**JULY 2011 PBAC MEETING OUTCOMES – Positive Recommendations**

| DRUG AND FORM | DRUG USE AND TYPE | LISTING REQUESTED BY SPONSOR | PBAC RECOMMENDATION |
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| ABATACEPT, injections 125 mg in 1 mL single use pre-filled syringes, 4, Orencia®<br><br>Bristol-Myers Squibb Australia Pty Ltd<br><br>Minor submission | Rheumatoid arthritis | Authority Required listing for a subcutaneous form for the treatment of adult rheumatoid arthritis. | The PBAC recommended an Authority Required listing for the treatment of severe active rheumatoid arthritis in adults who meet certain criteria on a cost minimisation basis to etanercept 50 mg weekly, with the price taking into account the intravenous (IV) loading dose of abatacept. The equi-effective doses are abatacept 125 mg in 1 mL subcutaneously (SC) weekly plus for patients not previously treated with IV abatacept, a weight based IV loading dose given on day one, and etanercept 50 mg subcutaneously weekly. |

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| ALENDRONATE SODIUM, tablet equivalent to 70 mg alendronic acid, Fosamax Once Weekly®;<br><br>ALENDRONATE SODIUM with COLECALCIFEROL, tablet equivalent to 70 mg alendronic acid with 70 micrograms colecalciferol, Fosamax Plus®;<br><br>ALENDRONATE SODIUM with COLECALCIFEROL tablet equivalent to 70 mg alendronic acid with 140 micrograms colecalciferol, Fosamax Plus 70 mg/140 mcg®;<br><br>ALENDRONATE SODIUM with COLECALCIFEROL and CALCIUM CARBONATE, pack containing 4 tablets containing the equivalent of 70 mg alendronic acid with 140 micrograms colecalciferol and 48 tablets calcium carbonate 1.25 g (equivalent to 500 mg elemental calcium), Fosamax Plus D-Cal®<br><br>Merck Sharp & Dohme (Australia) Pty Ltd<br><br>Major submission | Osteoporosis | Resubmission to extend the current Authority Required (STREAMLINED) listing to include treatment of osteoporosis in patients aged 70 years or older with a bone mineral density (BMD) T-score of -2.5 or less. | The PBAC recommended listing on the basis of acceptable cost effectiveness and safety compared to placebo. |

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| ANTI-DEMENTIA DRUGS:<br><br>DONEPEZIL HYDROCHLORIDE, tablets, 5 mg and 10 mg, Aricept®, tablets (disintegrating), 5 mg and 10 mg, Aricept- D®,Pfizer Australia Pty Ltd<br><br>GALANTAMINE HYDROBROMIDE, capsule, 8 mg (base), 16 mg (base) and 24 mg (base), (prolonged release), Reminyl®, Janssen-Cilag Pty Ltd; Galantyl®, Alphapharm Pty Ltd<br><br>RIVASTIGMINE, transdermal patch, 9 mg (releasing approximately 4.6 mg per 24 hours) and 18 mg (releasing approximately 9.5 mg per 24 hours), Exelon Patch®, Novartis Pharmaceuticals Pty Ltd<br><br>RIVASTIGMINE HYDROGEN TARTRATE, capsules 1.5 mg (base), 3 mg (base), 4.5 mg (base), and 6 mg (base); oral solution 2 mg (base) per mL, 120 mL, Exelon®, Novartis Pharmaceuticals Pty Ltd<br><br>MEMANTINE HYDROCHLORIDE, tablet, 10 mg, Ebixa®, Lundbeck Australia Pty Ltd, APO-Memantine®, Apotex Pty Ltd; tablet 20 mg, Ebixa®, Lundbeck Australia Pty Ltd, Memanxa®, Aspen Pharma Pty Ltd | Alzheimer disease | To ratify the proposed change by the PBAC to allow diagnosis to be made in consultation with a specialist/consultant physician in view of delays experienced in some remote areas for appointments to be made with such specialists. | Recommended. |

