NOVEMBER 2010 PBAC MEETING OUTCOMES – Positive Recommendations

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
Adalimumab, injection, 40 mg in 0.8 mL pre-filled syringe, 40 mg in 0.8 mL pre-filled pen, Humira® Abbott Australasia Pty Ltd Major submission	Crohn disease	Authority Required listing for the treatment of patients with Crohn disease and who have fistula(e).	The PBAC recommended listing on a cost-minimisation basis compared with infliximab, at the same price as the current listing for adalimumab in severe refractory Crohn disease.
Adapalene with benzoyl peroxide, gel, 1 mg–25 mg per g (0.1%-2.5%), 30 g, Epiduo Gel® Galderma Australia Pty Ltd Major submission	Acne	Restricted benefit listing for: 1) The acute management of severe acne vulgaris as adjunctive therapy to an oral antibiotic; and 2) Maintenance treatment of severe acne vulgaris.	The PBAC recommended listing for acute treatment in combination with an oral antibiotic and maintenance treatment on the basis of an acceptable cost-effectiveness ratio compared with placebo.
Amino acid formula with vitamins and minerals without lysine and low in tryptophan, sachets 25 g, GA Express® Vitaflo Australia Pty Ltd Minor submission	Medicinal food	Restricted benefit listing for a child aged from 3 to 10 years with proven glutaric aciduria type 1	The PBAC recommended listing for the treatment of glutaric aciduria type 1 in persons aged 3 years and over.

Amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine, sachets 20 g, MMA/PA Gel® Amino acid formula with vitamins and minerals without phenylalanine, sachets 20 g, PKU Gel® Amino acid formula with vitamins and minerals without methionine, sachets 20 g, HCU Gel® Amino acid formula with vitamins and minerals without valine, leucine and isoleucine, sachets 20 g, MSUD Gel® Amino acid formula with vitamins and minerals without phenylalanine and tyrosine, sachets 20 g, TYR Gel® Amino acid formula with vitamins and minerals without lysine and low in tryptophan, sachets 20 g, GA Gel® Vitaflo Australia Pty Ltd Minor submission	Medicinal foods	Request to increase the current sachet size from 20 g to 24 g	Recommended.
Amino acid formula with vitamins and minerals without phenylalanine, gel (ready prepared), 85 g, PKU Squeezie® Vitaflo Australia Pty Ltd Minor submission	Medicinal food	Restricted benefit listing for phenylketonuria.	Recommended.

Anti-diabetic drugs – dipeptidyl peptidase 4 inhibitors, thiazolidinediones and glucagon-like peptide-1 agents Exenatide, injection solution, 5 micrograms per dose in pre-filled pen, 10 micrograms per dose in pre-filled pen, Byetta 5 microgram®, Byetta 10 microgram®, Eli Lilly Australia Pty Ltd Pioglitazone hydrochloride, tablets, 15 mg (base), 30 mg (base) and 45 mg (base), Actos®, Eli Lilly Australia Pty Ltd Rosiglitazone maleate, tablets, 4 mg (base), and 8 mg (base), Avandia®, GlaxoSmithKline Australia Pty Ltd Rosiglitazone maleate with metformin hydrochloride, tablets, 2 mg (base)-500 mg, 2 mg (base)-1 g, 4 mg (base)-500 mg and 4 mg (base)-1 g, Avandamet®, GlaxoSmithKline Australia Pty Ltd Saxagliptin, tablets, 2.5 mg and 5 mg, Onglyza®, Bristol-Myers Squibb Australia Pty Ltd Sitagliptin, tablets, 25 mg, 50 mg and 100 mg (as phosphate monohydrate), Januvia®, Merck Sharp & Dohme (Australia) Pty Ltd Sitagliptin with metformin hydrochloride, tablets, 50 mg (as phosphate monohydrate) – 500 mg, 50 mg (as	Type 2 diabetes	The PBAC Secretariat suggested resolving inconsistencies in the current NOTEs and restrictions applied to the PBS listings for the thiazolidinediones and incretins (glucagon-like peptide-1 agents and dipeptidyl peptidase 4 inhibitors) for use in type 2 diabetes.	Recommended.

