MARCH 2012 PBAC MEETING OUTCOMES – Positive Recommendations

Drug and Form	Drug use and type	Listing requested by sponsor	PBAC Recommendation
Abiraterone, tablet, 250 mg (as acetate), Zytiga® Janssen-Cilag Pty Ltd Minor submission	Metastatic prostate cancer	Authority Required listing for the initial and continuing treatment, in combination with prednisone or prednisolone, of patients with metastatic advanced prostate cancer (castration resistant prostate cancer) in whom disease progression has occurred following treatment with docetaxel.	Recommended on a cost-minimisation basis with cabazitaxel. The PBAC noted that abiraterone has a better safety profile and is more convenient to administer (oral administration) than cabazitaxel.
Aflibercept, solution for intravitreal injection, 40 mg per mL, Eylea® Bayer Australia Ltd Major submission	Age-related macular degeneration	Authority Required listing for initial and continuing treatment by an ophthalmologist, as sole PBS-subsidised therapy, of subfoveal choroidal neovascularisation (CNV) due to age-related macular degeneration (AMD).	Recommended on a cost-minimisation basis with ranibizumab, with one aflibercept 2 mg injection being equivalent to one ranibizumab 0.5 mg injection.
Amino acid – synthetic, formula, compound powder 400 g, Neocate LCP+MCT® Amino acid – synthetic, formula, compound powder 400 g, Neocate Advance Vanilla® Nutricia Australia Pty Ltd Minor submission	Medicinal foods	Authority required listing for initial and continuing treatment by a clinical immunologist, suitably qualified allergist or gastroenterologist in patients 18 years of age or less with eosinophilic oesophagitis who require an amino acid based formula as a component of a dietary elimination program and who meet certain criteria.	Recommended.
Amino acid formula with vitamins and minerals without methionine, oral liquid 125 mL, 30, HCU Lophlex LQ® Nutricia Australia Pty Ltd Minor submission	Medicinal food	Restricted benefit listing for pyridoxine non-responsive homocystinuria.	Recommended.

MARCH 2012 PBAC MEETING OUTCOMES – Positive Recommendations

Drug and Form	Drug use and type	Listing requested by sponsor	PBAC Recommendation
Amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine, oral liquid, 130 mL, 30, MMA/PA Cooler® Vitaflo Australia Pty Ltd Minor submission	Medicinal food	Restricted benefit listing for methylmalonic acidaemia and propionic acidaemia.	Recommended.
Amino acid formula with vitamins and minerals without phenylalanine, oral liquid 125 mL, PKU Lophlex LQ 20® Nutricia Australia Pty Ltd Minor submission	Medicinal food	Request to replace one flavour and add one new flavour to the existing range, and to inform the PBAC of minor nutrient changes in the new flavour products. No change to the current PBS listing is requested.	Recommended.
Amino acid formula with vitamins and minerals without phenylalanine, sachets 34 g, 30, PKU Express 20® Amino acid formula with vitamins and minerals without valine, leucine and isoleucine, sachets 34 g, 30, MSUD Express 20® Vitaflo Australia Pty Ltd Minor submission	Medicinal foods	Restricted benefit listing for phenylketonuria for a new pack size to provide 20 g protein per sachet. Restricted benefit listing for maple syrup urine disease for a new pack size to provide 20 g protein per sachet.	Recommended.

MARCH 2012 PBAC MEETING OUTCOMES – Positive Recommendations

Drug and Form	Drug use and type	Listing requested by sponsor	PBAC Recommendation
Amino acid formula with vitamins and minerals without phenylalanine and tyrosine, oral liquid 125 mL, 30, TYR Lophlex LQ® Nutricia Australia Pty Ltd Minor submission	Medicinal food	Restricted benefit listing for tyrosinaemia.	Recommended.

