MARCH 2013 PBAC MEETING OUTCOMES – Positive Recommendation

Drug and Form	Drug use and type	Listing requested by sponsor	PBAC Recommendation
AMINO ACID FORMULA with VITAMINS and MINERALS (without various amino acids), 'Cooler'® range of products Vitaflo Australia Pty Ltd Minor Submission	Medicinal foods	1) To amend the brand names of currently PBS-listed Coolers to include the grams of protein; 2) To list additional pack sizes for the MSUD, HCU and TYR Cooler ranges with the same restriction as the currently listed Cooler 15; 3) To inform of minor nutritional amendments across the whole Cooler range, including PKU Cooler 10, 15 and 20.	Recommended
AMINO ACIDS WITH CARBOHYDRATE (various formulations) Vitaflo Australia Pty Ltd Minor Submission	Medicinal foods	To amend the brand names of currently PBS-listed single dose amino acids with carbohydrate to include amino acid doses, and to advise of packaging changes.	Recommended
AMYLOPECTIN MODIFIED LONG CHAIN, oral liquid: powder for, 30 x 60 g sachets, Glycosade® Vitaflo Australia Pty Ltd Minor Submission	Medicinal food	To amend the label to accurately reflect the sodium content.	Recommended
BOTULINUM TOXIN TYPE A, 100 units injection, 1 x 100 units vial, Botox® Allergan Pty Ltd Minor submission	Urinary incontinence	Re-submission for a Section 100 (Botulinum Toxin Program) listing for the treatment of urinary incontinence due to neurogenic detrusor overactivity (NDO) in patients with multiple sclerosis, spinal cord injury or adult spina bifida who meet certain criteria.	The PBAC recommended extending the current Section 100 Botulinum Toxin Program listing for botulinum toxin type A to include the treatment of urinary incontinence due to neurogenic detrusor overactivity in patients with multiple sclerosis, spinal cord injury or adult spina bifida, who meet certain criteria, on the basis of acceptable cost-effectiveness compared to best supportive care.

CORIFOLLITROPIN ALFA, injection, 150 micrograms in 0.5 mL, Elonva® Merck Sharp & Dohme (Australia) Pty Ltd Major Submission	Fertility drug	1) Extend the current Section 100 IVF/GIFT Program listing to include treatment of women who weigh over 90 kg; and 2) Review the therapeutic relativity and price compared to follicle stimulating hormone (FSH).	The PBAC recommended removal of the 90 kg weight restriction in the current Section 100 IVF/GIFT Program listing for corifollitropin. The PBAC rejected the request for a revised therapeutic relativity between corifollitropin and follitropin beta.
COBICISTAT+ELVITEGRAVIR +EMTRICITABINE+ TENOFOVIR, tablet, cobicistat 150 mg, elvitegravir 150 mg, emtricitabine 200 mg, tenofovir 300 mg Stribild®, Gilead Sciences Pty Ltd Major submission	Human immunodeficiency virus (HIV) infection	Section 100 Highly Specialised Drugs Program Private Hospital Authority Required and Public Hospital Authority required (STREAMLINED) listings for treatment of HIV infection in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease.	The PBAC recommended the listing of Stribild on the PBS, on a cost-minimisation basis with Atripla. The PBAC also recommended that a cost-offset be applied to account for increased renal monitoring required in patients using Stribild compared with those using Atripla.
DIAZEPAM, oral solution 10 mg/10mL, Orion Diazepam Elixir 10mg/10mL® Orion Laboratories Pty Ltd Minor Submission	Chronic spasticity	Restricted benefit listing for the treatment of chronic spasticity in children.	The PBAC recommended listing as an Authority Required benefit for treatment of chronic spasticity in patients up to the age of 18 years on the basis of clinical need in the paediatric population.
FERRIC CARBOXYMALTOSE, injection, 100 mg in 2 mL and 500 mg in 10 mL, Ferinject® Vifor Pharma Pty Ltd Major Submission	Anaemia	Authority Required listing for treatment of iron deficiency anaemia, where oral iron preparations are not tolerated, ineffective or otherwise inappropriate.	The PBAC recommended listing as an unrestricted benefit, on a cost-minimisation basis with iron polymaltose, with equi-effective doses based on a 1:1 ratio of iron delivered by the formulations.
FILGRASTIM, 300 µg/0.5 mL & 480 µg/0.5 mL solution for injection in pre-filled syringe, Zarzio® Sandoz Pty Ltd Minor submission	Immunostimulant	Section 100 Highly Specialised Drugs Program Private Hospital Authority Required and Public Hospital Authority required (STREAMLINED) listings for a new brand of filgrastim products biosimilar to currently listed filgrastim pre-filled syringes (Neupogen®).	The PBAC recommended listing under the same listing conditions and price as the currently PBS listed filgrastim products.

