients with HIV infection and CD4 cell counts of less than 500 per micro litre; and suppressive therapy of moderate to severe recurrent orolabial herpes in patients with HIV infection and CD4 cell counts of less than 200 per microliter; or other opportunistic infections or AIDS defining tumours.	The PBAC agreed to extend listing to include the suppressive therapy of moderate to severe recurrent oral or labial herpes in patients with HIV infection with CD4 cell counts of less than 150 per microliter or other opportunistic infections or AIDS defining tumours, on a cost-minimisation basis against aciclovir. The equi-effective doses are famciclovir 500 mg twice daily and aciclovir 800 mg four times daily. The PBAC recommended listing for the episodic treatment of moderate to severe recurrent oral or labial herpes in patients with HIV infection and CD4 cell counts of less than 500 per micro litre on a cost-effectiveness basis against placebo.
Glucose Indicator-Blood, electrode strips, 50, Touch-In Plus [®] Digiland Pty Ltd Minor submission	Diabetic testing strips	Unrestricted listing.	The PBAC had no objection to the Secretariat listing of an additional brand of electrode strips.
Glucose Indicator-Blood, electrode strips, 50, Omnitest Plus [®] B. Braun Australia Pty Ltd Minor submission	Diabetic testing strips	Unrestricted listing.	The PBAC had no objection to the Secretariat listing of an additional brand of electrode strips.
Glucose Indicator-Blood, pen sensor strips, 50, MWD PenSensor Strips [®] MedWatchDog Minor submission		Unrestricted listing.	The PBAC had no objection to the Secretariat listing of an additional brand of test strips.
Hydroxocobalamin, injection 1 mg in 1 mL, 3 ampoules, Neo-B12 [®] Mayne Pharma Limited Minor submission	Blood disorders	New 3 ampoule presentation to replace the current 2 ampoule listing.	The PBAC had no objection to the Secretariat listing of a new 3 ampoule presentation of hydroxocobalamin injection to replace the current 2 ampoule listing (Neo-Cytamen [®]).

Imatinib mesylate, tablet, 100 mg and 400 mg, Glivec [®] , Novartis Pharmaceuticals Australia Pty Limited Minor submission	Chronic myeloid leukaemia	Amend the restriction for continuing treatment for the chronic phase of chronic myeloid leukaemia.	The PBAC agreed to revise the criteria for continuing supply for patients with chronic phase chronic myeloid leukaemia to allow the response criteria to be met by a peripheral blood real time quantitative PCR assay-based criterion of < 1% BCR-ABL as an alternative to a major cytogenetic response in bone marrow by either karyotypic or FISH analysis.
Isotretinoin, capsule 40 mg, Oratane [®] , Douglas Pharmaceuticals Australia Ltd Minor Submission	Severe cystic acne	Listing of an additional strength.	The PBAC agreed to list on the grounds of an identified clinical need for patients requiring 1 mg/kg/day of isotretinoin and for those with higher body weights. The PBAC further recommended that the current NOTE prohibiting authorisation of increased maximum quantities not be applied to this listing and be removed from other isotretinoin listings.
Isotretinoin, capsules, 10 mg and 20mg, Chem mart Isotretinoin [®] , Chem mart Pty Limited ; GenRx Isotretinoin [®] , GenRx Pty Limited ; Oratane [®] , Douglas Pharmaceuticals Australia Limited ; Isohexal [®] , Hexal Australia Pty Limited ; Terry White Chemists Isotretinoin [®] , Terry White Chemists ; Roaccutane [®] , Roche Products Pty Limited Minor submission	Severe cystic acne		The PBAC recommended that the note preventing the authorisation of increased maximum quantities and repeats be removed from the listing.
Letrozole, tablet 2.5 mg, Femara [®] , Novartis Pharmaceuticals Australia Pty Limited Minor submission	Breast cancer	Increase number of repeats.	The PBAC agreed to increase the number of repeats to five for consistency with the current PBS listing for anastrozole.
Mesalazine, modified release tablet, 500 mg and modified release granules 1 g and 2 g, Pentasa [®] , Ferring Pharmaceuticals Pty Ltd Minor Submission	Intestinal antiinflammatory	Add authority required listings for mesalazine modified release tablets and granules to include Crohn's disease where hypersensitivity or intolerance to sulfonamides exists.	The PBAC recommended amending the listing as requested, in line with the indications newly approved for these products by the Therapeutic Goods Administration.