MARCH 2012 PBAC MEETING OUTCOMES – Positive Recommendations

Drug and Form	Drug use and type	Listing requested by sponsor	PBAC Recommendation
Amino acid formula with vitamins and minerals without phenylalanine, sachets 25 g, 30, PKU Express 15® Amino acid formula with vitamins and minerals without valine, leucine and isoleucine, sachets 25 g, 30, MSUD Express 15® Amino acid formula with vitamins and minerals without phenylalanine and tyrosine, sachets 25 g, 30, TYR Express 15® Amino acid formula with vitamins and minerals without methionine, sachets 25 g, 30, HCU Express 15® Amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine, sachets 25 g, 30, MMA/PA Express 15® Amino acid formula with vitamins and minerals without lysine and low in tryptophan, sachets 25 g, 30, GA Express 15® Vitaflo Australia Pty Ltd Minor submission	Medicinal foods	Request to change the name of the current 'Express' range of amino acid formulae to "XXX Express 15" to denote the amount of protein contained in each sachet. To advise of amendments to the vitamin, mineral and trace element profile of the 'Express' range of products.	Recommended with no changes to the current restrictions.

MARCH 2012 PBAC MEETING OUTCOMES – Positive Recommendations

Drug and Form	Drug use and type	Listing requested by sponsor	PBAC Recommendation
Amino acid formula with vitamins and minerals without valine, leucine and isoleucine, oral liquid 125 mL, 30, MSUD Lophlex LQ® Nutricia Australia Pty Ltd Minor submission	Medicinal food	Restricted benefit listing for maple syrup urine disease.	Recommended.
Apixaban, tablet, 2.5 mg, Eliquis Bristol-Myers Squibb Australia Pty Ltd Minor submission (Out of session)	Anti-thrombotic drug	Requests Authority Required listings of 20- and 30-tablet packs for the prevention of venous thromboembolism in patients undergoing total knee replacement and total hip replacement.	The PBAC recommended the restriction wording for all PBS-listed pack sizes should specify the duration of therapy in order to distinguish between the listings of the different pack sizes.
Apixaban, tablet 2.5 mg, Eliquis® Bristol-Myers Squibb Australia Pty Ltd Minor submission Secretariat listing	Anti-thrombotic drug	Amendment to the restriction wording for the listings for total hip replacement to avoid potential for prescriber confusion with regard to the recommended duration of anti-coagulant treatment.	Recommended.
Auranofin, capsules, 3 mg, Ridaura® BNM Group (incorporating Goldshield Healthcare (Australia) Pty Ltd) Minor submission	Disease modifying anti-rheumatic drug (DMARD)	Unrestricted benefit listing, for supply under s19A of the Therapeutic Goods Act 1989.	The PBAC recommended the temporary listing of auranofin 3 mg capsules as an unrestricted benefit, pending approval by the Therapeutic Goods Administration.