GLUCOSE INDICATOR BLOOD, glucose indicator blood strip: diagnostic, 50 diagnostic strips, OneTouch®Select® Johnson & Johnson Medical Pty Ltd Minor Submission	Blood glucose monitoring	To request an unrestricted listing, and a restricted benefit listing for use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements of a new brand of test strips.	Recommended
HIGH FAT FORMULA with VITAMINS, MINERALS and TRACE ELEMENTS and LOW IN PROTEIN and CARBOHYDRATE, oral liquid, powder for, 300 g, Ketocal 3:1 Nutricia Australia Pty Ltd Minor Submission	Medicinal food	Restricted benefit for treatment of an infant or young child up to the age of 6 years (as a sole source of nutrition); or a child over 6 years (as a supplementary feed) with: - intractable seizures requiring treatment with a ketogenic diet - Glucose transporter protein defects (GLUT-1) - Pyruvate Dehydrogenate Deficiency (PDH)	The PBAC recommended listing of KetoCal 3:1 as a restricted benefit with the same restrictions as KetoCal 4:1 formulation.
IVABRADINE, tablet, 5 mg and 7.5 mg (as hydrochloride), Coralan® Servier Laboratories (Australia) Pty Ltd Minor Submission	Heart failure	Re-submission for an Authority Required listing for the treatment of symptomatic systolic chronic heart failure (NYHA classes II or III) in patients in sinus rhythm, with a resting heart rate of at least 77 bpm, measured after 5 minutes rest, who are stabilised on optimal heart failure treatment.	The PBAC recommended listing as an Authority Required benefit for treatment of chronic heart failure in patients who meet certain criteria on a cost-effectiveness basis over placebo. The PBS use of ivabradine should be restricted to patients who are receiving concomitant optimal standard chronic heart failure which must include the maximum tolerated dose of a beta-blocker, unless contraindicated.

LENALIDOMIDE, capsule, 5 mg and 10 mg, Revlimid® Celgene Pty Ltd Major Submission	Myelodysplastic syndrome (MDS)	Re-submission to extend the current Section 100 Highly Specialised Drugs Program Public and Private Hospital Authority Required listings to include treatment of a patient with low or intermediate-1 myelodysplastic syndrome (MDS) with a deletion 5q abnormality who is transfusion dependent.	The PBAC recommended extending the current listing for lenalidomide to include treatment of transfusion-dependent, low risk/INT-1, 5q- myelodysplastic syndrome on the basis of acceptable cost effectiveness compared with best supportive care.
LIRAGLUTIDE, solution for injection, 6 mg per mL, 2 x 3 mL pre-filled pen, Victoza® Novo Nordisk Pharmaceuticals Pty Ltd Major Submission	Diabetes	Re-submission for an Authority Required listing for treatment of type 2 diabetes as: 1) Dual combination therapy with metformin or a sulphonylurea; and 2) Triple combination therapy with metformin and a sulphonylurea.	The PBAC recommended listing as an Authority required (STREAMLINED) benefit for dual combination therapy with metformin or a sulfonylurea, and as triple combination therapy with metformin and a sulfonylurea on a cost minimisation basis with exenatide. The accepted equi-effective doses are liraglutide 1.2 mg once daily and exenatide 10 micrograms twice daily. The PBAC did not accept the sponsor's claimed cost offsets.
MIFEPRISTONE, tablet, 200 mg, Mifepristone Linepharma®; MISOPROSTOL, tablet, 200 microgram, GyMiso® Marie Stopes (MS) Health Major submission	Medical termination of a developing intra-uterine pregnancy	Authority Required listing for use in women of childbearing age for the termination of an intra-uterine pregnancy of up to 49 days gestation.	The PBAC recommended listing of mifepristone and misoprostol for termination of an intra-uterine pregnancy of up to 49 days gestation on the basis of similar effectiveness and lower cost compared with surgical termination of pregnancy.

PANITUMUMAB, concentrated solution for infusion, 20 mg per mL, 5 mL, Vectibix® Amgen Australia Pty Ltd Major Submission	Colorectal cancer	Re-submission for Section 100 Efficient Funding of Chemotherapy Private Hospital Authority Required and Public Hospital Authority required (STREAMLINED) listings for: 1) Treatment, as monotherapy or in combination with FOLFIRI, of a patient with a WHO performance status of 2 or less and with a KRAS wild-type metastatic colorectal cancer after failure of first-line chemotherapy; and 2) Treatment, in combination with FOLFOX, of a patient with a WHO performance status of 2 or less with previously untreated KRAS wild-type metastatic colorectal cancer where treatment with bevacizumab is unsuitable.	The PBAC recommended the listing of panitumumab in the later-line setting in combination with an irinotecan based therapy. Listing was recommended on the basis of the comparison presented against cetuximab, but with the price for panitumumab to be lower than cetuximab's price given the lack of convincing evidence to confirm that panitumumab is non-inferior to cetuximab. The PBAC rejected the request for subsidy for first-line treatment on the basis of inadequate clinical trial data to support listing for the intended population.