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| APIXABAN, tablet, 2.5 mg, Eliquis®<br><br>Bristol-Myers Squibb Australia Pty Ltd<br><br>Major submission | Anti-thrombotic drug | Authority required listing for prevention of venous thromboembolism in a patient undergoing total knee replacement (TKR) or total hip replacement (THR). | The PBAC recommended listing on a cost minimisation basis compared with rivaroxaban. The equi-effective doses are apixaban 2.5mg twice daily over 10-14 days for TKR and over 30-35 days for THR and rivaroxaban 10mg daily over 10-14 days for TKR and over 30-35 days for THR. |
| ASENAPINE, sublingual wafer, 5 mg, 10 mg (as maleate), Saphris®<br><br>Lundbeck Australia Pty Ltd<br><br>Major submission | Anti-psychotic drug | Authority required (STREAMLINED) listing for treatment of bipolar I disorder. | The PBAC recommended listing for treatment, for up to 6 months, of an episode of acute mania or mixed episodes associated with bipolar I disorder (as monotherapy or in combination with lithium or sodium valproate) and as monotherapy for maintenance treatment of bipolar I disorder on a cost-minimisation basis with quetiapine. The equi-effective doses are asenapine 16.3 mg and quetiapine 556.9 mg in the monotherapy setting and asenapine 13.4 mg and quetiapine 506.7 mg in the adjunctive setting. |
| ASENAPINE, sublingual wafer, 5 mg, 10 mg (as maleate), Saphris®<br><br>Lundbeck Australia Pty Ltd<br><br>Major submission | Anti-psychotic drug | Authority required (STREAMLINED) listing for treatment of schizophrenia. | The PBAC recommended listing on a cost-minimisation basis with risperidone. The equi-effective doses are asenapine 8.3 mg daily and risperidone 5.3 mg daily. |

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| BORTEZOMIB, powder for injection 1 mg (solvent required), Velcade®<br><br>Janssen-Cilag Pty Ltd<br><br>Minor submission | Multiple myeloma | Requests an extension to the current Authority required listing to include treatment of a patient with newly diagnosed symptomatic multiple myeloma who has severe acute renal failure who meets certain criteria. | The PBAC reiterated its recommendation to list bortezomib for initial treatment of multiple myeloma in newly diagnosed patients with symptomatic multiple myeloma who have severe acute renal failure on the basis of acceptable cost-effectiveness in patients with a high clinical need and in whom the currently available treatment (thalidomide) may exacerbate renal failure. Patients must require dialysis or be at high risk of requiring dialysis in the opinion of a nephrologist. |
| CHORIOGONADOTROPIN ALFA (rch), solution for injection 250 micrograms in 0.5 mL pre-filled pen, Ovidrel®<br><br>Merck Serono Australia Pty Ltd<br><br>Minor submission (out-of-session) | Fertility drug | Requests a Section 100 (IVF/GIFT Treatment Program) listing of a new presentation of an existing strength. | Recommended at the same price as the currently listed pre-filled syringe presentation. |
| CLOPIDOGREL, tablet 75 mg (free base), Clopidogrel-DRLA®<br><br>Dr Reddy's Laboratories (Australia) Pty Ltd<br><br>Minor submission (out-of-session) | Anti-platelet drug | Request for listing for a free-base form of clopidogrel. | The PBAC recommended listing for prevention of recurrence of ischaemic stroke and transient cerebral ischaemic events and prevention of recurrence of myocardial infarction or unstable angina in patients with a history of symptomatic ischaemic events while on low-dose aspirin, patients where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding, and patients where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates or NSAIDs, on a cost-minimisation basis with the currently listed clopidogrel products. |

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| CLOSTRIDIUM BOTULINUM type A toxin-haemagglutinin complex, lyophilised powder for I.M. injection, 300 units per vial, 500 units per vial, Dysport®<br><br>Ipsen Pty Ltd<br><br>Major submission | Facial muscle spasm | 1) Extend the current Section 100 (Botulinum Toxin Program) listing for treatment of blepharospasm and hemifacial spasm in adults.<br><br>2) List a new 300 units per vial strength presentation of Dysport. | The PBAC recommended extending the listing to include treatment of blepharospasm or hemifacial spasm in adults on a cost-minimisation basis with botulinum toxin type A (Botox®) with 4 Ipsen units of Dysport being equivalent to 1 unit of Botox.<br><br>The PBAC recommended listing of a new vial size (300 units) for the same indications for which the 500 unit vial is listed. |
| CORIFOLLITROPIN ALFA(rch), solution for injection, 100 micrograms in 0.5 mL pre-filled syringe, 150 micrograms in 0.5 mL pre-filled syringe, Elonva®<br><br>Merck Sharp & Dohme (Australia) Pty Ltd (as Schering-Plough Pty Ltd)<br><br>Major submission | Fertility drug | Resubmission for a Section 100 (IVF/GIFT Program) listing for patients who are receiving medical treatment as described in items 13200, 13201 or 13202 of the Medicare Benefits Schedule. | The PBAC recommended listing on a cost minimisation basis compared to follitropin beta. The equi-effective doses based on the key trials ENGAGE and ENSURE are corifollitropin alfa 150 micrograms as a single dose over seven days and follitropin beta 200 IU as daily doses over seven days for patients weighing greater than 60 kg; and corifollitropin alfa 100 micrograms as a single dose over seven days and follitropin beta 150 IU as daily doses over seven days for patients weighing 60 kg or less. |
| DARUNAVIR, tablet 400 mg and 600 mg (as ethanolate), Prezista®<br><br>Janssen-Cilag Pty Ltd<br><br>Minor submission | HIV infection | Section 100 (Highly Specialised Drugs Program) Authority required listing of two higher strengths for treatment of HIV infection. | The PBAC recommended listing darunavir 600 mg on the basis of bioequivalence with 2 x 300 mg tablets and at the same price as 2 x darunavir 300 mg tablets.<br><br>The PBAC also recommended listing of darunavir 400 mg on the basis that darunavir 800 mg with ritonavir 100 mg daily is non-inferior to darunavir 600 mg with ritonavir 100 mg twice daily in patients with no demonstrated darunavir resistance associated mutations. |

