NOVEMBER 2011 PBAC MEETING OUTCOMES – Positive Recommendations

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
ADRENALINE, I.M. injection 500 micrograms in 0.3 mL single dose syringe auto-injector, Anapen® 500 Link Medical Products Pty Ltd Minor submission	Anaphylaxis prevention	List a higher strength (500 microgram) adrenaline auto-injector, under the same listing conditions, with the addition of an extra clause in the restriction to indicate the 500 microgram strength is for use in an adult with a mean weight of at least 60 kg, or in an adult at high risk of severe anaphylaxis in whom the 300 microgram dose may not be sufficient.	The PBAC recommended the listing of adrenaline I.M. injection, 500 micrograms in 0.3 mL single dose syringe auto-injector, on the PBS as an Authority Required listing for anticipated emergency treatment of acute allergic reactions with anaphylaxis and also in patients where a 300 microgram adrenaline dose may not be sufficient because the patient has a mean body weight of 60 kg or more or the patient has been assessed to be at high risk of severe anaphylaxis. The recommendation is on a cost minimisation basis with adrenaline I.M. injection 300 micrograms in 0.3 mL single dose syringe auto-injector.
AMINO ACID SYNTHETIC FORMULA supplemented with LONG CHAIN POLYUNSATURATED FATTY ACIDS, compound powder, 400 g, Neocate LCP® AMINO ACID SYNTHETIC FORMULA supplemented with LONG CHAIN POLYUNSATURATED FATTY ACIDS and MEDIUM CHAIN, compound powder, 400 g, Neocate LCP+MCT® Nutricia Australia Pty Ltd Minor submission Secretariat listing	Medicinal food	To request the substitution of Neocate LCP and Neocate LCP+MCT with new formulations of the same products (with an altered macronutrient and increased docosahexaenoic acid (DHA) level) under the same PBS listing codes as the currently listed products.	Recommended.
AMINO ACID SYNTHETIC FORMULA, compound powder, 400 g, Neocate Advance Vanilla® Nutricia Australia Pty Ltd Minor submission	Medicinal food	List a new vanilla flavoured Neocate product with pre-biotics, under the same listing conditions as Neocate.	The PBAC recommended listing Neocate Advance Vanilla (a new vanilla flavoured Neocate product with prebiotics) on the PBS as an Authority Required benefit under the same listing conditions as the currently listed Neocate products.

NOVEMBER 2011 PBAC MEETING OUTCOMES – Positive Recommendations

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
AMLODIPINE (as besylate) with VALSARTAN and HYDROCHLOROTHIAZIDE, tablets, 5 mg-160 mg-12.5 mg, 5 mg-160 mg-25 mg, 10 mg-160 mg-12.5 mg, 10 mg-160 mg-25 mg, and 10 mg-320 mg-25 mg, Exforge HCT®, Novartis Pharmaceuticals Australia Pty Ltd Minor submission Secretariat listing	High blood pressure	Request Nurse Practitioner prescribing under collaborative arrangements for the triple combination therapy, amlodipine with valsartan and hydrochlorothiazide (Exforge HCT®) for the treatment of hypertension in a patient who is not adequately controlled with any two of the drugs in the combination.	Recommended.
DALTEPARIN SODIUM, injection, 10,000 units (anti-Xa) in 1 mL and 12,500 units (anti-Xa) in 0.5 mL, single dose pre-filled syringe, Fragmin® Pfizer Australia Pty Ltd Minor submission	Blood thinner for use in haemodialysis	Restricted Benefit listing for two new strengths 10,000 and 12,500 units, of dalteparin for use in haemodialysis.	Recommended.
DENOSUMAB, injection 60 mg in 1 mL pre-filled syringe, Prolia® Amgen Australia Pty Ltd Minor submission	Osteoporosis	Request a change from Authority Required to Authority Required (Streamlined) and inclusion in Nurse Practitioner PBS Prescribing.	Recommended.