PEGINTERFERON ALFA-2A (&) RIBAVIRIN, peginterferon alfa-2a 135 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [168 tablets], 1 pack; peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [112 tablets], 1 pack; peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [140 tablets], 1 pack; peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [168 tablets], 1 pack; Pegasys RBV® Roche Products Pty Ltd Minor Submission	Hepatitis C	Re-submission for Section 100 Private Hospital Authority required and Public Hospital Authority required (STREAMLINED) listings for the same chronic hepatitis C indications as the current Pegasys RBV combination packs.	Recommended.
RALTEGRAVIR, chewable tablet, 25 mg and 100 mg, Isentress® Merck Sharp & Dohme (Australia) Pty Ltd Minor Submission	HIV infection	Section 100 Highly Specialised Drugs Program Private Hospital Authority required and Public Hospital Authority required (STREAMLINED) listing for treatment of HIV-1 infection in adolescents and children from 2 years of age, or weighing at least 10 kg.	The PBAC recommended listing raltegravir chewable tablets under Section 100 Highly Specialised Drugs Program for patients aged 2 years and older, with use to be limited to treatment experienced patients.

REVIEW OF ANTICOAGULATION THERAPIES IN ATRIAL FIBRILLATION	Anticoagulation	To consider updated analyses of the novel oral anti-coagulant drugs, dabigatran, rivaroxaban and apixaban in response to the findings of the Review of Anticoagulation Therapies in Atrial Fibrillation.	The PBAC recommended the PBS listing of rivaroxaban as an Authority Required (Streamlined) benefit for the prevention of stroke in patients with non-valvular atrial fibrillation who meet certain criteria, at the price proposed in the submission on a cost-effectiveness basis in comparison with warfarin for the two outcomes, intracranial bleeding and haemorrhagic stroke, identified by the Review as being of most significance. The PBAC advised that the calculations of the total cost to government should be based on the advice provided by the Drug Utilisation SubCommittee (DUSC) to the PBAC following the DUSC's extraordinary meeting of 6 March 2013. The listing should be subject to a risk sharing arrangement between the sponsor and the government with 100% of expenditure above the agreed estimates to be rebated to the government. The PBAC made a new recommendation for dabigatran which varies its initial recommendation of March 2011: The PBAC recommended the listing of dabigatran on the PBS on a cost-minimisation basis to rivaroxaban for the prevention of stroke in patients with non-valvular atrial fibrillation, with the equi-effective dose based on average doses in the trials, and subject to the same risk-sharing arrangement and PBS restriction. The PBAC recommended the listing of apixaban on the PBS for the prevention of stroke in patients with non-valvular atrial fibrillation on a cost-minimisation basis to rivaroxaban with the equi-effective dose based on doses in the trials, and subject to the same risk-sharing arrangement and PBS restriction.

RISEDRONATE SODIUM, tablet 5 mg, Actonel®, tablet 35 mg (enteric coated), Actonel EC®, tablet 150 mg, Actonel Once-a-Month®; RISEDRONATE SODIUM and CALCIUM CARBONATE, pack containing 4 tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium), Actonel Combi®, pack containing4 enteric coated tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium), Actonel EC Combi®; RISEDRONATE SODIUM and CALCIUM CARBONATE with COLECALCIFEROL, pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms, Actonel EC Combi D® Sanofi-aventis Australia Pty Ltd Major Submission	Osteoporosis	Extend the current Authority required (STREAMLINED) listing to include treatment of a patient aged 70 years of age or older with a BMD T-score less than or equal to -2.5.	The PBAC recommended extending the current listing of risedronate and its combinations for treatment of osteoporosis to include treatment of patients aged 70 years of age or older with a bone mineral density (BMD) T-score less than or equal to -2.5, on a cost-minimisation basis with alendronate monotherapy.

RIVAROXABAN, tablet, 15 mg and 20 mg, Xarelto® Bayer Australia Ltd Major submission	Anticoagulant	Extend the current Authority required (STREAMLINED) listing to include treatment of acute symptomatic pulmonary embolism (PE) and prevention of recurrent venous thromboembolism (VTE).	The PBAC recommended the requested extension to listing on a cost minimisation basis compared with enoxaparin 80 mg twice daily followed by INR adjusted warfarin.
SORAFENIB, tablet, 200 mg, Nexavar® Bayer Australia Limited Minor Submission	Liver cancer	Request to change the current Authority required listing for initial and continuing treatment of hepatocellular carcinoma to an Authority required (STREAMLINED) listing.	Recommended
VINORELBINE, capsule, 20 mg and 30 mg, Navelbine® Pierre Fabre Medicament Minor submission	Breast cancer	Re-submission for an Authority required listing for treatment of advanced breast cancer after failure of standard prior therapy which includes an anthracycline, as a single agent or in combination.	The PBAC recommended listing vinorelbine tablets on the PBS as an Authority Required benefit for treatment of advanced breast cancer (ABC) after failure of standard prior therapy which includes an anthracycline, on the basis of clinical need, at the price offered in the resubmission.