July 2013 PBAC Meeting Outcomes – Positive Recommendation

Drug and Form	Drug use and type	Listing requested by sponsor	PBAC Recommendation
Alogliptin, tablets, 6.25 mg, 12.5 mg and 25 mg, Nesina® Takeda Pharmaceuticals Australia Pty Ltd Major submission	Type 2 Diabetes	To request an Authority required (Streamlined) listing for dual oral combination therapy with metformin or a sulfonylurea in type 2 diabetes.	The PBAC recommended listing of alogliptin as an Authority required (Streamlined) benefit for treatment in combination with metformin or a sulfonylurea of patients whose HbA1c is greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1 despite treatment with metformin or a sulfonylurea, without the requirement for patients to be contraindicated or intolerant of a combination of metformin and a sulfonylurea. Listing should be at a reduced price, which takes into account the likely proportion of use in patients who have not trialled a sulfonylurea and where cost-effectiveness has not been established.
Amino acid formula-synthetic, oral liquid, powder for, 400 g, Alfamino® Nestlé Australia Ltd Minor submission	Medicinal food	Requests an Authority required listing for infants and children with cow's milk allergy.	The PBAC recommended listing Alfamino as an Authority required benefit for the same indications as those applying to Neocate Gold, on a cost-minimisation basis compared to Neocate Gold and at an equivalent price per gram of protein.
Amino acid formula with vitamins and minerals without phenylalaline, oral liquid, 60 x 62.5 mL cans, PKU Lophlex LQ® 10 Nutricia Australia Pty Ltd Minor submission	Medicinal food	Requests a Restricted benefit listing for two additional flavour variants to the current PKU Lophlex LQ 10 range.	Recommended

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Amino acid formula with vitamins and minerals without phenylalanine Oral, semi-solid, carton of 36 x 109 g, PKU Lophlex Sensation 20® Nutricia Australia Pty Ltd Minor submission	Medicinal food	Restricted benefit listing of a phenylalanine-free protein substitute for the management of Phenylketonuria (PKU).	Recommended
Amino acid synthetic formula, oral liquid, powder for, 400 g, Neocate® Advance Vanilla with Prebiotics Nutricia Australia Pty Ltd Minor submission	Medicinal food	To highlight minor changes to the formulation and confirm that the product remains compliant with the FSANZ Standard for Foods for Special Medical Purposes 2.9.5.	Recommended
Amlodipine and hydrochlorothiazide and olmesartan, tablets, 5 mg-12.5 mg-20 mg, 5 mg-12.5 mg-40 mg, 5 mg-25 mg-40 mg, 10 mg-12.5 mg-40 mg and 10 mg-25 mg-40 mg, Sevikar HCT® Merck Sharp & Dohme (Australia) Pty Limited Major submission	High blood pressure	Restricted benefit listing for the treatment of hypertension where the condition is not adequately controlled with two of either an angiotensin II receptor antagonist, calcium channel blocker or diuretic.	The PBAC recommended listing of amlodipine and hydrochlorothiazide and olmesartan tablets 5/12.5/20 mg, 5/12.5/40 mg, 5/25/40 mg, 10/12.5/40 mg and 10/25/40 mg (Sevikar HCT®) as a Restricted benefit for treatment of hypertension in a patient who meets certain criteria, on a cost minimisation basis compared to the individual l components given concomitantly.

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Botulinum toxin, lyophilised powder for injection, 100 units, Botox® Allergan Pty Ltd Major submission	Chronic migraine	Re-submission to extend the current Section 100 (Botulinum Toxin Program) listing to include the prophylaxis of headaches in adult patients with chronic migraine who meet certain criteria.	The PBAC recommended extending the current Section 100 Botulinum Toxin Program listing for botulinum toxin type A to include prophylaxis of headaches in adults patients with chronic migraine who meet certain criteria, on the basis of acceptable cost-effectiveness compared to best supportive care. To address uncertainty in the cost-effectiveness being reflected in practice, the PBAC recommended that a tighter Risk Sharing Arrangement be negotiated with the sponsor, with larger rebates and caps based on the smaller estimates of use provided in the July 2012 re-submission.
Budesonide, foam enema, 2 mg per application, Budenofalk® Orphan Australia Pty Ltd Major submission	Ulcerative colitis	Unrestricted benefit for treatment of active rectal and rectosigmoid disease in ulcerative colitis.	The PBAC recommended listing of budesonide foam enema as an Unrestricted benefit for treatment of ulcerative colitis on a cost-minimisation basis with prednisolone enema. The accepted equi-effective doses are budesonide 2 mg and prednisolone 20 mg.
Budesonide with eformoterol fumarate dihydrate, oral pressurised inhalation, 50 mcg-3 mcg, 100 mcg-3 mcg, 200 mcg-6 mcg per dose, Symbicort Rapihaler® AstraZeneca Pty Ltd Major submission	Asthma	Re-submission requesting a Restricted benefit listing for maintenance and reliever therapy in patients with frequent asthma symptoms.	The PBAC recommended the listing of budesonide with eformoterol pressurised metered dose inhalers (MDI) for treatment of asthma and COPD on a cost-minimisation basis with budesonide with eformoterol DPI.