NOVEMBER 2011 PBAC MEETING OUTCOMES – Positive Recommendations

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
EPOPROSTENOL SODIUM, powder for I.V. infusion, 500 microgram and 1.5 mg (base), with diluent, cassette reservoir and extension set, Flolan Kit® GlaxoSmithKline Australia Pty Ltd Minor submission Out of Session	Pulmonary arterial hypertension	Request listing of a new presentation of epoprostenol, that contains diluent and an administration set (one cassette reservoir and one extension set) under the same listing conditions as the currently listed products.	Recommended.
EPOPROSTENOL SODIUM, powder for I.V. infusion, 500 micrograms (base) with diluent, 1.5 mg (base) with diluent, Flolan® GlaxoSmithKline Australia Pty Ltd Major submission	Pulmonary arterial hypertension secondary to the scleroderma spectrum of diseases	Extend the current Section 100 (Highly Specialised Drugs Program) Authority Required listing to include the treatment of: 1) WHO functional class III pulmonary arterial hypertension (PAH) secondary to the scleroderma spectrum of diseases in patients who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; 2) WHO functional class IV PAH secondary to the scleroderma spectrum of diseases.	The PBAC recommended listing epoprostenol on the PBS in the Section 100 (Highly Specialised Drugs Program) as a Public and Private Hospital Authority Required benefit for second-line therapy for WHO functional class III pulmonary arterial hypertension (PAH) secondary to connective tissue disease and first line therapy for WHO functional class IV PAH secondary to connective tissue disease on a cost minimisation basis compared with iloprost and bosentan.
ESSENTIAL AMINO ACIDS FORMULA, powder, 200 g, 2, Essential Amino Acid Mix® Nutricia Australia Pty Ltd Minor submission Secretariat listing	Medicinal food	Change the description of the maximum quantity to 6 (instead of 2x3).	Recommended.

NOVEMBER 2011 PBAC MEETING OUTCOMES – Positive Recommendations

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
EXENATIDE, injection solution, 5 micrograms and 10 micrograms per dose, pre-filled pen, 60 doses, Byetta 5 microgram® and Byetta 10 microgram® Eli Lilly Australia Pty Ltd Minor submission	Type 2 diabetes	Request a change from Authority Required to Authority Required (Streamlined) for the current listing for dual combination therapy with metformin or a sulfonylurea, and triple combination therapy with metformin and a sulfonylurea in type II diabetic patients.	Recommended.
FILGRASTIM, injection, 300 micrograms in 0.5 mL and 480 micrograms in 0.8 mL, single use pre-filled syringe, Tevagrastim® Aspen Pharma Pty Ltd Minor submission	Bone marrow cell stimulator	S100 listing (Highly Specialised Drugs Program) Authority Required listing for a new biosimilar filgrastim, with the same listing conditions as Neupogen and Nivestim.	Recommended.
GEMCITABINE, solution concentrate for I.V. infusion, 200 mg in 5 mL, 1000 mg in 25 mL and 2000 mg in 50 mL (as hydrochloride), Gemcitabine Ebewe® Sandoz Pty Ltd Minor submission	Anti-cancer drug	Request to list a third new concentration of gemcitabine solution concentrated for I.V. infusion under the current listing conditions as the currently listed gemcitabine powder for I.V infusion.	Recommended.

NOVEMBER 2011 PBAC MEETING OUTCOMES – Positive Recommendations

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
GLUCOSE INDICATOR-BLOOD, test strips, 50 and 100 strips, BGStar® Blood Glucose Test Strips Sanofi-Aventis Australia Pty Ltd Minor submission Out of Session	Blood glucose indicator	Unrestricted Benefit listing for a new blood glucose indicator, with two pack sizes, under the same listing conditions as the currently listed products.	Recommended.
GLUCOSE INDICATOR-BLOOD, test strips, 50, Accu-Chek® Aviva Roche Diagnostics Australia Pty Ltd Minor submission Out of Session	Blood glucose indicator	List a new glucose indicator-blood test strip as an Unrestricted and Restricted Benefit (GP Management Plan), under the same listing conditions as the currently listed products.	Recommended.