MARCH 2012 PBAC MEETING OUTCOMES – Positive Recommendations

Drug and Form	Drug use and type	Listing requested by sponsor	PBAC Recommendation
Bortezomib, powder for injection 1 mg (solvent required), Velcade® Janssen-Cilag Pty Ltd Major submission	Anti-cancer drug for multiple myeloma.	Extend the current Authority Required listing to include induction therapy in patients with newly diagnosed symptomatic multiple myeloma who are eligible for high dose chemotherapy, as part of combination therapy.	The PBAC recommended listing as a Section 100 (Efficient Funding of Chemotherapy) Public and Private Hospital Authority Required listing for the treatment in combination with chemotherapy, of a patient with newly diagnosed symptomatic multiple myeloma who is eligible for high dose chemotherapy and a primary stem cell transplant on a cost-minimisation basis compared with thalidomide. The equi-effective doses were considered to be bortezomib 1.3 mg/m2 on days 1, 4, 8, and 11 for four 21-day cycles and thalidomide 200 mg daily for three months, based on the trial data which provided the evidence of non-inferiority.
Cabazitaxel, solution concentrate for I.V. infusion, 60 mg in 1.5 mL, Jevtana® Sanofi-Aventis Australia Pty Ltd Minor submission	Metastatic prostate cancer	Authority Required listing for treatment of hormone refractory metastatic carcinoma of the prostate in patients previously treated with a docetaxel containing regimen.	The PBAC recommended a Section 100 (Efficient Funding of Chemotherapy) listing as an Authority Required (Private Hospital/Clinic) and an Authority Requried (STREAMLINED) (Public Hospital) listing on the basis of acceptable cost-effectiveness compared with mitozantrone.
Carbomer and triglyceride lipids, eye gel, 2 mg-10 mg per g (0.2%-1%), 10 g and single dose units 0.6 g, 30, Artelac® Gel Tears Bausch & Lomb (Australia) Pty Ltd Minor submission	Ocular lubricant	1) Restricted benefit listing for the multi-dose presentation in the general and optometrical schedules for severe dry eye syndrome, including Sjogren's syndrome; 2) Authority Required (STREAMLINED) listing and an Authority Required listing in the General and Optometric sections of the Schedule respectively for the unit dose formulation for severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.	Recommended on a cost minimisation basis with the other PBS listed multi-dose and single-dose unit lubricant eye drops.

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Drug and Form	Drug use and type	Listing requested by sponsor	PBAC Recommendation
Dabigatran etexilate, capsules, 75 mg and 110 mg (as mesilate), Pradaxa® Boehringer Ingelheim Pty Ltd	Anti-thrombotic drug	Amend restriction wording to specify the duration of therapy in order to distinguish between the listings of the different pack sizes and to avoid potential for prescriber confusion with regard to the recommended duration of anti-coagulant treatment following total hip replacement.	Recommended.
Denosumab, injection 120 mg in 1.7 mL, Xgeva® Amgen Australia Pty Ltd Minor submission	Bone metastases from prostate cancer	Request to change the restriction wording for the Authority Required listing for bone metastases from hormone resistant cancer to either: Option 1: Bone metastases from castrate-resistant prostate cancer; OR Option 2: Bone metastases from prostate cancer.	The PBAC recommended the current restriction wording for denosumab injection 120 mg in 1.7 mL be amended to "bone metastases from castration-resistant prostate cancer" to reflect the current terminology used in clinical practice and to ensure that the PBS listing remained consistent with the originally intended treatment population.
Denosumab, injection 60 mg in 1 mL pre-filled syringe, Prolia® Amgen Australia Pty Ltd Major submission	Osteoporosis	Change the Authority Required (Streamlined) listing for treatment as the sole PBS subsidised anti-resorptive agent for osteoporosis in a women aged 70 years or older from patients with a Bone Mineral Density (BMD) T-score of -3.0 or less to patients with a BMD T-score of -2.5 or less.	Recommended on a cost-minimisation basis compared with alendronate 70 mg once weekly tablets. The equi-effective doses are based on the recommended doses, denosumab 60 mg once every 6 months and alendronate 70 mg once weekly.
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; injection 50 mg in 1 mL single use auto-injector, Enbrel® Pfizer Australia Pty Ltd Major submission	Chronic plaque psoriasis.	Extend the current Authority Required listing to include the initial and continuing treatment of severe chronic plaque psoriasis in a patient less than 18 years of age who meets certain criteria.	Recommended on the basis of acceptable cost effectiveness compared to placebo in the context of a high clinical need.