Canagliflozin, tablets, 100 mg and 300 mg, Invokana® Janssen-Cilag Pty Ltd Major submission	Type 2 diabetes	Authority required listing for patients with type 2 diabetes as dual oral combination therapy with metformin or a sulfonylurea	The PBAC recommended the listing of canagliflozin on the PBS on a cost minimisation basis with sitagliptin. The equi-effective doses are canagliflozin 300 mg to sitagliptin 100 mg. The Committee recommended the restriction reflect current clinical practice in which patients whose diabetes cannot be successfully managed with a combination of metformin and a sulfonylurea, irrespective of reason, are moved to dual therapy with metformin or a sulfonylurea, and a sodium glucose transporter 2 inhibitor, a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), or a glucagon-like peptide-1.
Carbomer 980, eye gel, 2 mg per mL (0.2%), 10 g tube, Optifresh Eye Gel® Petrus Pharmaceuticals Minor submission	Ocular lubricant	Restricted benefit listing in the general and optometrical schedules for severe dry eye syndrome, including Sjogren's syndrome.	The PBAC recommended a Restricted benefit listing and an Optometric Schedule Restricted benefit listing (maximum quantity of 1 and 5 repeats) for patients with severe dry eye syndrome, including Sjogren's syndrome, and a Restricted benefit listing (maximum quantity of 1 and 11 repeats) for patients with severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements on a cost minimisation basis compared with the currently listed carbomer 980 eye gel, 2 mg per mL, (0.2 %) 10 g products.
Carmellose sodium, eye drops, 5 mg per mL (0.5%), 0.4 ml x 30 unit doses, Optifresh Tears Eye Drops® Carmellose sodium, eye drops, 10 mg per mL (1%), 0.4 ml x 30 unit doses, Optifresh Plus® Petrus Pharmaceuticals Minor submission	Ocular lubricant	Authority required (Streamlined) and Authority required listings in the general and optometrical schedules respectively for severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops	The PBAC recommended a Section 85 Authority required (Streamlined) listing and an Optometric Schedule Authority required listing for severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops with a maximum quantity of 3 packs and 5 repeats on a cost minimisation basis compared with the currently listed carmellose sodium 5 mg per mL (0.5%) and 10 mg per mL (1%) eye drops 0.4 mL.

Dabrafenib capsules, 50 mg and 75 mg, Tafinlar® GlaxoSmithKline Australia Pty Ltd Minor submission	Melanoma	To provide further information to the Committee to allow the PBAC to make a recommendation on the March 2013 submission seeking an Authority required listing for treatment of patients with BRAF V600 mutation positive advanced (unresectable stage III) or metastatic (stage IV) melanoma.	The PBAC recommended the PBS listing of dabrafenib on the basis of acceptable cost effectiveness with dacarbazine at the revised price offered in the minor submission. The PBAC recommended that PBS access be limited to previously untreated patients who have a tumour which harbours a BRAF V600 mutation. The PBAC also recommended that PBS eligibility should extend to patients severely intolerant of other BRAF inhibitors, should other drugs become PBS-listed.
Dapagliflozin, tablet, 10 mg, Forxiga® Bristol-Myers Squibb Australia Pty Ltd Major submission	Type 2 diabetes	Authority required listing for patients with type 2 diabetes as dual oral combination therapy with metformin or a sulfonylurea.	The PBAC recommended the listing of dapagliflozin on the PBS on a cost minimisation basis with sitagliptin. The equi-effective doses accepted for the purposes of cost-minimisation are dapagliflozin 10 mg being equivalent to sitagliptin 100 mg. The Committee recommended the restriction reflect current clinical practice in which patients whose diabetes cannot be successfully managed with a combination of metformin and a sulfonylurea, irrespective of reason, are moved to dual therapy with metformin or a sulfonylurea, and a sodium glucose transporter 2 inhibitor, a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), or a glucagon-like peptide-1.
Darunavir, tablet, 800 mg, Prezista® Janssen-Cilag Pty Ltd Minor submission	Human immunodeficiency virus (HIV) infection	Request to replace the currently PBS listed 400 mg tablet with an 800 mg tablet for patients with HIV infection.	The PBAC recommended the PBS listing of darunavir 800 mg tablet on a cost minimisation basis compared with the currently listed darunavir 400 mg tablet.
Denosumab, injection, 60 mg per mL, Prolia® Amgen Australia Pty Ltd Major submission	Osteoporosis	Requests extension of Authority required (Streamlined) listing to include males with osteoporosis who meet the same eligibility criteria that currently apply to women (i.e. sole PBS-subsidised anti-resorptive agent for osteoporosis in a patient aged 70 years of age or older with a T-score of -2.5 or less).	The PBAC recommended listing of denosumab as an Authority required (Streamlined) benefit as the sole PBS-subsidised anti-resorptive agent for osteoporosis to include both male and female patients.