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
HEPATITIS B ANTIVIRALS ADEFOVIR DIPIVOXIL, tablet 10 mg, Hepsera®, Gilead Sciences Pty Ltd; ENTECAVIR MONOHYDRATE, tablet 0.5 mg, 1 mg, Baraclude®, Bristol-Myers Squibb Pharmaceuticals A Division of Bristol-Myers Squibb Australia Pty Ltd; INTERFERON ALFA-2a, injection 3,000,000 i.u. in 0.5 mL single dose pre-filled syringe, injection 4,500,000 i.u. in 0.5 mL single dose pre-filled syringe, injection 6,000,000 i.u. in 0.5 mL single dose pre-filled syringe, injection 9,000,000 i.u. in 0.5 mL single dose pre-filled syringe, Roferon-A®, Roche Products Pty Ltd;	Treatment of hepatitis B	Review further proposed changes to the anti-viral therapy drug group restrictions with regards to patients who have evidence of cirrhosis.	The PBAC recommended that the restrictions for the anti-virals listed for the treatment of chronic hepatitis B be further changed to allow treatment in patients with cirrhosis with any detectable HBV DNA, and that elevated serum ALT levels not be required for these patients. See also July 2011 PBAC Outcomes.

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
INTERFERON ALFA-2b, solution for injection 18,000,000 i.u. in 1.2 mL multi-dose injection pen, solution for injection 30,000,000 i.u. in 1.2 mL multi-dose injection pen, solution for injection 60,000,000 i.u. in 1.2 mL multi-dose injection pen, Intron A Redipen®, solution for injection 18,000,000 i.u. in 3 mL single dose vial, solution for injection 25,000,000 i.u. in 2.5 mL single dose vial, solution for injection 10,000,000 i.u. in 1 mL single dose vial, Intron A®, Merck Sharp & Dohme (Australia) Pty Ltd;			

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
LAMIVUDINE, tablet 100 mg, oral solution 5 mg per mL, 240 mL, Zeffix®, GlaxoSmithKline Australia Pty Ltd; PEGINTERFERON ALFA-2a, Injection 135 micrograms in 0.5 mL single use pre-filled syringe, injection 180 micrograms in 0.5 mL single use pre-filled syringe, Pegasys®, Roche Products Pty Ltd; TELBIVUDINE, tablet 600 mg, Sebivo®, Novartis Pharmaceuticals Australia Pty Ltd; TENOFOVIR, tablet containing tenofovir disoproxil fumarate 300 mg, Viread®, Gilead Sciences Pty Ltd. Non-sponsor submission			
HYDROXOCOBALAMIN, injection 1 mg (as acetate) in 1 mL, Goldshield Hydrocobalamin® Goldshield Healthcare (Australia) Pty Ltd Minor submission	Vitamin B12 supplement	Restricted Benefit listing of a new salt (acetate) of hydroxocobalamin injection under the same listing conditions as the currently listed hydroxocobalamin chloride.	Recommended. The PBAC considered that the hydroxocobalamin (as acetate) is equivalent for the purposes of substitution to the currently listed brands of the pharmaceutical item hydroxocobalamin injection 1 mg in 1 mL (as chloride) Neo-B12®, Hydroxo-B12®.