phosphate monohydrate) – 850 mg and 50 mg (as phosphate monohydrate) – 1,000 mg, Janumet®, Merck Sharp & Dohme (Australia) Pty Ltd Vildagliptin, tablet, 50 mg, Galvus®, Novartis Pharmaceuticals Pty Ltd PBAC Secretariat Minor submission			
Arginine with carbohydrate, sachets 4 g containing 2000 mg arginine, Arginine 2000 Amino Acid Supplement® Vitaflo Australia Pty Ltd Minor submission	Medicinal food	Restricted benefit listing of a higher strength product for urea cycle disorders.	Recommended.
BCG immunotherapeutic (Bacillus Calmette-Guerin/Connaught strain), 1 vial powder for intravesical administration containing 6.6 to 19.2 x 108 CFU, ImmuCyst® Sanofi-Aventis Australia Pty Ltd Minor submission	Bladder cancer	Request listing of a new presentation that does not contain a 3 mL vial of diluent.	Recommended.

Biological disease modifying anti-rheumatic drugs (bDMARDs) used in rheumatoid arthritis. Abatacept, powder for I.V. infusion 250 mg, Orencia®, Bristol-Myers Squibb Pharmaceuticals Adalimumab, injection 40 mg in 0.8 mL pre-filled syringe and pre-filled pen, Humira®, Abbott Australasia Pty Ltd Certolizumab pegol, injection 200 mg in 1 mL single use pre-filled syringe, Cimzia®, UCB Pharma Etanercept, injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL, injections 50 mg in 1 mL single use pre-filled syringes, 4, injection 50 mg in 1 mL single use auto-injector, 4, Enbrel®, Wyeth Australia Pty Ltd Infliximab, powder for I.V. infusion 100 mg, Remicade®, Schering-Plough Pty Ltd Rituximab, solution for I.V. infusion, 500 mg in 50 mL, Mabthera®, Roche Products Pty Ltd The Australian Rheumatology Association (ARA)	Rheumatoid arthritis	The ARA requested an extension to the time-period that patients can cease therapy with a bDMARD before being required to requalify for treatment under the “Initial 1 treatment restriction” from the current 12 months to 24 months.	Recommended.

Budesonide with eformoterol fumarate dihydrate, powder for oral inhalation in breath activated devices, 400 mcg – 12 mcg per dose, Symbicort Turbuhaler 400/12® AstraZeneca Pty Ltd Major submission	Asthma and chronic obstructive pulmonary disease (COPD)	Restricted benefit listing for the symptomatic treatment of moderate to severe chronic obstructive pulmonary disease in patients who meet certain criteria.	The PBAC recommended listing on a cost minimisation basis compared with salmeterol 25 mcg with fluticasone 250 mcg. The equi-effective doses are salmeterol 50 mcg with fluticasone 500 mcg twice daily and eformoterol 12 mcg with budesonide 400 mcg twice daily.
Calcipotriol with betamethasone dipropionate, gel, 50 micrograms-500 micrograms (base) per g, (0.005%-0.05%), 30 g, Daivobet® CSL Limited Minor submission (out-of-session)	Psoriasis	Request a Restricted benefit listing for a new form of the combination product for the treatment of chronic stable plaque type psoriasis of the scalp in patients who are not adequately controlled with either calcipotriol or potent topical corticosteroid monotherapy.	The PBAC recommended listing on a cost-minimisation basis with the currently PBS-listed ointment formulation.
Cephalexin, capsule, 250 mg Correspondence from the Royal Australian College of General Practitioners Minor submission	Anti-infective	Request to have increased maximum quantities and repeats available for antibiotics used in the prevention of recurrent urinary tract infections.	The PBAC recommended a new streamlined Authority listing for cephalexin with a maximum quantity of 40 and 2 repeats for the prophylaxis of urinary tract infections. The PBAC noted that this change will require further discussion within the Department prior to implementation.
Cinacalcet hydrochloride, tablet 30 mg, 60 mg and 90 mg (base), Sensipar® Amgen Australia Pty Ltd Minor submission	Chronic kidney disease	Request a change to the Section 85 listing from Authority Required to Authority Required (Streamlined).	Recommended. The Section 100 Highly Specialised Drugs Program listings for cinacalcet will remain unchanged.