Methylphenidate hydrochloride, extended release tablet, 18 mg, 36 mg and 54 mg, Concerta [®] , Janssen-Cilag Pty Ltd Minor Submission	Attention deficit hyperactivity disorder	Authority required listing for the treatment of attention deficit hyperactivity disorder in children and adolescents aged 6-18 years who have demonstrated a response to immediate release methylphenidate hydrochloride with no emergence of serious adverse events, and who require continuous coverage over 12 hours.	The PBAC recommended listing as an authority required benefit on a cost effectiveness basis over immediate release methylphenidate at the new price proposed.
Modafinil, tablet, 100 mg, Modavigil [®] CSL Limited Minor submission	Narcolepsy	Remove the requirement that the results of eligibility tests must be no more than 5 years old at the time of the first application for PBS subsidy.	The PBAC agreed with this request, noting that the diagnosis of narcolepsy would not change with time and that as long as a valid test had been conducted, its age was not important.
Monovalent Human Rotavirus oral vaccine, oral, 1mL (reconstituted), Rotarix [®] , GlaxoSmithKline Pty Ltd Minor submission	Rotavirus gastroenteritis	Inclusion on the National Immunisation Program for all Australian infants at 2 and 4 months of age to prevent rotavirus gastroenteritis.	The PBAC recommended listing of Rotarix for the indication requested by the sponsor on the basis of cost-minimisation with RotaTeq.
Oxaliplatin, 50 mg powder for injection, 100 mg powder for injection, Oxaliplatin Ebewe [®] , Interpharma Pty Ltd Minor submission	Colorectal cancer	Authority required listing of new form with a maximum quantity of 1 and 2 repeats.	The PBAC had no objection to the Secretariat listing of a new form (powder for injection) of oxaliplatin with a maximum quantity of 1 and 2 repeats.
Pegfilgrastim, pre-filled syringe and pre-filled pen, 6mg in 0.6ml, Neulasta [®] and Neulasta Sureclick [®] , Amgen Australia Pty Ltd Major submission	Prevention of neutropenia	Extend the section 100 (Highly Specialised Drug) authority required to include patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjuvant chemotherapy with a docetaxel-containing regimen).	The PBAC agreed to extend the listing to include primary prophylaxis of chemotherapy induced neutropenia in patients with breast cancer who are undergoing adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide.
Pentavalent Human-Bovine Rotavirus oral vaccine, oral, 2mL, RotaTeq [®] , CSL Limited Minor submission	Rotavirus gastroenteritis.	Inclusion on the National Immunisation Program for all Australian infants at 2, 4 and 6 months of age to prevent rotavirus gastroenteritis.	The PBAC recommended inclusion of RotaTeq on the National Immunisation Program for the indication requested by the sponsor on the basis of acceptable cost-effectiveness. RotaTeq was considered to be of similar safety and efficacy to Rotarix.

Protein hydrolysate formula with medium chain triglycerides, compound powder 400g, Alfaré®, Nestlé Australia Ltd; compound powder 450g, Pepti-Junior®, Nutricia Australia Pty Ltd Minor submission	Nutritional supplement		The PBAC accepted the advice of the Nutritional Products Working Party that the requirement to demonstrate intolerance to soy protein prior to treatment be removed from the restriction. Soy protein is no longer recommended for use in intolerance.
Riluzole, tablet, 50 mg, Rilutek®, Sanofi-aventis Australia Pty Ltd Minor Submission	Amyotrophic lateral sclerosis	Removal of the age requirement of 75 years or less from the current authority required restriction.	The PBAC agreed to the request on the basis of an extension to the “rule of rescue” under which riluzole was originally recommended, and because the number of patients and total cost associated with this change are small.
Risperidone, tablet, 0.5 mg 1 mg and 2 mg, Risperdal®, disintegrating tablet, 0.5 mg, 1 mg and 2 mg, Risperdal Quicklet® and oral solution, 1 mg per mL, Risperdal®, Janssen-Cilag Pty Ltd Major submission	Behavioural disturbances associated with autism	Authority required for the treatment by or under the supervision of a paediatrician or psychiatrist for severe behavioural disturbances in children and adolescents with autism who meet certain criteria.	The PBAC recommended listing on a cost-effectiveness basis compared with placebo. The listing restriction should specify that treatment take place under the supervision of a paediatrician or psychiatrist; that non-pharmacological measures are continued; that the diagnosis of autism is made according to the DSM-IV or ICD10 criteria; and that the number of repeats is limited to two.