NOVEMBER 2011 PBAC MEETING OUTCOMES – Positive Recommendations

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
INTERFERON BETA-1a, injection, 30 micrograms (6,000,000 iu) in 0.5 mL single dose pre-filled pen, Avonex® Pre-filled pen Biogen Idec Australia Pty Ltd Minor submission Secretariat listing	Multiple sclerosis	Request listing of a new 30 microgram presentation (single dose pre-filled pen) of interferon beta-1a under the same listing conditions as the 30 micrograms single dose pre-filled syringe.	Recommended.
LINAGLIPTIN, tablet, 5 mg, Ondero®/Trajenta® Boehringer Ingelheim Pty Ltd Minor submission	Type 2 diabetes	Authority required (Streamlined) listing for treatment of patients with type 2 diabetes in combination with metformin or a sulfonylurea.	The PBAC recommended listing linagliptin on the PBS on a cost-minimisation basis compared with sitagliptin. On the basis of the clinical data, the equi-effective doses are estimated as linagliptin 5mg daily and sitagliptin 100mg daily.
NICOTINE, transdermal patch releasing approximately 25 mg per 16 hours, Nicorette® 16 hr Invisipatch® Johnson&Johnson Pacific Pty Ltd Minor submission	Smoking cessation	Request listing of a new higher 25 mg strength of nicotine patches, under the same listing conditions as the currently listed nicotine patches.	Recommended.
NILOTINIB, capsule, 200 mg (as hydrochloride monohydrate), Tasigna® Novartis Pharmaceuticals Australia Pty Ltd Minor submission	Anti-cancer drug	Request to change the current maximum quantity of 112 capsules for 28-days supply to 120 capsules for 30-days supply for the currently PBS listed 200 mg capsules.	Recommended.

NOVEMBER 2011 PBAC MEETING OUTCOMES – Positive Recommendations

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
OLANZAPINE, tablet (oral disintergrating), 5 mg, 10 mg, 15 mg and 20 mg, Apo-Olanzapine ODT®, Chemart Olanzapine ODT® and Terry White Chemists Olanzapine ODT® Apotex Pty Ltd Minor submission	Schizophrenia	Request listing of a new disintegrating tablet formulation of olanzapine under the same listing conditions as the currently listed olanzapine wafers.	Recommended. The PBAC considered that olanzapine tablets (oral disintergrating) are equivalent for the purposes of substitution to the corresponding strengths of the currently-listed brand of the pharmaceutical item olanzapine wafers (Zyprexa® Zydis).
QUADRIVALENT HUMAN PAPILLOMAVIRUS (TYPES 6, 11, 16, 18) recombinant vaccine, solution for injection, 0.5 mL, solution for injection pre-filled syringe single dose, Gardasil® CSL Limited Major submission	Vaccine for prevention of human papillomavirus	Resubmission for extension of the current listing of Gardasil on the National Immunisation Program (NIP) to include prevention of human papillomavirus (HPV) in males 12 – 13 years of age and a catch-up program over 2 years for Year 9 males.	The PBAC recommended extension of the National Immunisation Program listing of quadrivalent human papillomavirus (types 6, 11, 16, 18) (HPV) recombinant vaccine, solution for injection 0.5 mL, to include ongoing administration to males approximately twelve to thirteen years of age in a school-based program and for two catch-up cohorts for all males in the two year groups above the ongoing cohort, delivered over two years for Year 9 males, on the basis of acceptable cost effectiveness compared with female-only vaccination.
RILPIVIRINE, tablet (film-coated), 25 mg (as hydrochloride), (brand name-to be assigned) Janssen-Cilag Pty Ltd Major submission	HIV treatment	S100 (Highly Specialised Drugs Program) Authority Required listing for the initial and continuing treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease.	The PBAC recommended the listing of rilpivirine tablets on the PBS in the Section 100 Highly Specialised Drugs Program as Private Hospital Authority Required and Public Hospital Authority Required (Streamlined) listings for the initial and continuing treatment of HIV infection in combination with other anti-retroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease on a cost-minimisation basis with efavirenz. The equi-effective doses are rilpivirine 25 mg once daily over 96 weeks and efavirenz 600 mg once daily over 96 weeks, based on the fixed dosing used in the ECHO and THRIVE trials.