Citrulline with carbohydrate, sachets 4 g containing 1000 mg citrulline, Citrulline Amino Acid Supplement® Vitaflo Australia Pty Ltd Minor submission	Medicinal food	Restricted benefit listing for urea cycle disorders excluding arginase deficiency.	Recommended.
Dalteparin sodium (Low Molecular Weight Heparin Sodium – porcine mucous), single dose pre-filled syringes, 7,500 IU (anti-Xa) in 0.75 mL, 10,000 IU (anti-Xa) in 1 mL, 12,500 IU (anti-Xa) in 0.5 mL, 15,000 IU (anti-Xa) in 0.6 mL and 18,000 IU (anti-Xa) in 0.72 mL, Fragmin® Pfizer Australia Pty Ltd Major submission	Anti-blood clotting agent	Restricted benefit listing for: 1) Treatment of symptomatic venous thromboembolism (VTE) in patients with active solid tumour cancers; and 2) Secondary prevention of VTE in patients with active solid tumour cancers and previous VTE.	The PBAC recommended listing for management of symptomatic venous thromboembolism in a patient with a solid tumour(s) on a cost-minimisation basis compared with enoxaparin. The equi-effective doses are dalteparin 200IU/kg daily for 1 month, then 150 IU/kg (max 18,000 IU) daily for 5 months, equivalent to enoxaparin 1.5 mg/kg daily for entire treatment course of 6 months.
Docetaxel, solution concentrate for I.V. infusion, 20 mg in 1 mL and 80 mg in 4 mL, Taxotere® Sanofi-Aventis Australia Pty Ltd Minor submission	Anti-cancer drug	Request listing of a new formulation of the two existing docetaxel strengths.	The PBAC recommended listing for the same indications as the currently PBS-listed docetaxel products on a cost-minimisation basis with the corresponding strengths of docetaxel powder for I.V infusion.
Dutasteride with tamsulosin hydrochloride, capsules, 500 mcg – 400 mcg, Duodart® GlaxoSmithKline Australia Pty Ltd Major submission	Symptoms associated with an enlarged prostate gland	Authority Required (Streamlined) listing for the treatment of moderate to severe lower urinary tract symptoms due to benign prostatic hyperplasia where treatment has been initiated by a urologist.	The PBAC recommended listing on a cost minimisation basis compared with dutasteride and prazosin. The equi-effective doses are dutasteride 0.5 mg and prazosin 2 mg twice daily.

Esomeprazole magnesium trihydrate, table (enteric coated), equivalent to 40 mg esomeprazole, Nexium® AstraZeneca Pty Ltd Minor submission	Gastro-oesophageal reflux disease	Requests removal of the words "…and or repeats" from the NOTE, to allow an increased number of repeats to be prescribed for the healing of gastro-oesophageal reflux disease.	The PBAC recommended that the NOTE attached to the current listing for esomeprazole 40 mg tablets be amended to remove the statement that no increased repeats will be authorised.
Ezetimibe, tablet, 10 mg, Ezetrol® Merck Sharp & Dohme (Australia) Pty Ltd Major submission	High cholesterol levels	Requests amending the current Authority Required (Streamlined) listing definition of 'inadequate control' to allow the addition of ezetimibe to 20 mg of rosuvastatin or atorvastatin as opposed to the current "…40 mg or above of a statin".	The PBAC recommended that the restriction for ezetimibe be amended to incorporate wording that does not specify a particular dose of a statin be attempted to achieve an appropriate lowering of cholesterol, rather that the wording should stipulate a three month trial with the maximum tolerated dose of a statin. This option allows ezetimibe to be added as clinically appropriate while continuing to support up-titration of statins as the first line treatment of hypercholesterolaemia.
Filgrastim (rbe), injection, single use pre-filled syringe, 120 micrograms in 0.2 mL, 300 micrograms in 0.5 mL, 480 micrograms in 0.5 mL, Nivestim® Hospira Australia Pty Ltd Minor submission	Prevention of neutropenia	Requests listing for the same indications as the currently listed filgrastim product.	The PBAC recommended a Section 100 Highly Specialised Drugs Program listing of the requested filgrastim products, with the same restrictions and for the same indications as the currently listed filgrastim reference products.
Fluconazole, powder for oral suspension, 50 mg in 5 mL, 35 mL, Diflucan® Pfizer Australia Pty Ltd Minor submission	Anti-infective	Requests listing of an oral suspension form for the same indications as the capsule and I.V. forms.	The PBAC recommended listing as an Authority Required listing for the same indications as the currently listed fluconazole capsules for patients unable to take a solid dose form of fluconazole.