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Drug and Form	Drug use and type	Listing requested by sponsor	PBAC Recommendation
Etonogestrel, subcutaneous implant 68 mg, Implanon NXT® Merck Sharp & Dohme (Australia) Pty Ltd Minor submission	Contraception	Request for inclusion in the PBS medicines for prescribing by authorised midwives.	The PBAC recommended that etonogestrel subcutaneous implant is suitable for inclusion in the list of PBS medicines for prescribing by authorised midwives under collaborative arrangements.
Fentanyl, lozenges, 200 micrograms, 400 micrograms, 600 micrograms, 800 micrograms, 1200 micrograms and 1600 micrograms (as citrate), Actiq® Aspen Pharma Pty Ltd Minor submission Secretariat listing	Analgesic	Request for listing of a 9-lozenge pack to replace the current 3-lozenge packs (listed with a maximum quantity of 3 packs of 3 lozenges) for dose titration for breakthrough pain in palliative care patients with cancer. Amend the product description in the listings for initiation and continuing treatment to remove the pack size, and change the maximum quantity accordingly to 9 and 60 lozenges respectively.	Recommended.
Gefitinib, tablet 250 mg, Iressa® AstraZeneca Pty Ltd Minor submission	Lung cancer	Request to: 1. Change the listing for locally advanced or metastatic non-small cell lung cancer in patients with a WHO performance status of 2 or less who meet certain criteria from an Authrotiy Required (applications in writing, specialised drug) to a standard Authority Required listing; and 2. Increase the number of repeats from 1 to 3.	Recommended.

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Drug and Form	Drug use and type	Listing requested by sponsor	PBAC Recommendation
Human menopausal gonadotrophin , powder for injection, 600 units and 1200 units, with solvent Menopur® Ferring Pharmaceuticals Pty Ltd Major submission	Fertility drug	Section 100 (IVF/GIFT Program) listing for a patient who is receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medical Benefits Schedule.	The PBAC recommended a Section 100 (IVF/GIFT Program) listing on a cost minimisation basis with follitropin alfa. The equi-effective doses are hMG 1.01 I.U. and follitropin alfa 1.00 I.U. based on the weighted average dose estimates from the key trials.
Icatibant, injection, 30 mg in 3 mL (as acetate), single use pre-filled syringe, Firazyr® Shire Australia Pty Ltd Minor submission	Hereditary angioedema	Re-submission for an Authority Required listing for the treatment of hereditary angioedema	Recommended on the basis of high but acceptable cost-effectiveness in the context of high clinical need, compared to placebo as proxy for best supportive care, with delayed use of C1-INH concentrate if required.
Mannitol, capsule containing powder for oral inhalation, 40 mg (for use in inhaler device), Bronchitol® Pharmaxis Ltd Minor submission	Cystic Fibrosis	Authority Required listing, as monotherapy, for the treatment of cystic fibrosis in: 1) Patients who fail initiation criteria for dornase alfa; 2) Patients using dornase alfa intermittently; 3) Patients who are using dornase alfa, but are inadequately responsive, and it is considered may improve with mannitol as an alternative to dornase alfa.	The PBAC recommended a Section 100 (Highly Specialised Drugs Program) Public Hospital Authority Required (STREAMLINED) and Private Hospital Authority Required listing of mannitol for the treatment of cystic fibrosis, as the sole PBS subsidised therapy, on a cost-minimisation basis based on a mixed comparator split of dornase alfa and hypertonic saline.
Pazopanib, tablet, 200 mg and 400 mg (as hydrochloride), Votrient® GlaxoSmithKLine Pty Ltd Major submission	Anti-cancer drug	Authority Required listing for the initial and continuing treatment as the sole PBS subsidised tyrosine kinase inhibitor (TKI) therapy of stage IV clear cell variant renal cell carcinoma in a newly diagnosed patient who meets certain criteria.	Recommended on a cost-minimisation basis compared with sunitinib. The PBAC advised that the relevant dose relativity in this context is 1 mg sunitinib to 24 mg pazopanib.