NOVEMBER 2011 PBAC MEETING OUTCOMES – Positive Recommendations

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
RITUXIMAB, solution for I.V infusion, 100 mg, in 10 mL, 500 mg in 50 mL, Mabthera® Roche Products Pty Ltd Minor submission Secretariat listing	Anti-cancer drug	To request the PBAC consider a maximum quantity of 1,100 mg and repeats of 5 (i.e. 500 mg x 2.2 m2 accommodating up to 6 cycles) for rituximab for the treatment of chronic lymphocytic leukaemia, for listing under the Section 100 Revised Arrangement for Efficient Funding of Chemotherapy.	Recommended.
SAXAGLIPTIN, tablet, 2.5 mg (as hydrochloride), Onglyza® Bristol-Myers Squibb Australia Pty Ltd Minor submission Out of Session	Type 2 diabetes	Request listing of a new lower 2.5 mg strength tablet of saxagliptin under the current listing conditions.	Recommended.
SOMATROPIN (recombinant human growth hormone), solution for injection, 6 mg (18 iu) in 1.03 mL, 12 mg (36 iu) in 1.5 mL and 20 mg (60iu) in 2.5 mL, multi-dose cartridge, Saizen® Merck Serono Australia Pty Ltd Minor submission Secretariat listing	Growth hormone deficiency	Section 100 (Human Growth Hormone) listing of a new presentation and strengths of somatropin (Saizen).	Recommended

NOVEMBER 2011 PBAC MEETING OUTCOMES – Positive Recommendations

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
TADALAFIL, tablet, 20 mg, Adcirca® Eli Lilly Australia Pty Ltd Major submission	Pulmonary arterial hypertension	S100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of WHO functional class III primary pulmonary arterial hypertension (PAH) and WHO functional class III PAH secondary to connective tissue disease in a patient who meets certain criteria.	The PBAC recommended listing tadalafil on the PBS in the Section 100 Highly Specialised Drugs Program as Public and Private Hospital Authority Required listings on a cost minimisation basis compared with sildenafil for the treatment of WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease. The equi-effective doses are tadalafil 40 mg (2 x 20 mg once daily) and sildenafil 60 mg (20 mg three times a day).
TENOFOVIR with EMTRICITABINE and RILPIVIRINE, tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg and rilpivirine hydrochloride 25 mg, Eviplera® Gilead Sciences Pty Ltd Major submission	HIV treatment	S100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of HIV infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease.	The PBAC recommended listing tenofovir disoproxil fumarate with emtricitabine and rilpivirine hydrochloride (Eviplera®) in the Section 100 Highly Specialised Drugs (HSD) Program for the treatment of human immunodeficiency virus (HIV) infection on a cost-minimisation basis compared with the Atripla® (tenofovir disoproxil fumarate with emtricitabine and efavirenz). The PBAC considered the therapeutic relativity of Eviplera and Atripla depended on the equi-effective doses of ripilvirine and efavirenz, as both of the combinations have identical doses of tenofovir and emtricitabine. The PBAC considered the equi-effective doses to be 25 mg/day rilpivirine and 600 mg/day efavirenz.
TOCILIZUMAB, concentrate for injection, 80 mg in 4 mL, 200 mg in 10 mL and 400 mg in 20 mL, Actemra® Roche Products Pty Ltd Major submission	Juvenile arthritis	Extend the current S100 (Highly Specialised Drugs Program) Authority Required listing to include treatment by a paediatric rheumatologist or under the supervision of a paediatric treatment centre, of severe active systemic juvenile idiopathic arthritis in a patient under18 years of age, who meets certain criteria.	The PBAC recommended listing tocilizumab on the PBS in the Section 100 (Highly Specialised Drugs Program) as a Public and Private Hospital Authority Required benefit on a cost minimisation basis compared with etanercept and adalimumab. The equi-effective doses estimated using the weight distribution from the TENDER trial are, tocilizumab: <30kg 12mg/kg and ≥30kg 8mg/kg administered by 60min IV infusion every 2 weeks compared with etanercept: 0.4mg/kg up to 25mg SC twice weekly and adalimumab 24mg/m^2 second weekly (Lovell 2008 trial).