Haemophilus influenzae type b and group C Meningococcal polysaccharide conjugate vaccine, lyophilised powder for injection, 1 vial with 0.5 mL pre-filled syringe diluent, 10 vials with 10 x 0.5 mL pre-filled syringe diluent, Menitorix® GlaxoSmithKline Australia Pty Ltd Major submission	Childhood vaccination against diseases caused by *H. influenzae* and *N. meningitis C*	National Immunisation Program (NIP) listing for the active immunisation of all Australian children, at 12 months of age, for the prevention of diseases caused by *Haemophilus influenzae* and *Neisseria meningitis serogroup C.*	The PBAC recommended listing on the NIP under the same conditions as the existing single antigen Hib and Men C vaccines on the NIP.
Levodopa with carbidopa (as monohydrate), intestinal gel, 20 mg-5 mg per mL, 100 mL, Duodopa® Abbott Australasia Pty Ltd Minor submission	Parkinson disease	Section 100 Highly Specialised Drugs Program (Public and Private Hospital Authority Required) listing for the treatment of advanced Parkinson disease in patients who meets certain criteria; and for a Section 85 Authority Required listing for maintenance therapy in advanced Parkinson disease in patients who meet certain criteria.	The PBAC recommended a Section 100 Highly Specialised Drugs Program listing and a Section 85 Authority Required listing (maintenance therapy) on the basis of a high but acceptable cost-effectiveness ratio compared with current interventions including oral therapy, apomorphine and deep brain stimulation.
Morphine sulfate, capsules, 10 mg, 20 mg, 50 mg and 100 mg (containing sustained release pellets), Kapanol® GlaxoSmithKline Australia Pty Ltd Morphine sulfate, tablets, 10 mg, 30 mg, 60 mg and 100 mg (controlled release), Momex SR® Sigma Pharmaceuticals (Australia) Pty Ltd	Pain relief	The sponsors were asked if their respective products could be manufactured in a quantity sufficient to provide 14 days worth of treatment.	The PBAC recommended amending the current pack size (maximum quantity) to 28.

Nafarelin, nasal spray (pump pack), 200 micrograms (base) per dose (60 doses), (as acetate), Synarel® Pfizer Australia Pty Ltd Minor submission	Fertility drug	Request a Section 100 IVF/GIFT Program listing for the prevention of premature luteinisation and ovulation in patients undergoing controlled ovarian stimulation, who meet certain criteria.	The PBAC recommended a Section 100 IVF/GIFT Treatment Program listing under the same circumstances as ganirelix. The equi-effective doses for the purposes of cost-minimisation are nafarelin 800 micrograms daily and ganirelix 250 micrograms daily.
Olanzapine, wafer, 15 mg and 20 mg, Zyprexa Zydis® Eli Lilly Australia Pty Ltd Minor submission	Anti-psychotic drug	Request listing of two higher strengths of olanzapine in wafer form with the same indications as the lower strength tablets and wafers.	Recommended.
Omalizumab (rch), powder for injection, 150 mg, Xolair® Novartis Pharmaceuticals Australia Pty Ltd Major submission	Severe allergic asthma	Section 100 (Highly Specialised Drugs Program) Public and Private hospital Authority Required listing for uncontrolled, severe allergic asthma in patients who meet certain criteria.	The PBAC recommended a Section 100 Highly Specialised Drugs Program listing on the basis of an acceptable cost effectiveness ratio compared with placebo in addition to optimal asthma therapy.
Ondansetron, tablet (dispersible), 4 mg and 8 mg, Ondansetron ODT-DRLA® Dr Reddy's Laboratories (Australia) Pty Ltd Minor submission	Anti-nausea drug	Requests listing of an oral disintegrating form of ondansetron tablets with a NOTE stating bioequivalence to the wafer form.	The PBAC recommended the listing of the new dose form of ondansetron, oral dispersible tablets, under the same circumstances as the currently listed ondansetron wafers and with a NOTE to the effect that bioequivalence has been demonstrated between the oral dispersible tablet and wafer forms of ondansetron.
Oxycodone (as hydrochloride) with naloxone (as hydrochloride) dihydrate, tablet, 5 mg-2.5 mg, 10 mg-5 mg, 20 mg-10 mg and 40 mg-20 mg (controlled release), Targin®	Severe pain	Restricted benefit listing for the treatment of chronic severe disabling pain not responding to non-narcotic analgesics.	The PBAC recommended listing on the basis of an acceptable cost-effectiveness ratio compared with oxycodone controlled release, without prophylactic laxatives.

