JULY 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	Re-submission to request a review of the March 2012 PBAC recommendation for an 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.	The PBAC recommended listing abiraterone tablets as an Authority Required listing for the treatment, in combination with prednisone or prednisolone, of castration resistant metastatic carcinoma of the prostate in a patient who has failed treatment with docetaxel on a cost-minimisation basis with cabazitaxel and cost-effectiveness basis when compared with best supportive care.
Aprepitant, capsule 165 mg, Emend®, Merck Sharp & Dohme (Australia) Minor Submission	Anti-emetic	Authority Required (STREAMLINED) listing of a higher strength, single dose oral presentation with the same indications as the current PBS listing for the three day dose pack.	The PBAC recommended listing aprepitant capsules as an Authority Required (STREAMLINED) benefit in the General Schedule and in Section 100 (Related Pharmaceutical Benefit, not subject to the revised arrangements for Efficient Funding of Chemotherapy) as a Public Hospital Authority Required (STREAMLINED) listing for the management of nausea and vomiting associated with cytotoxic chemotherapy (moderately emetogenic, highly emetogenic and combination anthracycline/cyclophosphamide regimens for breast cancer) as a single dose oral regimen on a cost-minimisation basis compared with the aprepitant 3 day dose regimen of 1 x 125 mg capsule and 2 x 80 mg capsules.
Atenolol, oral solution, 50 mg in 10 mL, 300 mL, Atenolol-AFT®, AFT Pharmaceuticals Pty Limited Minor Submission	Antihypertensive	Restricted Benefit listing of an oral solution presentation for patients who cannot tolerate atenolol tablets.	The PBAC recommended listing atenolol oral solution, as a Restricted Benefit for patients who are unable to take a solid dose form of atenolol.
Aztreonam, powder for inhalation, 75 mg (as lysine), with diluent, Cayston®, Gilead Sciences Pty Ltd Major Submission	Cystic fibrosis	Re-submission for a Section100 (Highly Specialised Drugs Program) Private Hospital Authority Required and Public Hospital Authority Required (Streamlined) listing for the management of a proven *P. aeruginosa* infection in patients with cystic fibrosis.	The PBAC recommended listing aztreonam as an Authority Required (Streamlined) listing for the management of a proven *Pseudomonas aeruginosa* infection in patients with cystic fibrosis on a cost-minimisation basis compared to tobramycin solution for inhalation.

JULY 2012 PBAC MEETING OUTCOMES – Positive Recommendations

Drug and Form	Drug use and type	Listing requested by sponsor	PBAC Recommendation
Boceprevir, capsule, 200 mg, Victrelis®, Merck Sharp & Dohme Australia Pty Ltd Minor Submission	Hepatitis C	Re-submission for a Section 100 (Highly Specialised Drugs Program) Private Hospital Authority Required and Public Hospital Authority Required (Streamlined) listing for treatment, managed by an accredited treatment centre, of chronic hepatitis C genotype 1 infection in combination with peginterferon alfa and ribavirin in patients 18 years or older who have compensated liver disease and who have received no prior or no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C and who meet certain criteria.	The PBAC recommended listing boceprevir as Section 100 Highly Specialised Drugs Program Private Hospital Authority Required and Public Hospital Authority Required (Streamlined) benefits only for treatment, managed by an accredited treatment centre, of chronic hepatitis C genotype 1 infection in combination with peginterferon alfa and ribavirin in patients 18 years or older who have compensated liver disease and who have received no prior treatment or no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C and who meet certain criteria. Listing was recommended on the basis of acceptable cost effectiveness over peginterferon with ribavirin at the price proposed in the submission and subject to a risk share agreement between the sponsor and the Government with a 100% rebate of the cost of boceprevir above the estimates accepted by the PBAC.
Dabigatran etexilate, capsules, 110 mg and 150 mg (as mesilate), Pradaxa®, Boehringer Ingelheim Pty Ltd Minor Submission	Anti-thrombotic and anti-coagulant	The submission sought to address the matters raised by the PBAC in its advice to the Minister in March 2011 in recommending an extension to the Authority Required listing to include the prevention of stroke or systemic embolism in patients with non-valvular atrial fibrillation (NVAF) who are at moderate to high risk of developing stroke or systemic embolism, who meet certain criteria.	After consideration of the evidence and analyses presented in the submission the PBAC did not change its previous recommendation and advice to the Minister. The PBAC also noted that the Government is undertaking a Review of Anticoagulation Therapies in Atrial Fibrillation.
Denosumab, injection, 120 mg in 1.7 mL, Xgeva®, Amgen Australia Pty Ltd Minor Submission	Bone metastases from prostate cancer or breast cancer	Change the current PBS listing from Authority Required for bone metastases from breast cancer or hormone-resistant prostate cancer to Authority Required (STREAMLINED).	The PBAC recommended an Authority required (Streamlined) listing be applied to the PBS listing of denosumab, injection, 120 mg in 1.7 mL as requested.