Dimethyl fumarate, capsules, 120 mg and 240 mg, Tecfidera® Biogen Idec Australia Pty Ltd Major submission	Multiple sclerosis	Authority required listing a monotherapy, of clinically definite relapsing-remitting multiple sclerosis in an ambulatory (without assistance or support) patient with multiple sclerosis who meets certain criteria.	The PBAC rejected the listing of dimethyl fumarate at the price requested in the submission, on the grounds that the claims of superior efficacy over the ABCR therapies (intramuscular interferon beta-1a, subcutaneous interferon beta-1a, interferon beta-1b and glatiramer acetate) and non-inferior efficacy compared to fingolimod were not adequately supported by the evidence presented. The PBAC considered that the appropriate clinical claim based on the data provided was that dimethyl fumarate is non-inferior to the ABCR therapies in terms of efficacy and safety. Therefore the Committee recommended the listing of dimethyl fumarate on a cost-minimisation basis with the ABCR therapies.
Everolimus, tablets, 5 mg and 10 mg, Afinitor®, Novartis Pharmaceuticals Australia Pty Ltd Minor submission	Hormone-receptor positive, HER2 negative advanced breast cancer	Authority required listing for the treatment of post-menopausal women with hormone-receptor positive, HER2 negative advanced breast cancer in combination with exemestane after failure of treatment with letrozole or anastrozole.	The PBAC deferred the submission to allow the Department to negotiate with the sponsor a price in line with an ICER that would recognise the value of everolimus for this indication while at the same time acknowledging the lack of overall survival (OS) data. Following advice of the PBAC's deferral, the sponsor made an offer of further price reduction. The PBAC considered this acceptable and recommended out of session approval of everolimus for breast cancer, in combination with exemestane.
Ezetimibe with atorvastatin, tablets, 10 mg-10 mg, 20 mg-10 mg, 40 mg-10 mg and 80 mg-10 mg, Atozet® co-pack Merck Sharp & Dohme (Australia) Pty Limited Major submission	High cholesterol	Re-submission for an Authority required (Streamlined) listing for hypercholesterolaemia in patients meeting certain criteria.	The PBAC recommended Authority required (Streamlined) listing of ezetimibe and atorvastatin co-pack for hypercholesterolaemia in combination with dietary therapy and exercise where cholesterol levels are inadequately controlled by a statin and patients have hypertension, coronary heart disease (or a family history), diabetes, peripheral vascular disease, heterozygous familial hypercholesterolaemia or cerebrovascular disease, on a cost-minimisation basis with the corresponding doses of the components (ezetimibe and atorvastatin) given concomitantly.