Rosuvastatin, tablet, 40 mg, Crestor®, Astra Zeneca Pty Ltd Minor Submission	Lipid-lowering agent	Removal of the cautionary note regarding doses higher than 20 mg from the PBS restriction.	The PBAC agreed to the sponsor’s request, accepting that, based on a further review of the evidence, there was insufficient justification for concluding that a 40 mg dose of rosuvastatin represents a higher risk of toxicity than the highest doses of other statins.
Sildenafil citrate, tablet, 20 mg, Revatio®, Pfizer Australia Pty Ltd Major submission	Pulmonary arterial hypertension	Section 100 private hospital authority required for the treatment of pulmonary arterial hypertension (PAH) patients categorised as functional Class III, with the wording to be consistent with the other PAH-specific therapies.	The PBAC recommended listing on a cost minimisation basis with bosentan. The equi-effective doses are sildenafil 20 mg three times daily and bosentan 62.5 mg twice daily for 4 weeks followed by a maintenance dose of 125 mg twice daily. The PBS restriction should be the same as that for bosentan, taking into account the differences in the TGA approved indications and dosage recommendations of the two agents.

Sodium bicarbonate, capsule, 840 mg, Sodibic [®] , Aspen Pharmacare Pty Ltd Minor submission	Kidney failure	New listing for use in metabolic acidosis associated with chronic renal impairment.	The PBAC recommended listing on a cost effectiveness basis compared to no treatment.
Sodium Chloride, I.V. injection, sterile ampoules, 90 mg in 10 mL, Pfizer Australia Pty Ltd. Minor submission	Electrolyte for intravenous use	Unrestricted listing	The PBAC had no objection to the Secretariat listing of sodium chloride 10 mL in a pack of 5.
Trandolapril with verapamil hydrochloride sustained release, tablets, 4 mg – 240mg, Tarka [®] , Abbott Australasia Pty Ltd Major submission	Antihypertensive	Restricted benefit listing for the treatment of hypertension in patients who are not adequately controlled with 4 mg of trandolapril monotherapy.	The PBAC recommended listing on a cost-minimisation basis compared with the corresponding strengths of the trandolapril and verapamil hydrochloride sustained release constituents. The listing restriction will require that a patient is stabilised on monotherapy with both drugs at the doses contained in the combination, before moving to the combination.
Trastuzumab, powder for I.V. infusion, 150 mg, Herceptin [®] , Roche Products Pty Ltd Minor submission	Early breast cancer	Add a statement to the restriction for patients who have had a break in treatment.	The PBAC agreed to a request from Medicare Australia to add a statement to the restriction to indicate that a patient who has a break in therapy of more than 1 but less than 6 weeks is eligible for a new loading dose.
Triptorelin embonate, powder for injection and vial solvent 2 mL, 3.75mg (1 month) and 11.25 mg (3 month) (base), Diphereline [®] , Ipsen Pty Ltd Major submission	Prostatic carcinoma	Authority required for locally advanced (equivalent to Stage C) or metastatic (equivalent to Stage D) carcinoma of the prostate.	The PBAC recommended listing on a cost minimisation basis with goserelin acetate. The equi-effective doses are triptorelin embonate (Diphereline) 3.75mg once monthly and goserelin acetate (Zoladex [®]) 3.6mg once monthly; and triptorelin embonate (Diphereline) 11.25mg once every three months and goserelin acetate (Zoladex), 10.8mg once every three months.
Ziprasidone hydrochloride, capsule, 20 mg, 40 mg, 60 mg and 80 mg, Zeldox [®] , Pfizer Australia Pty Ltd Major submission	Schizophrenia	Authority required listing for the treatment of schizophrenia.	The PBAC recommended listing on a cost minimisation basis with olanzapine at the price proposed in the submission. The equi-effective doses are ziprasidone 120.30 mg/day and olanzapine 14.38 mg/day.