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| DASATINIB, tablet, 20 mg, 50 mg, 70 mg, 100 mg, Sprycel®<br><br>Bristol-Myers Squibb Australia Pty Ltd<br><br>Major submission | Chronic myeloid leukaemia | Extend the current Authority required listing to include treatment of newly diagnosed patients in the chronic phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, BCR-ABL tyrosine kinase, and who have a primary diagnosis of chronic myeloid leukaemia. | The PBAC recommended listing on a cost-minimisation basis compared with imatinib 400 mg. The equi-effective doses are dasatinib 93.88 mg and imatinib 395.77 mg based on the average doses from Study 056. |
| DENOSUMAB, injection, 120 mg in 1 mL, Xgeva®<br><br>Amgen Australia Pty Ltd<br><br>Major submission | Bone metastases | Authority required (STREAMLINED) listing for treatment of bone metastases from breast cancer and hormone resistant prostate cancer. | The PBAC recommended the listing as an Authority Required benefit on the basis of acceptable cost-effectiveness compared with zoledronic acid 4 mg in 5 mL injection concentrate for I.V. infusion. |
| DOCETAXEL, injection set containing 1 single use vial powder for I.V. infusion, 20 mg (anhydrous) and 80 mg (anhydrous), with solvent, Docetaxel SUN®<br><br>Sun Pharmaceutical Industries Pty Ltd<br><br>Minor submission (out-of-session) | Anti-cancer drug | Authority required listing of a new presentation of docetaxel under the same conditions as the currently listed products. | The PBAC recommended listing under the same conditions as the currently listed products, for those indications for which TGA approval has been granted. |
| ETRAVIRINE, tablet 200 mg, Intelence®<br><br>Janssen-Cilag Pty Ltd<br><br>Minor submission (out-of-session) | HIV infection | Section 100 (Highly Specialised Drugs Program) Authority required listing of a higher strength for treatment of HIV infection, at an equivalent price to existing listings. | Recommended at an equivalent price to the current listing for the 100 mg strength on a mg to mg basis. |

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| FENTANYL, lozenges, 200 micrograms, 400 micrograms, 600 micrograms, 800 micrograms, 1200 micrograms and 1600 micrograms (as citrate), Actiq®<br><br>Aspen Pharma Pty Ltd<br><br>Minor submission (out-of-session) | Analgesic for use in palliative care | Requests listing of an additional pack size of 30 lozenges. | Recommended for continuing supply for breakthrough pain for palliative care patients. |
| GLUCOSE INDICATOR – BLOOD, test strips, 100, Contour Link®<br><br>Bayer HealthCare<br><br>Minor submission (out-of-session) | Blood glucose monitoring | Requests listing of a new brand under the same conditions as existing listed brands. | Recommended. |
| GLUCOSE INDICATOR – BLOOD, test strips, 50, True Balance®<br><br>Nipro Australia Pty Ltd<br><br>Minor submission (out-of-session) | Blood glucose monitoring | Requests listing of a new brand under the same conditions as existing listed brands. | Recommended. |
| GLUCOSE INDICATOR – BLOOD, test strips, 50, True Result®<br><br>Nipro Australia Pty Ltd<br><br>Minor submission (out-of-session) | Blood glucose monitoring | Requests listing of a new brand under the same conditions as existing listed brands. | Recommended. |