Mundipharma Pty Ltd Minor submission			
Paliperidone palmitate, aqueous suspension for injection, pre-filled syringe, 25 mg, 50 mg, 75 mg, 100 mg and 150 mg, Invega Sustenna® Janssen-Cilag Pty Ltd Major submission	Schizophrenia	Authority Required (Streamlined) listing for the treatment of schizophrenia.	The PBAC recommended listing on a cost-minimisation basis compared with risperidone modified release injection. The pragmatic dose relativity accepted by the PBAC for pricing purposes was 1:1.32 for injected risperidone and injected paliperidone respectively.
Pneumococcal conjugate vaccine, 13 valent, pre-filled syringe, 0.5 mL, 1 vial and 10 vial packs, Prevenar 13® Wyeth Australia Pty Ltd Major submission	Vaccine for Pneumococcal disease	National Immunisation Program (NIP) listing as a single dose for children under 3 years of age who have completed primary vaccination with Prevenar®.	The PBAC recommended an extension to the recommended listing in the NIP to include a single supplementary (catch-up) dose for children aged between 12 and 23 months who have completed primary vaccination with 3 doses of Prevenar (7-valent pneumococcal polysaccharide conjugate vaccine) on the basis of acceptable cost-effectiveness. The PBAC did not recommend the catch-up program for Prevenar 13 include children aged from 24 to 35 months on the basis of unacceptable cost-effectiveness in this patient cohort.
Quetiapine, tablet (modified release), 150 mg (as fumarate), Seroquel XR® AstraZeneca Pty Ltd Minor submission (out-of-session)	Anti-psychotic drug	Request listing of a new strength.	The PBAC recommended listing for the same indications as the existing PBS-listed quetiapine products on a cost-minimisation basis with the currently listed quetiapine tablets.

Rituximab, solution for I.V. infusion, 100 mg in 10 mL and 500 mg in 50 mL, Mabthera® Roche Products Pty Ltd Major submission	Anti-cancer drug	Authority Required and Section 100 (Chemotherapy Pharmaceutical Access Program) listing for the treatment of CD20 positive, chronic lymphocytic leukaemia, in combination with chemotherapy.	The PBAC recommended Authority Required and Section 100 Chemotherapy Pharmaceutical Access Program listings for rituximab in combination with fludarabine and cyclophosphamide (R-FC) on the basis of a high but acceptable cost-effectiveness ratio compared with fludarabine and cyclophosphamide.
Somatropin (recombinant human growth hormone), solution for injection, 5 mg (15 i.u.) in 1.5 mL cartridge (with preservative), Omnitrope® Sandoz Pty Ltd Minor submission	Growth hormone	Listing in the Section 100 Human Growth Hormone program.	The PBAC recommended listing of a new brand of an existing strength and presentation of somatropin at the same price as the currently listed product.
Tamsulosin hydrochloride, tablet (prolonged release), 400 mcg, Flomaxtra® CSL Biotherapies Minor submission	Symptoms associated with an enlarged prostate gland	Restricted benefit listing for the treatment of lower urinary tract symptoms due to benign prostatic hyperplasia.	The PBAC recommended listing as an unrestricted benefit on a cost-minimisation basis compared with prazosin. The equi-effective doses are tamsulosin 400 micrograms daily and prazosin 2 mg twice daily.
Temozolomide, capsule, 180 mg, Temodal® Merck Sharp & Dohme / Schering Plough Pty Ltd Minor submission (out-of-session)	Anti-cancer drug	Request listing of a new strength.	Recommended.
Trimethoprim, tablet, 300 mg Correspondence from the Royal	Anti-infective	Request to have increased maximum quantities and repeats available for antibiotics used in the prevention of	The PBAC recommended a new streamlined Authority listing for trimethoprim tablets with a maximum quantity of 14 and 2 repeats for

Australian College of General Practitioners Minor submission		recurrent urinary tract infections.	the prophylaxis of urinary tract infections. The PBAC noted that this change will require further discussion within the Department prior to implementation.
Vildagliptin with metformin, tablets, 50 - 500 mg, 50-850 mg and 50-1000 mg, Galvumet® Novartis Pharmaceuticals Australia Pty Ltd Minor submission	Type 2 diabetes	Authority Required (Streamlined) listing for treatment of type-2 diabetes.	The PBAC recommended listing of the fixed dose combination in accordance with the combination guidelines on a cost-minimisation compared with the corresponding strengths of the constituent components given concomitantly, with a cost-offset to account for the cost of liver function testing.