JULY 2012 PBAC MEETING OUTCOMES – Positive Recommendations

Drug and Form	Drug use and type	Listing requested by sponsor	PBAC Recommendation
Dorzolamide hydrochloride with Timolol maleate, eye drops 20 mg (base)-5 mg (base) per mL (2%-0.5%), single dose units 0.6 mL, 60, Cosopt® Preservative Free Eye Drops, Merck Sharp & Dohme (Australia) Pty Limited Major Submission	Glaucoma and ocular hypertension	Restricted Benefit listings in the general and optometrical schedules for the reduction of elevated intra-ocular pressure in patients with open-angle glaucoma or ocular hypertension that is not adequately controlled with monotherapy.	The PBAC recommended listing dorzolamide hydrochloride with timolol maleate eye drops, preservative free, on the PBS as Restricted Benefit listings in the General and Optometrical Schedules for the reduction of elevated intra-ocular pressure in patients with open-angle glaucoma or ocular hypertension that is not adequately controlled with monotherapy. Listing should be on a cost minimisation basis with dorzolamide hydrochloride with timolol maleate eye drops (preservative containing). The equi-effective doses are one drop of dorzolamide hydrochloride with timolol maleate eye drops preservative free (PF) twice daily and one drop of dorzolamide hydrochloride with timolol maleate eye drops preservative containing (P) twice daily. The PBAC considered that the listing should not result in any additional cost to the PBS.
Eculizumab, solution concentrate for I.V. infusion, 300 mg in 30 mL, Soliris® Alexion Pharmaceuticals Australasia Pty Ltd Minor Submission	Paroxysmal nocturnal haemoglobinuria	To provide data regarding eculizumab's dosing schedule for patients with paroxysmal nocturnal haemoglobinuria who are experiencing breakthrough haemolysis under the Life Saving Drugs Program.	The PBAC accepted the need for dosing flexibility using criteria accepted by the Expert Advisory Committee and recommended that dose escalation be allowed under current rules. The PBAC considered that the Life Savings Drugs Program is well placed to generate clinical data on alternative doses and/or frequencies, and that the concerned patient group and Paroxysmal Nocturnal Haemoglobinuria Disease Advisory Committee (PDAC) were likely to be supportive of such a trial. The PBAC therefore recommended that the Government commission a clinical trial, independent of the sponsor, to investigate the potential to reduce exposure to eculizumab without the loss of disease control and that the PDAC be tasked with the design and conduct of such a trial. The PBAC also recognised that in addition to achieving reduced drug costs, meningococcal infection might be avoided if some patients move to a 3-weekly dosing regimen.
Ezetimibe with Simvastatin, tablet, 10 mg-10 mg, 10 mg-20 mg, Vytorin® Merck Sharp & Dohme (Australia) Pty Ltd Minor Submission	High cholesterol	Requests extension to the listing of the 10 mg-10 mg and 10 mg-20 mg strengths to include the additional indication of treatment, in conjunction with dietary therapy and exercise, in patients whose cholesterol levels are inadequately controlled with an HMG CoA reductase inhibitor (statin) and who meet certain criteria.	The PBAC recommended the extension of listing as requested in order to remove inequities for those patients whose maximum tolerated dose of simvastatin was 10 mg or 20 mg per day.