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| HEPATITIS B ANTIVIRALS<br><br>ADEFOVIR DIPIVOXIL, tablet 10 mg, Hepsera®, Gilead Sciences Pty Ltd;<br><br>ENTECAVIR MONOHYDRATE, tablet 0.5 mg, 1 mg, Baraclude®, Bristol-Myers Squibb Pharmaceuticals A Division of Bristol-Myers Squibb Australia Pty Ltd;<br><br>INTERFERON ALFA-2a, injection 3,000,000 i.u. in 0.5 mL single dose pre-filled syringe, injection 4,500,000 i.u. in 0.5 mL single dose pre-filled syringe, injection 6,000,000 i.u. in 0.5 mL single dose pre-filled syringe, injection 9,000,000 i.u. in 0.5 mL single dose pre-filled syringe, Roferon-A®, Roche Products Pty Ltd;<br><br>INTERFERON ALFA-2b, solution for injection 18,000,000 i.u. in 1.2 mL multi-dose injection pen, solution for injection 30,000,000 i.u. in 1.2 mL multi-dose injection pen, solution for injection 60,000,000 i.u. in 1.2 mL multi-dose injection pen, Intron A Redipen®, solution for injection 18,000,000 i.u. in 3 mL single dose vial, solution for injection 25,000,000 i.u. in 2.5 mL single dose vial, solution for injection 10,000,000 i.u. in 1 mL single dose vial, Intron A®, Merck Sharp & Dohme (Australia) Pty Ltd;<br><br>LAMIVUDINE, tablet 100 mg, oral solution 5 mg per mL, 240 mL, Zeffix®, GlaxoSmithKline Australia Pty Ltd; | Hepatitis B infection | Review of proposed changes to restrictions. | The PBAC recommended that for treatment naïve patients the evidence of chronic liver injury should be determined by confirmed elevated serum ALT (without specifying a specific threshold) or by liver biopsy, and that the specific thresholds for HBV DNA recommended at the March 2011 PBAC meeting be applied to the restrictions. |

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| PEGINTERFERON ALFA-2a, Injection 135 micrograms in 0.5 mL single use pre-filled syringe, injection 180 micrograms in 0.5 mL single use pre-filled syringe, Pegasys®, Roche Products Pty Ltd;<br><br>TELBIVUDINE, tablet 600 mg, Sebivo®, Novartis Pharmaceuticals Australia Pty Ltd;<br><br>TENOFOVIR, tablet containing tenofovir disoproxil fumarate 300 mg, Viread®, Gilead Sciences Pty Ltd. | | | |
| INDACATEROL, capsule containing powder for oral inhalation, 150 microgram and 300 microgram (as maleate), Onbrez®<br><br>Novartis Pharmaceuticals Australia Pty Ltd<br><br>Major submission | Chronic obstructive pulmonary disease (COPD) | Resubmission for a Restricted Benefit listing for long-term maintenance treatment of bronchospasm and dyspnoea associated with chronic obstructive pulmonary disease. | The PBAC recommended listing on a cost-minimisation basis compared with fluticasone in combination with salmeterol. The equi-effective doses were considered to be indacaterol 150 micrograms daily , fluticasone with salmeterol 250/25 micrograms, 2 puffs twice daily and tiotropium 18 micrograms daily. |
| MAGNESIUM, tablet 37.4 mg (as aspartate dihydrate), MagMin®<br><br>Blackmores Ltd<br><br>Minor submission | Magnesium supplement | Restricted benefit for patients with chronic renal failure to treat hypomagnesaemia. | The PBAC recommended listing as an Authority Required benefit for the treatment of hypomagnesaemia and for chronic renal disease in Aboriginal and Torres Strait Islander persons on the basis of a clinical need in this patient population and acceptable cost effectiveness. |
| MAGNESIUM, tablet 37.4 mg (as aspartate dihydrate), Mag-Sup®<br><br>Petrus Pharmaceuticals Pty Ltd | Magnesium supplement | Restricted benefit listing for patients with documented hypomagnesaemia | The PBAC recommended listing as an Authority Required benefit for the treatment of hypomagnesaemia and for chronic renal disease in Aboriginal and Torres Strait |

