

**NOVEMBER 2009 PBAC MEETING OUTCOMES – Positive Recommendations**

<b>DRUG AND FORM</b>	<b>DRUG USE AND TYPE</b>	<b>LISTING REQUESTED BY SPONSOR</b>	<b>PBAC RECCOMENDATION</b>
<p>Albendazole, tablet, 200 mg, Zentel<sup>®</sup></p> <p>GlaxoSmithkline Australia Pty Ltd</p> <p>Minor submission</p>	<p>Worm infection</p>	<p>Extend the current Authority Required (STREAMLINED) listing to include treatment of hookworm infection in a refugee or humanitarian entrant or an Aboriginal or a Torres Strait Islander person, and treatment of intestinal Strongyloidiasis in a refugee or humanitarian entrant or an Aboriginal or a Torres Strait Islander person less than 12 years of age.</p>	<p>The PBAC recommended an Authority Required (Streamlined) listing for strongyloidiasis, and treatment of hookworm infestation on the grounds of clinical need in these patient populations.</p>
<p>Alendronate sodium with colecalciferol and calcium, pack containing 4 tablets equivalent to 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<sup>®</sup></p> <p>Merck Sharp &amp; Dohme (Australia) Pty Ltd</p> <p>Minor submission</p>	<p>Osteoporosis</p>	<p>Authority Required (STREAMLINED) listing for the treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a patient aged 70 years of age or older with a Bone Mineral Density (BMD) T-score of -3.0 or less.</p> <p>Authority Required (STREAMLINED) for the treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma.</p>	<p>Recommended for listing on a cost-minimisation basis with alendronate 70 mg with colecalciferol 140 micrograms (Fosamax Plus 70 mg/ 140 micrograms<sup>®</sup>)</p>
<p>Amino acid formula with fat, carbohydrate with vitamins and minerals, and trace elements, without methionine and supplemented with docosahexanoic acid, oral liquid, 125 mL, HCU Anamix Junior LQ<sup>®</sup></p> <p>Nutricia Australia Pty Ltd</p> <p>Minor submission</p>	<p>Medicinal food</p>	<p>Restricted Benefit listing for pyridoxine non-responsive homocystinuria.</p>	<p>Recommended for listing at the same cost per gram of protein as currently listed products for this condition.</p>

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<p>Amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine and tyrosine, and supplemented with docosahexanoic acid, oral liquid, 125 mL, TYR Anamix Junior LQ<sup>®</sup></p> <p>Nutricia Australia Pty Ltd</p> <p>Minor submission</p>	<p>Medicinal food</p>	<p>Restricted Benefit listing for tyrosinaemia</p>	<p>Recommended for listing at the same cost per gram of protein as currently listed products for this condition.</p>
<p>Amino acid formula with vitamins and minerals without lysine and low in tryptophan, infant formula, powder 400 g, XLYS, LOW TRY Analog<sup>®</sup></p> <p>Amino acid formula with vitamins and minerals without methionine, infant formula, powder 400 g, XMET Analog<sup>®</sup></p> <p>Amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine, infant formula, powder 400 g, XMTVI Analog<sup>®</sup></p> <p>Amino acid formula with vitamins and minerals without phenylalanine and tyrosine, infant formula, powder 400 g, XPhen Tyr Analog<sup>®</sup></p> <p>Amino acid formula with vitamins and minerals without valine, leucine and isoleucine, infant formula, powder 400 g, MSUD</p>	<p>Medicinal food.</p>	<p>(1) Formulation change to include long chain polyunsaturated fatty acids and prebiotic oligosaccharides.</p> <p>(2) Brand name change.</p>	<p>The PBAC had no objections to the proposed formulation and name changes:</p> <ul style="list-style-type: none"> <li>○ XP Analog LCP to PKU Anamix Infant</li> <li>○ MSUD Analog to MSUD Anamix Infant</li> <li>○ XMTVI Analog to MMA/PA Anamix Infant</li> <li>○ XPHEN TYR Analog to TYR Anamix Infant</li> <li>○ XMET Analog to HCU Anamix Infant</li> <li>○ XLYS LOW TRY Analog to GA1 Anamix Infant</li> </ul>