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Drug and Form	Drug use and type	Listing requested by sponsor	PBAC Recommendation
Pregabalin, capsules, 25 mg, 75 mg, 150 mg and 300 mg, Lyrica® Pfizer Australia Pty Ltd Major submission	Neuropathic (nerve) pain	Authority Required (Streamlined) listings for: 1. Initiation and up-titration of treatment for neuropathic pain (75 mg) 2. Initiation of treatment for neuropathic pain in patients requiring a reduced dose due to renal impairment (25 mg) 3. Continuation of treatment in patients who have received a PBS prescription for initiation of treatment and have shown an adequate clinical response (all strengths) 4. Continuation of treatment in patients who had shown clinical response to pregabalin prior to PBS listing (all strengths)	The PBAC recommended an Authority Required (Streamlined) listing of pregabalin (all strengths) for the treatment of refractory neuropathic pain not controlled by other drugs on the basis of acceptable cost-effectiveness compared with placebo in patients dissatisfied with their current pain relief.
Rasagiline, tablet, 1 mg (as mesilate), Azilect® Lundbeck Australia Pty Ltd Major submission	Parkinson Disease	Authority Required (STREAMLINED) listing for Parkinson disease as adjunctive therapy in patients being treated with levodopa-decarboxylase inhibitor combinations who are experiencing fluctuations in motor function due to end-of-dose effect.	The PBAC recommended an Authority Required (STREAMLINED) listing of rasagiline for Parkinson disease on a cost-minimisation basis primarily against selegiline.
Rivaroxaban, tablet, 15 mg and 20 mg, Xarelto® Bayer Australia Ltd Major submission	Anti-thrombotic drug	Authority Required (Streamlined) listing for: 1) Initial treatment of confirmed acute symptomatic deep vein thrombosis (DVT) without symptomatic pulmonary embolism (PE) – 15 mg tablets; and 2) Continuing treatment of confirmed acute symptomatic DVT without symptomatic PE, and for the prevention of recurrent venous thromboembolism (VTE) with appropriate treatment duration of up to two years, dependent on the risk of VTE recurrence – 20 mg tablets.	Recommended on a cost minimisation basis compared with enoxaparin and warfarin.
Rivaroxaban, tablets 10 mg, Xarelto® Bayer Australia Limited Secretariat listing	Anti-thrombotic drug	Amend restriction wording to specify the duration of therapy in order to distinguish between the listings of the different pack sizes and to avoid potential for prescriber confusion with regard to the recommended duration of anti-coagulant treatment.	Recommended.

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Drug and Form	Drug use and type	Listing requested by sponsor	PBAC Recommendation
Tafluprost, eye drops (preservative-free), 15 micrograms per mL (0.0015%), single dose units 0.3 mL, 30, Saflutan® Merck Sharp & Dohme (Australia) Pty Ltd Major submission	Glaucoma	Unrestricted benefit listing on the General and Optometrical Schedules, for the treatment of ocular hypertension and primary open-angle glaucoma.	Recommended.
Teriparatide, injection 250 micrograms per mL, 2.4 mL in multi-dose pre-filled pen, Forteo® Eli Lilly Australia Pty Ltd Minor submission	Osteoporosis	Request to change the current Authority Required listing (applications in writing, specialised drug) to a standard Authority Required listing.	Recommended.
Testosterone, solution for topical administration, 30 mg in 1.5 mL per dose, 60 doses, 110 mL metered-dose pump, Axiron® Eli Lilly Australia Pty Ltd Minor submission	Testosterone replacement therapy	1. Authority Required listing for the treatment of: i) androgen deficiency in males with established pituitary or testicular disorders ii) androgen deficiency in males 40 years and older who do not have established pituitary or testicular disorders other than ageing, and meet certain criteria. iii) micropenis, pubertal induction, or constitutional delay of growth or puberty, in males under 18 years of age;	The PBAC recommended the Authority Required listing of testosterone solution on a cost minimisation basis compared with testosterone gel, following its deferral at the November 2011 PBAC meeting pending TGA approval. The equi-effective doses are considered to be testosterone solution 70 mg and testosterone gel 50 mg.
Triglycerides – medium chain, formula, powder 400 g, LipiStart® Vitaflo Australia Pty Ltd Minor submission	Medicinal food	Restricted benefit listing for chylous ascites, chylothorax, fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders, hyperlipoproteinaemia type 1 and long chain fatty acid oxidation disorders (LCFAODs).	Recommended.