JULY 2012 PBAC MEETING OUTCOMES – Positive Recommendations

Drug and Form	Drug use and type	Listing requested by sponsor	PBAC Recommendation
Glycomacropeptide with Vitamins and Minerals GLYCOMACROPEPTIDE with VITAMINS and MINERALS, ready-to-eat bar, 54 g per bar, 81g per bar, 7, Camino Pro® Complete™ with Glytactin™ GLYCOMACROPEPTIDE, oral liquid, 500 mL, 12, Camino Pro® Restore™ with Glytactin™ GLYCOMACROPEPTIDE with VITAMINS and MINERALS, powder, 49 g, 28, Camino Pro® Bettermilk™ with Glytactin™, Cambrooke Australia Pty Ltd Minor Submission	Phenylketonuria	Restricted Benefit listing for phenylketonuria.	The PBAC recommended listing glycomacropeptide with vitamins and minerals, available as ready-to-eat bars, and glycomacropeptide, available as oral liquid, on the PBS as Restricted benefits for treatment of phenylketonuria.
Mycophenolate Sodium, tablet (enteric coated), 180 mg and 360 mg (mycophenolic acid), Myfortic®, Novartis Pharmaceuticals Australia Pty Ltd Major Submission	Lupus nephritis	Re-submission to extend the current Section 100 (Highly Specialised Drugs Program) Private Hospital Authority Required and Public Hospital Authority Required (Streamlined) and general schedule Authority Required listings to include the treatment, initiated by or in consultation with a nephrologist, of patients with biopsy-proven WHO Class III, IV or V lupus nephritis.	The PBAC recommended extending the current General Schedule Authority Required listing to include maintenance treatment, following initiation and stabilisation, of patients with biopsy-proven WHO Class III, IV or V lupus nephritis, where therapy remains under the supervision and direction of a nephrologist reviewing the patient, and extending the Section 100 Highly Specialised Drugs Program Private Hospital Authority Required and Public Hospital Authority Required (Streamlined) listings to include management by or in consultation with a nephrologist, of patients with biopsy-proven WHO Class III, IV or V lupus nephritis. The PBAC recommended mycophenolate sodium on a cost minimisation basis to IV cyclophosphamide in the induction phase and on a cost minimisation basis to azathioprine in the maintenance phase.

Drug and Form	Drug use and type	Listing requested by sponsor	PBAC Recommendation
Olmesartan with Amlodipine, tablet containing olmesartan medoxomil 20 mg with amlodipine 5 mg (as besylate), tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besylate), tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besylate), Sevikar®, Merck Sharp & Dohme (Australia) Pty Ltd Minor Secretariat Listing	Antihypertensive	Requests inclusion of PBS prescribing by nurse practitioners.	Recommended
Omeprazole, capsule, 20 mg, Maxor®, Alphapharm Pty Limited Minor Submission	Gastrointestinal conditions such as peptic ulcer and gastro-oesophageal reflux disease	Requests the addition NOTE of an indicator of equivalence for the purposes of substitution between the Maxor® (omeprazole) 20 mg capsules and Acimax® (omeprazole magnesium) 20 mg tablets.	The PBAC recommended that the note "Pharmaceutical benefits that have the form omeprazole tablet or capsule 20 mg and pharmaceutical benefits that have the form omeprazole tablet 20 mg (as magnesium) are equivalent for the purposes of substitution" be added to the restrictions for omeprazole capsules and tablets 20 mg and omeprazole tablets 20 mg (as magnesium) to allow substitution to occur at the pharmacy.
Paraffin Compound, eye ointment, 5 g, VitA-POS®, AFT Pharmaceuticals Pty Limited Minor Submission	Ocular lubricant	Requests unrestricted benefit listings in the General and Optometric Schedules and a General Schedule Restricted benefit listing for use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.	The PBAC recommended listing paraffin with retinol palmitate eye ointment on the PBS in the General Schedule as an Unrestricted Benefit and a Restricted Benefit for use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements and in the Optometric Schedule as an Unrestricted Benefit at the requested price.
Phenobarbitone, injection, 200 mg (as sodium) in 1 mL, 5, Phenobarbitone Injection®, Aspen Pharma Pty Ltd Minor Secretariat Listing	Epilepsy	To replace the current PBS listed 200 mg in 1 mL strength injection.	The PBAC recommended the listing of phenobarbitone injection 219 mg in 1 mL at the same price as the 200 mg in 1 mL strength.

JULY 2012 PBAC MEETING OUTCOMES – Positive Recommendations

Drug and Form	Drug use and type	Listing requested by sponsor	PBAC Recommendation
Sodium Hyaluronate, eye drops, 1 mg per mL (0.1 %), 10 mL, Hylo®-Fresh, Eye drops, 2 mg per mL (0.2 %), 10 mL, Hylo®-Forte AFT Pharmaceuticals Pty Limited Minor submission	Ocular lubricant	Requests a General Schedule Authority Required (Streamlined) listing for severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops and an Optometric Schedule Authority Required listing for severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.	The PBAC recommended listing sodium hyaluronate eye drops in the General Schedule as Authority Required (Streamlined) benefits and in the Optometric Schedule as Authority Required benefits for the treatment of severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops. The PBAC considered that there should be no additional cost to the PBS with the listing of these eye drops.
Strontium Ranelate, sachet containing granules for oral suspension, 2g, Protos® Servier Laboratories (Aust.) Pty Ltd Major Submission	Osteoporosis	Extend the current Authority Required (Streamlined) listing for primary and secondary osteoporosis to include male patients.	The PBAC recommended extending the PBS listing for strontium to include men aged 70 years of age or older with a Bone Mineral Density (BMD) T-score of -3 or less and men with established osteoporosis with fracture due to minimal trauma on a cost minimisation basis compared with alendronate alone. The equi-effective doses are 2 g strontium daily being equivalent to 70 mg alendronate weekly.