Fluticasone with eformoterol, metered dose inhalers, 50 mcg-5 mcg, 125 mcg-5 mcg and 250 mcg-10 mcg MDI Flutiform® Mundipharma Pty Ltd Major submission	Asthma	Restricted benefit listing for patients who previously had frequent episodes of asthma while receiving treatment with oral corticosteroids and/or optimal doses of inhaled corticosteroids requiring treatment with a combination of an inhaled corticosteroid and a long acting beta-2 agonist.	The PBAC recommended the listing of fluticasone with eformoterol pressurised metered dose inhalers (MDI) for maintenance treatment of asthma on a cost-minimisation basis with fluticasone with salmeterol pressurised MDI.
Glucose indicator – Blood, test strips, 2 x 50 per pack, Contour® Next, Blood Glucose Test Strips Medtronic Australasia Pty Ltd Minor submission	Blood glucose monitoring	Requests an unrestricted benefit listing and also a Restricted benefit listing for patients receiving treatment under a GP management plan or team care arrangements.	Recommended
High fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate, oral liquid, powder for: 300g, Ketocal® 4:1 Nutricia Australia Pty Ltd Minor submission	Medicinal food	To highlight minor changes to the formulation and confirm that the product remains compliant with the FSANZ Standard for Foods for Special Medical Purposes 2.9.5.	Recommended
Ivermectin, tablet, 3 mg, Stromectol® Merck, Sharp & Dohme (Australia) Pty Limited Minor submission	Round worm infestation	To request an amendment of the current Authority required (Streamlined) listing for an increased maximum quantity and number of repeats.	The PBAC agreed that the current PBS listing for ivermectin with a maximum quantity of 4 tablets and nil repeats was not sufficient for patients, particularly those who weigh >66 kg. The PBAC therefore accepted the proposed changes of increased maximum quantity of 8 tablets with 2 repeats for the strongyloidiasis indication.

Milk powder lactose free formula predigested Oral liquid: powder for, 900 g, Karicare Aptamil Gold De-Lact® Nutricia Australia Pty Ltd Minor submission	Medicinal food	Requests listing of a new formula to replace the currently listed Authority required product.	The PBAC recommended listing Karicare Aptamil Gold De-Lact at the same price as that applying to Karicare Aptamil De-Lact and under the same listing circumstances as Karicare Aptamil De-Lact.
Olanzapine pamoate monohydrate, injection, 210 mg, 300 mg and 405 mg, Zyprexa Relprevv® Eli Lilly Australia Pty Ltd Minor submission	Bipolar disorder	Request to update the Caution note linked to this restriction to reflect the updated TGA approved Product Information. The submission sought to amend the current CAUTION note advising to 'Monitor for post-injection syndrome for at least three hours after each injection' to reflect the updated TGA approved Product Information which advises to monitor for at least two hours.	The PBAC agreed to amend the Caution note for consistency with the approved Product Information.
Pazopanib, tablet, 200 mg and 400 mg, Votrient® GlaxoSmithKline Australia Pty Ltd Major submission	Cancer in soft tissue	Re-submission to extend the current Authority required listing to include advanced (unresectable and/or metastatic) soft tissue sarcoma	The PBAC accepted the extension of pazopanib to the recommended Authority required listing to include the initial and continuing treatment of advanced (unresectable and/or metastatic) soft tissue sarcoma in a patient who meets certain criteria. Although the PBAC noted the high ICER of pazopanib, the PBAC accepted the submission in the context of high unmet clinical need in a population that has limited treatment options and the modest overall cost to the Commonwealth
Terbutaline sulfate, turbuhaler, 500 microgram per dose, 100 dose, Bricanyl Turbuhaler® AstraZeneca Pty Ltd Minor submission	Asthma	Request to replace existing 200-dose turbuhaler with a 100-dose turbuhaler.	The PBAC recommended an unrestricted benefit listing of terbutaline sulphate (Bricanyl Turbuhaler®) 500 micrograms per dose, 100 dose pack with a maximum quantity of two packs and 5 repeats to replace the currently PBS listed 200 dose pack at an equal price to the currently listed 200 dose pack.

Teriflunomide, 14 mg tablet, Aubagio® Genzyme (Sanofi-Aventis Pty Ltd) Major submission	Multiple sclerosis	Resubmission for an Authority required listing for the initial and continuing treatment of Relapsing-Remitting Multiple Sclerosis in an ambulatory patient who meets certain criteria	The PBAC recommended teriflunomide 14 mg tablet as an Authority required listing for the initial and continuing treatment of relapsing-remitting multiple sclerosis (RRMS) in ambulatory patients who meet certain criteria on a cost minimisation basis to interferon β-1a and interferon β-1b.
Whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, low in protein, phosphate, potassium and lactose powder, Powder, 400 g can RenaStart® Vitaflo Australia Pty Ltd Minor submission	Medicinal food	Notification of a pack size change and minor amendments to the kilojoule, linoleic acid and alpha linolenic acid contents to Renastart	The PBAC recommended listing RenaStart packaged in a can as an Authority required benefit with a maximum quantity of 4 and 5 repeats, at an equivalent price per gram of powder as RenaStart packaged in sachets, and under the same listing circumstances as RenaStart sachets.