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| Minor submission | | | Islander persons on the basis of a clinical need in this patient population and acceptable cost effectiveness. |
| MESALAZINE, suppository 1 g, Pentasa®<br><br>Ferring Pharmaceuticals Pty Ltd<br><br>Minor submission (out-of-session) | Anti-inflammatory for bowel disease | Request to change the pack size from 28 to 30. | Recommended. |
| MOMETASONE FUROATE, powder for oral inhalation, 200 micrograms per dose and 400 micrograms per dose, Asmanex® Twisthaler®<br><br>Merck Sharp & Dohme (Australia) Pty Ltd<br><br>Minor submission | Asthma | Request to reinstate the June 2002 recommendation for an unrestricted benefit listing. | The PBAC recommended the listing as an unrestricted benefit, intended for use in the management of asthma, on a cost-minimisation basis compared with fluticasone. The equi-effective doses are mometasone furoate 200 micrograms daily and fluticasone propionate 250 micrograms daily, and mometasone furoate 400 micrograms daily and fluticasone propionate 500 micrograms daily. |
| NILOTINIB, capsule, 150 mg (as hydrochloride), Tasigna®<br><br>Novartis Pharmaceuticals Australia Pty Ltd<br><br>Major submission | Chronic myeloid leukaemia | Extend the current Authority required listing to include treatment of newly diagnosed patients in the chronic phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase, and who have a primary diagnosis of chronic myeloid leukaemia. | The PBAC recommended listing on a cost-minimisation basis compared with imatinib 400 mg. The PBAC considered that the equi-effective doses are nilotinib 553.9 mg and imatinib 423 mg. |
| PRAMIPEXOLE, tablet, 2.25 mg and 3.75 mg (extended release), Sifrol ER®<br><br>Boehringer-Ingelheim Pty Ltd<br><br>Minor submission | Parkinson disease | Restricted benefit listing of two additional strengths for treatment of Parkinson disease. | The PBAC recommended listing on a cost-minimisation basis against the sum of the corresponding strengths of the existing extended release tablets (i.e. for the 2.25 mg strength, the corresponding strengths are the 1.5 mg and 0.75 mg extended release |

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| | | | tablets, for the 3.75 mg strength, the corresponding strengths are the 3 mg and 0.75 mg extended release tablets). |
| RIBAVIRIN and PEGINTERFERON ALFA-2b, pack containing 84 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 50 micrograms with diluent; pack containing 84 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 80 micrograms with diluent; pack containing 84 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 100 micrograms with diluent; pack containing 84 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 120 micrograms with diluent; pack containing 112 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 50 micrograms with diluent; pack containing 112 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 100 micrograms with diluent, Pegatron®<br><br>Merck Sharp & Dohme (Australia) Pty Ltd (as Schering-Plough Pty Ltd)<br><br>Major submission | Hepatitis C infection | Extend the current Section 100 (Highly Specialised Drugs) listing to include treatment of chronic hepatitis C in children and adolescents with a bodyweight of greater than or equal to 27 kg with compensated liver disease and who have not received previous interferon treatment. | The PBAC recommended extending the listing to patients under the age of 18 years who have not received previous interferon treatment on the basis of acceptable cost effectiveness compared with standard of care, in the context of a high clinical need. |

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| SOMATROPIN (Recombinant human growth hormone), solution for injection, 5 mg (15 i.u.) in 1.5 mL cartridge (with preservative), 10 mg (30 i.u.) in 1.5 mL cartridge (with preservative), 15 mg (45 i.u.) in 1.5 mL cartridge (with preservative), Norditropin® FlexPro®<br><br>Novo Nordisk Pharmaceuticals Pty Ltd<br><br>Minor submission | Growth hormone | Requests listing of a new formulation. | Recommended. |
| TICAGRELOR, tablet, 90mg, Brilinta®<br><br>AstraZeneca Pty Ltd<br><br>Major submission | Acute coronary syndrome | Authority Required (STREAMLINED) listing for treatment of acute coronary syndromes (myocardial infarction or unstable angina) in combination with aspirin. | The PBAC recommended listing on the basis of acceptable cost-effectiveness compared with clopidogrel in combination with aspirin. |
| WHEY PROTEIN FORMULA supplemented with AMINO ACIDS, VITAMINS and MINERALS, and low in PROTEIN, PHOSPHATE, POTASSIUM and LACTOSE, powder 400 g, Kindergen®<br><br>Nutricia Australia Pty Ltd<br><br>Minor submission | Medicinal food | Request formulation changes comprising of minor alterations to iodine, vitamin C, inositol and pantothenic acid, and a change to the declaration of niacin equivalence. | Recommended. |
| ZOLEDRONIC ACID, solution for I.V. infusion 5 mg (as monohydrate) in 100 mL, Aclasta®<br><br>Novartis Pharmaceuticals Australia Pty Ltd<br><br>Minor submission | Osteoporosis | Request change to listing to remove the 3-year treatment limit for patients with osteoporosis. | The PBAC recommended extending the listing of zoledronic acid for osteoporosis by removal of the life-time limit of one treatment each year for three years from each of the osteoporosis indications. The PBAC noted that the TGA has extended the registration of zoledronic acid for osteoporosis to remove all time limits relating to the duration of |

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