JULY 2012 PBAC MEETING OUTCOMES – Positive Recommendations

Drug and Form	Drug use and type	Listing requested by sponsor	PBAC Recommendation
Telaprevir, tablet, 375 mg, Incivo®, Janssen-Cilag Pty Ltd Minor Submission	Hepatitis C	Section 100 (Highly Specialised Drugs Program) Private Hospital Authority Required and Public Hospital Authority Required (Streamlined) listing for the treatment, in combination with peginterferon-alfa and ribavirin and managed by an accredited treatment centre, of chronic hepatitis C genotype 1 infection in patients 18 years or older who have compensated liver disease and who meet certain criteria.	The PBAC recommended the listing of telaprevir as Section 100 Highly Specialised Drugs Program Private Hospital Authority Required and Public Hospital Authority Required (STREAMLINED) benefits only for treatment, managed by an accredited treatment centre, of chronic hepatitis C genotype 1 infection in combination with peginterferon alfa and ribavirin in patients 18 years or older who have compensated liver disease and who have received no prior or no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C and who meet certain criteria. Listing was recommended on the basis of acceptable cost effectiveness over peginterferon with ribavirin, however not at the price proposed in the submission, nor the price proposed in the Pre-PBAC Response. The PBAC recommended that the price of a course of treatment with telaprevir in combination with peginterferon alfa and ribavirin (telaprevir/PR) should be the same as the price for a course of treatment of boceprevir in combination with peginterferon and ribavirin (boceprevir/PR). The PBAC considered that there was no basis on which to recommend a higher price for telaprevir/PR over boceprevir/PR; that is, there was no basis on which to make a cost effectiveness recommendation for telaprevir/PR over boceprevir/PR. The recommendation was subject to a risk share agreement between the sponsor and the Government with a 100% rebate of the cost of telaprevir above the estimates accepted by the PBAC.
Trastuzumab, powder for I.V infusion, 60 mg and 150 mg, Herceptin®, Roche Products Pty Limited Major Submission	Breast cancer	Extend the current Section 100 Efficient Funding of Chemotherapy (Public Hospital or Private Hospital/Clinic) listing to include: 1. Initial and continuing treatment of human epidermal growth factor receptor-2 (HER2) positive early breast cancer commencing concurrently with neoadjuvant chemotherapy; and 2. Initial and continuing treatment of HER2 positive locally advanced breast cancer commencing concurrently with neoadjuvant chemotherapy.	The PBAC recommended listing trastuzumab for neoadjuvant therapy in patients with HER2 positive locally advanced breast cancer on the PBS on the basis that this would likely at least maintain the current overall effectiveness, cost-effectiveness and total financial implications to government of trastuzumab compared to the status quo. The PBAC noted that some patients receiving a 52-week course of PBS-subsidised trastuzumab started in the neoadjuvant setting would subsequently become eligible for trastuzumab through the Herceptin Program.

JULY 2012 PBAC MEETING OUTCOMES – Positive Recommendations

Drug and Form	Drug use and type	Listing requested by sponsor	PBAC Recommendation
Ustekinumab (rmc), injection, 45 mg in 0.5 mL pre-filled syringe, Stelara®, Janssen-Cilag Pty Ltd Minor Submission	Psoriasis	Requests listing of a pre-filled syringe presentation to replace the currently PBS listed single use vial presentation at the same price.	The PBAC recommended listing ustekinumab injection, as an Authority Required Benefit for initial and continuing treatment of severe chronic plaque psoriasis in patients who meet certain criteria on a cost minimisation basis with ustekinumab 45 mg in 0.5 mL glass vial for injection.
Zoledronic Acid, solution for I.V infusion, 4 mg in 100 mL, Zometa®, Novartis Pharmaceuticals Australia Pty Ltd Minor Submission	Bone metastases from prostate cancer or breast cancer, multiple myeloma, hypercalcaemia of malignancy	Section 100 (Highly Specialised Drugs Program) listing of a ready-to-use 4 mg in 100 mL presentation with the same indications as the current PBS listing for the 4 mg in 5 mL liquid concentrate for infusion at the same price.	The PBAC recommended listing zoledronic acid 4 mg in 100 mL, ready-to-use solution for I.V infusion on the PBS as a Section 100 Public Hospital Authority Required (Streamlined) and Private Hospital Authority Required benefit on a cost-minimisation basis with the zoledronic acid 4 mg in 5 mL liquid injection concentrate for infusion for the same indications (multiple myeloma; bone metastases from breast cancer; bone metastases from castration resistant prostate cancer and treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy).