MARCH 2011 PBAC MEETING OUTCOMES – Positive Recommendations

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC RECOMMENDATION
Azacitidine, powder for injection, 100 mg, Vidaza® Celgene Pty Ltd Minor submission (out-of-session)	Myelodysplastic syndrome	To ratify the Secretariat proposed maximum quantity and repeats for the Section 100 (Highly Specialised Drug) Streamlined Authority listing for Public hospitals and the Authority Required listing for Private hospitals.	The PBAC recommended a maximum quantity of 14 vials which would allow daily dosing of 75 mg/m^2 for a patient up to 2.2 m^2 (165 mg) and a repeat of 2 for initial PBS subsidised treatment and 5 for continuing PBS subsidised treatment.
bDMARD Restrictions for Rheumatoid Arthritis: Abatacept, powder for infusion 250 mg, Orencia®, Bristol-Myers Squibb Pharmaceuticals Pty Ltd Adalimumab, injection, 40 mg in 0.8 mL, pre-filled syringe and pre-filled pen, Humira®, Abbott Australasia Pty Ltd Certolizumab pegol, injection, 200 mg in 1 mL, single use pre-filled syringe, Cimzia®, UCB Australia Pty Ltd Etanercept, powder for injection, 25 mg (with pre-filled solvent syringe 1 mL), injection, 50 mg in 1 mL single use pre-filled syringe and single use pre-filled auto-injection, Enbrel®, Wyeth Australia Pty Limited Golimumab, injection, 50 mg in 0.5 mL, pre-filled syringe and single use pre-filled pen, Simponi®, Schering-Plough Pty Ltd	Rheumatoid arthritis	To ratify the change proposed by the PBAC Chair that both the full 6-month trial of DMARD therapy immediately prior to an initial application for bDMARD therapy **and** the time-period that patients can cease therapy with a bDMARD before being required to requalify for treatment under the Initial 1 treatment restriction both be set at **2 years** for consistency.	The PBAC agreed that both the full 6-month trial of DMARD therapy immediately prior to an initial application for bDMARD therapy and the time-period that patients can cease therapy with a bDMARD before being required to requalify for treatment under the Initial 1 treatment restriction be set at 2 years for consistency.

Infliximab, powder for I.V. infusion, 100 mg, Remicade®, Schering-Plough Pty Ltd Rituximab, solution for I.V. infusion, 500 mg in 50 mL, Mabthera®, Roche Products Pty Ltd Tocilizumab, solution for I.V. infusion, 80 mg in 4 mL, 200 mg in 10 mL and 400 mg in 20 mL, Actemra®, Roche Products Pty Ltd Minor submission (out-of-session)			
Buprenorphine with naloxone, soluble film (sublingual), 2 mg (as hydrochloride) - 0.5 mg (as hydrochloride), 8 mg (as hydrochloride) - 2 mg (as hydrochloride), Suboxone® Reckitt Benckiser (Australia) Pty Ltd Minor submission	Opiate Dependence	Requests the same Section 100 (Opiate Dependence Treatment Program) Restricted benefit listing as the sublingual tablets for the new sublingual soluble film form.	The PBAC recommended listing on a cost-minimisation basis compared with the currently listed sublingual tablets.
Calcium folinate, injection, (equivalent to 1000 mg folinic acid in 100 mL), Calcium Folinate Ebewe® Interpharma Pty Ltd Minor submission (out-of-session)	Used in chemotherapy protocols	Unrestricted benefit listing of an additional higher strength of an existing product.	The PBAC recommended listing on a cost-minimisation basis compared with calcium folinate 100 mg in 10 mL.
Capecitabine, tablets, 150 mg and 500 mg, Xeloda® Roche Products Pty Ltd Major submission	Anti–cancer drug	Change the current Authority Required restriction for the adjuvant treatment of stage III (Dukes C) colon cancer following complete resection of the primary tumour to include 'either as monotherapy or in combination with oxaliplatin' or remain unchanged.	The PBAC recommended the listing of capecitabine in combination with oxaliplatin (XELOX) on the PBS for the adjuvant treatment of stage III (Dukes C) colon cancer on a cost-minimisation basis compared with modified FOLFOX-6.

		Change the wording of the current restriction for oxaliplatin adjuvant treatment to "adjuvant treatment of stage III (Dukes C) colon cancer, in combination with a fluoropyrimidine agent" instead of in combination with 5 – fluorouracil and folinic acid.	
Dabigatran etexilate, capsules, 110 mg and 150 mg (as mesilate), Pradaxa® Boehringer Ingelheim Pty Ltd Major submission	Anti-thrombotic and anti-coagulant	Extend the current Authority Required listing to include the prevention of stroke or systemic embolism in patients with non-valvular atrial fibrillation who are at moderate to high risk of developing stroke or systemic embolism, who meet certain criteria. The submission requests an Authority Required (STREAMLINED) listing for this indication.	The PBAC recommended an Authority required (STREAMLINED) listing of dabigatran 150 mg and an extension to the listing of dabigatran 110 mg on the basis of acceptable cost effectiveness.
Dalteparin sodium, injection, 2,500 units (anti-Xa) in 0.2 mL, 5,000 units (anti-Xa) in 0.2 mL, 12,500 units (anti-Xa) in 0.5 mL, single dose pre-filled syringe, Fragmin® Pfizer Australia Pty Ltd Minor submission	Anti-coagulant	Requests maximum quantities of the 2,500 and 5,000 strengths be increased from 10 to 20 with Nil repeats. Unrestricted benefit listing for a new 12,500 strength.	Recommended. The PBAC recommended listing on a cost-minimisation basis compared with the currently listed dalteparin injections.
Desmopressin acetate, wafer, 240 micrograms (base), Minirin® Melt Ferring Pharmaceuticals Pty Ltd Minor submission (out-of-session)	Nocturnal enuresis	Authority Required (STREAMLINED) listing of a higher strength desmopressin wafer under the same listings conditions.	Recommended.
Docetaxel, solution concentrate for I.V. infusion, 140 mg in 7 mL, Oncotaxel® Generic Health Pty Ltd	Anti-cancer drug	New presentation (anhydrous concentrate only currently listed) and a new higher strength of docetaxel under the same listing conditions as the	Recommended.

Minor submission (out-of-session)		currently listed products.	
Docetaxel, concentrate injection, 160 mg in 16 mL, DBL Docetaxel® Hospira Pty Ltd Minor submission (out-of-session)	Anti-cancer drug	New presentation (anhydrous concentrate only currently listed) and a new higher strength of docetaxel under the same listing conditions as the currently listed products.	Recommended.
Donepezil hydrochloride, tablets (disintegrating), 5 mg and 10 mg, Aricept- D® Pfizer Australia Pty Ltd Minor submission (out-of-session)	Alzheimer disease	Authority required listing for an oral disintegrating tablet under the same listing conditions as the currently listed tablets.	The PBAC recommended listing on a cost-minimisation basis compared with the PBS listed 5 mg and 10 mg tablets.
Eltrombopag, tablets, 25 mg and 50 mg (as olamine), Revolade® GlaxoSmithKline Australia Pty Ltd Minor submission	Idiopathic thrombocytopenia purpura (ITP) – a bleeding disorder	Resubmission for a Section 100 (Highly Specialised Drugs Program) Public and Private hospital authority required listing for severe thrombocytopenia in adult patients with severe chronic immune (idiopathic) thrombocytopenic purpua (ITP) meeting certain criteria.	The PBAC recommended listing on the basis of acceptable cost effectiveness compared with romiplostim (less effective and less expensive), restricted to the same population as romiplostim.
Enoxaparin, injection, 80 mg (8,000 i.u. anti-Xa) in 0.8 mL, 100 mg (10,000 i.u. anti-Xa) in 1 mL, pre-filled syringe, Enoxaparin® Sanofi-Aventis Australia Pty Ltd Minor submission	Anti-coagulant	Restricted benefit listing of the 80 mg and 100 mg strengths for haemodialysis.	The PBAC recommended listing on the basis of clinical need.
Ezetimibe, tablet, 10 mg, Ezetrol® Ezetimibe with simvastatin, tablet, 10 mg-10 mg and 10 mg-20 mg, Vytorin®, Merck Sharp & Dohme (Australia) Pty Ltd Minor submission	High cholesterol levels	Requests a change to the restriction wording recommended at the November 2010 PBAC meeting to allow treatment of a patient with inadequate control after at least 3 months of treatment with 40 mg or greater of a statin, or at a maximum tolerated dose of a statin.	The PBAC re-affirmed that the amended restriction wording of the definition of inadequate control with a statin to “at a maximum tolerated dose of a statin” as recommended at the November 2010 meeting remains appropriate. The PBAC recommended that the restriction

			wording for ezetimibe (and ezetimibe with simvastatin), for the restriction with streamlined authority code 2669 (and 3194) be amended to remove the daily dose statement of "to a dose of 20 mg or less per day as follows: Authority Required (STREAMLINED) Patients eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs) where treatment with an HMG CoA reductase inhibitor (statin) must be discontinued or reduced ~~to a dose of 20 mg or less per day,~~ because the patient developed a clinically important product-related adverse event during treatment with a statin.
Fentanyl, transdermal patch, 1.28 mg (releasing approximately 12 micrograms per hour),1.28 mg (releasing approximately 12.5 micrograms per hour), 2.55 mg (releasing approximately 25 micrograms per hour), 5.10 mg (releasing approximately 50 micrograms per hour), 7.65 mg (releasing approximately 75 micrograms per hour),10.20 mg (releasing approximately 100 micrograms per hour), Denpax® Alphapharm Pty Ltd Minor submission	Severe pain	Restricted Benefit listing of a different brand of fentanyl patch which releases the same amount of fentanyl per hour but has a different amount of drug in the reservoir compared with the originator brand (Durogesic®)	The PBAC recommended listing on a cost-minimisation basis compared with Durogesic® brand of fentanyl patches.
Ferrous fumarate, tablet, 200mg, , (equivalent to 65.7mg elemental iron), Ferro-Tab® AFT Pharmaceuticals Pty Ltd	Iron supplement	Unrestricted benefit listing as an additional option for the treatment of anaemia.	The PBAC recommended listing as an additional option for the treatment of anaemia.

Minor submission			
Fingolimod, capsule, 0.5 mg (as hydrochloride), Gilenya® Novartis Pharmaceuticals Australia Pty Ltd Major submission	Multiple sclerosis	Authority Required listing for the initial and continuing treatment of clinically relapsing-remitting multiple sclerosis (RRMS) in an ambulatory patient who has experienced at least two documented attacks of neurological dysfunction, believed to be due to multiple sclerosis in the preceding two years who meets certain criteria.	After a revised offer from the sponsor, the PBAC recommended out-of-session listing on the basis of an acceptable cost-effectiveness ratio compared with interferon beta-1a.
Fluorouracil, injection, 2500 mg in 50 mL, Fluorouracil Ebewe® Interpharma Pty Ltd Minor submission (secretariat listing)	Anti-cancer drug	Unrestricted listing of a higher strength of fluorouracil.	The PBAC recommended listing on a cost-minimisation basis compared with the 1000 mg in 20 mL presentation.
Fluorouracil, injection, 5000 mg in 100 mL, Fluorouracil Ebewe® Interpharma Pty Ltd Minor submission (out-of-session)	Anti-cancer drug	Unrestricted listing of a higher strength of fluorouracil.	The PBAC recommended listing on a cost-minimisation basis compared with the 1000 mg in 20 mL presentation.
Fosaprepitant, powder for I.V. infusion, 150 mg, (as dimeglumine), Emend IV® Merck Sharp and Dohme Pty Ltd Minor submission	Anti-emetic	Authority required (STREAMLINED) listing for management of nausea and vomiting associated with cytotoxic chemotherapy (moderately emetogenic, highly emetogenic and combination anthracycline/cyclophosphamide regimens for breast cancer).	The PBAC recommended an Authority Required listing on a cost-minimisation basis compared with aprepitant, pack containing 1 capsule 125 mg and 2 capsules 80mg. The PBAC considered that 5 repeats was appropriate which would allow up to 6 cycles of chemotherapy to be administered per script of fosaprepitant. The PBAC recommended that 5 repeats should also be allowed for aprepitant.
Imatinib, tablet, 100mg and 400 mg, (as mesylate), Glivec® Novartis Pharmaceuticals Australia Pty	Anti-cancer drug	Resubmission for an Authority Required listing for the adjuvant treatment of an adult patient at high risk of recurrence following complete	The PBAC recommended listing on the basis of an acceptable cost-effectiveness ratio compared with placebo.

Ltd Minor submission		resection of primary gastrointestinal stromal tumour which has been histologically confirmed by the detection of CD117 on immunohistochemical staining, at a dose not exceeding 400 mg/day for a period of 12 months.	
Interferon beta-1a, injection, 44 micrograms (12,000,000 i.u) in 0.5mL, single dose auto-injector, RebiDose® Merck Serono Australia Pty Ltd Minor submission (out-of-session)	Multiple Sclerosis	Authority Required listing of a new presentation of a pre-filled syringe, each pre-assembled in a disposable RebiDose autoinjector and ready for use.	The PBAC recommended the listing of a new form of injector for interferon beta-1a on a cost-minimisation basis with the 44 micrograms in 0.5 mL single dose pre-filled syringe under the current listing conditions.
Lacosamide, oral solution 15 mg per mL, 200 mL, Vimpat® UCB Australia Pty Ltd Minor submission (secretariat listing)	Epilepsy	<u>Authority Required</u> Treatment, initiated by a neurologist, in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs in a patient aged 16 years or older with intractable epilepsy. A patient must have trialled and failed to achieve satisfactory seizure control with: (i) at least one first-line anti-epileptic agent; and (ii) at least two second-line adjunctive anti-epileptic agents; Continuing treatment, in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, of partial epileptic seizures in a patient aged 16 years or older, who has previously been treated	The PBAC recommended the listing of a 200 mL oral solution on a cost-minimisation basis compared with lacosamide tablets.

		with PBS-subsidised lacosamide. Note Continuing Therapy Only: For prescribing by nurse practitioner as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.	
Methylprednisolone, powder for injection, 40 mg and 1 g (as sodium succinate), Methylpred® Aspen Pharmacare Australia Pty Ltd Minor submission (secretariat listing)	Anti-inflammatory	Unrestricted benefit	The PBAC recommended the listing of a new presentation of methyprednisolone powder for injection (without diluent) on a cost-minimisation basis compared with methylprednisolone powder for injection with diluent.
Pegfilgrastim, injection 6 mg in 0.6 mL, single use pre-filled syringe, Neulasta® Filgrastim, injection, 300 micrograms in 0.5 mL and 480 micrograms in 1.6 mL; 300 micrograms in 0.5ml and 480 micrograms in 0.5 mL, single use pre-filled syringe, Neupogen® Amgen Australia Pty Ltd Filgrastim, injection, 120 micrograms in 0.2 mL single use pre-filled syringe, 300 micrograms in 0.5 mL single use pre-filled syringe, 480 micrograms in 0.5 mL single use pre-filled syringe, Nivestim® Hospira Australia Pty Ltd	Bone marrow cell stimulator	Requests to extend the current Section 100 (HSD) Authority required listing to include primary prophylaxis of febrile neutropenia in Hodgkin Disease patients treated with escalated BEACOPP chemotherapy.	The PBAC recommended listing on the basis of clinical need and acceptable cost-effectiveness. The PBAC also recommended that any new PBS eligible patient population should flow on to filgrastim, as reaffirmed by the PBAC at the July 2008 meeting (allowing flexibility in treatment options for chemotherapy induced neutropenia).

Minor submission			
Phenoxymethylpenicillin, powder for oral liquid, 125 mg per 5 mL and 250 mg per 5 mL (as potassium salt), 100 mL, Phenoxymethylpenicillin-AFT® AFT Pharmaceuticals Pty Ltd Minor submission (secretariat listing)	Antibiotic	Unrestricted benefit <u>Dental Listing</u> Unrestricted benefit	The PBAC recommended the listing of two new strengths of phenoxymethylpenicillin on a cost-minimisation basis compared with phenoxymethylpenicillin 150 mg (as benzathine) per 5 mL, 100 mL.
Risedronate sodium**,** tablet, 35 mg (enteric coated), Actonel EC® Risedronate sodium and Calcium carbonate, pack containing 4 tablets risedronate sodium 35 mg (enteric coated) and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium), Actonel EC Combi® Risedronate sodium with Calcium carbonate and Colecalciferol, pack containing 4 tablets risedronate sodium 35 mg (enteric coated) 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 Minor submission (out-of-session)	Osteoporosis	Authority Required (STREAMLINED) listing of a new enteric coated formulation under the same listing conditions as risedronate 35 mg tablet products.	The PBAC recommended the listing on a cost-minimisation basis with the PBS listed products containing risedronate sodium 35 mg and under the current listing conditions.
Risperidone, powder for I.M. injection, 25 mg, 37.5 mg and 50 mg (modified release), with 2 mL diluent in pre-filled syringe, Risperdal	Bipolar disorder	Extend the current Authority Required (STREAMLINED) listing to include maintenance treatment, in combination with a mood stabiliser, of treatment	The PBAC recommended listing on a cost-minimisation basis with oral olanzapine. The PBAC agreed that the restriction should specify use in combination with lithium or

Consta® Janssen – Cilag Pty Ltd Major submission		refractory bipolar 1 disorder.	sodium valproate for consistency with the TGA approved indication and that the requested listing for treatment of treatment refractory disease, without further qualification, was appropriate.
Rosiglitazone, tablet 4mg and 8mg (as maleate), Avandia®; ROSIGLITAZONE with METFORMIN, tablet, 2 mg rosiglitazone (as maleate) with 500 mg metformin hydrochloride, 2 mg rosiglitazone (as maleate) with 1 g metformin hydrochloride, 4 mg rosiglitazone (as maleate) with 500 mg metformin hydrochloride, 4 mg rosiglitazone (as maleate) with 1 g metformin hydrochloride, Avandamet®, GlaxoSmithKline Australia Pty Ltd	Diabetes	Response from sponsor regarding PBAC's decision to change the current Authority Required (STREAMLINED) listing to Authority Required.	The PBAC considered that the listing should be changed to an Authority Required and that this would highlight that there was still concern regarding the side effects and safety of rosiglitazone and that it should not be prescribed without due consideration of the risk versus the benefit.
Sirolimus, tablet, 0.5 mg, Rapamune® Wyeth Australia Pty Ltd Minor submission (out-of-session)	Immunosuppressant	<u>Section 100 - Private Hospital Authority Required</u> <u>Section 100 - Public Hospital Authority Required (Streamlined)</u> Caution: Careful monitoring of patients is mandatory Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required. <u>Section 85 – General Schedule</u> Caution: Careful monitoring of patients is mandatory. <u>Authority Required</u> Maintenance therapy, following	The PBAC recommended listing of a new lower strength of sirolimus on a cost-minimisation basis compared with sirolimus 1 mg tablets.

		initiation and stabilisation of treatment with sirolimus and where therapy remains under the supervision and direction of the transplant unit reviewing that patient, of patients with renal transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application.	
Somatropin, injection, 10 mg (30 i.u), vial with diluent in single use syringe (with preservative), Zomacton® Ferring Pharmaceuticals Pty Ltd Minor submission (out-of-session)	Growth hormone deficiency	Section 100 (Human Growth Hormone) Restricted Benefit listing of a new higher strength of somatropin for the treatment of short stature in accordance with the "Guidelines for the Availability of Human Growth Hormone (hGH) as a Pharmaceutical Benefit".	Recommended
Telmisartan with amlodipine, tablets, 40 mg–5 mg, 40 mg–10 mg, 80 mg–5 mg and 80 mg–10 mg (as besylate), Twynsta® Boehringer Ingelheim Pty Ltd Major submission	Antihypertensive	Restricted Benefit listing for the treatment of hypertension in a patient who is not adequately controlled with either of the drugs in the combination.	The PBAC recommended listing, in accordance with the Combination Product Guidelines, on a cost-minimisation basis compared with the corresponding strengths of the constituent components, telmisartan and amlodipine, given concomitantly.
Tobramycin, nebuliser solution single dose units, 300 mg in 5 mL, 56, Tobi® Novartis Pharmaceuticals Australia Pty Ltd Major submission	Inhaled antibiotic for the treatment of lung infections in patients with cystic fibrosis	Resubmission seeking a Section 100 listing for treatment of a patient with cystic fibrosis and pulmonary infection with Pseudomonas aeruginosa initiated by a specialist physician or paediatrician in consultation with a cystic fibrosis clinic/centre and who met certain criteria.	The PBAC recommended the listing of tobramycin solution for inhalation (TSI) on the PBS with an Authority Required (STREAMLINED) listing for the management of proven Pseudomonas aeruginosa infection in a patient with cystic fibrosis on the basis of acceptable cost effectiveness compared with placebo.
Varenicline, box containing 11 tablets 0.5 mg (as tartrate) and 14 tablets 1 mg (as tartrate) in the first pack and 28 tablets	Smoking Cessation	Requests to amend the NOTE of the current restriction to allow re-treatment 6 months from the commencement of a	The PBAC reiterated its intention that only one course of varenicline of up to 24 weeks of continuous therapy should be subsidised

1 mg (as tartrate) in the second pack; tablet, Champix® Pfizer Australia Pty Ltd Minor submission		course of varenicline with another course of PBS-subsidised smoking cessation treatment.	under the PBS per year, and recommended that a NOTE stipulating this be re-instated in the restriction.
Zonisamide, capsule, 25 mg, 50 mg, 100 mg, Zonegran® Eisai Australia Pty Ltd Dutasteride, capsule 500 micrograms, Avodart®, GlaxoSmithKline Australia Pty Ltd Pancreatic extract, granules (enteric coated) providing not less than 5,000 BP units of lipase activity per 100 mg, 20 g, Creon Micro®, Abbott Products Pty Ltd Minor submission	Epilepsy Benign Prostatic Hyperplasia Cystic Fibrosis	Seeks PBAC advice on suitability for inclusion in the PBS medicines for prescribing by nurse practitioners.	Recommended for prescribing by nurse practitioners within collaborative arrangements as continuing therapy only (NP-CTO).