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<p>Analog<sup>®</sup></p> <p>Amino acid formula with vitamins, minerals and long chain polyunsaturated fatty acids without phenylalanine, infant formula, powder 400 g, XP Analog LCP<sup>®</sup></p> <p>Nutricia Australia Pty Ltd</p> <p>Minor submission</p>			
<p>Amino acid, synthetic formula supplemented with long chain polyunsaturated fatty acids, compound powder 400 g, EleCare LCP<sup>®</sup></p> <p>Abbott Australasia Pty Ltd</p> <p>Minor submission</p>	Medicinal food	<p>Authority Required listing for initial and continuing treatment for combined intolerance (not infant colic) to cows' milk protein, soy protein and protein hydrolysate formulae, severe intolerance (not infant colic) to cows' milk protein, and severe intestinal malabsorption including short bowel syndrome, in patients who meet certain criteria.</p>	<p>Recommended on a cost-minimisation basis with Neocate LCP<sup>®</sup> (amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids).</p>
<p>Bicalutamide, tablet 50 mg, Cosudex<sup>®</sup></p> <p>Goserelin acetate, subcutaneous implant (long acting) 10.8 mg (base), in pre-filled injection syringe, Zoladex 10.8 Implant<sup>®</sup></p> <p>Goserelin acetate and bicalutamide, packs containing 1 subcutaneous implant goserelin 3.6 mg, and 10.8 mg in pre-filled injection syringe and 28 tablets bicalutamide 50 mg, ZolaCos CP</p>	Anti-cancer drug	<p>Request Authority Required (Streamlined) listings for bicalutamide, goserelin acetate 10.8 mg, and the combination products containing bicalutamide and goserelin acetate.</p>	<p>The PBAC recommended the change as requested for these products listed for treatment of carcinoma of the prostate.</p>

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<p>3.6/50<sup>®</sup>, ZolaCos CP 10.8/50(28)<sup>®</sup> and pack containing 1 subcutaneous implant goserelin 10.8 mg in pre-filled injection syringe and 84 tablets bicalutamide 50 mg, ZolaCos CP 10.8/50 (84)<sup>®</sup>.</p> <p>AstraZeneca Pty Ltd</p> <p>Minor submission</p>			
<p>Candesartan cilexetil with hydrochlorothiazide, tablets, 32 mg-12.5 mg and 32 mg-25mg, Atacand Plus 32/12.5<sup>®</sup>, Atacand Plus 32/25<sup>®</sup></p> <p>AstraZeneca Pty Ltd</p> <p>Minor submission</p>	Anti-hypertensive	Restricted Benefit listing for 2 new strengths for treatment of hypertension in patients who are not adequately controlled with candesartan monotherapy.	Recommended for listing on a cost-minimisation basis compared with the corresponding strengths of the individual components for the treatment of hypertension in patients who are not adequately controlled with monotherapy.
<p>Clopidogrel with aspirin, tablet, 75 mg-100 mg, CoPlavix<sup>®</sup>, Sanofi-Aventis Australia Pty Ltd and DuoCover<sup>®</sup>, Bristol-Myers Squibb</p> <p>Minor submission</p>	Anti-platelet drug	Extension of the recommended indications to include treatment following cardiac stent insertion.	The PBAC recommended consequential amendments to the recommended restrictions following recent recommendations (November 2008) for clopidogrel.
<p>Clopidogrel, tablet, 75 mg (base), Plavix<sup>®</sup>, Sanofi-Aventis Australia Pty Ltd, Iscover<sup>®</sup>, Bristol Myers Squibb Pharmaceuticals</p> <p>Clopidogrel with aspirin, tablet, 75 mg-100 mg, CoPlavix<sup>®</sup>, Sanofi-Aventis Australia Pty Ltd and</p>	Anti-platelet drug	Removal of the words 'to prevent early and long-term atherothrombotic events' from the current PBS restrictions for use in acute coronary syndromes to be consistent with the restriction wording for prasugrel, which was recommended for listing at the July 2009 PBAC meeting.	Recommended

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<p>DuoCover<sup>®</sup>, Bristol Myers Squibb Pharmaceuticals</p> <p>Minor submission</p>			
<p>Dabigatran etexilate mesylate, capsules, 75 mg (base) and 110 mg (base), Pradaxa<sup>®</sup></p> <p>Boehringer-Ingelheim Pty Ltd</p> <p>Major submission</p>	<p>Anti-thrombotic drug</p>	<p>Authority Required listing for prevention of venous thromboembolic events in patients undergoing total hip replacement (THR) surgery and total knee replacement (TKR) surgery.</p>	<p>Recommended for listing on a cost-minimisation basis with enoxaparin, where the equi-effective doses are dabigatran 220 mg and enoxaparin 40 mg.</p>
<p>Darunavir, tablets, 150 mg and 300 mg (as ethanolate), Prezista<sup>®</sup></p> <p>Janssen-Cilag Pty Ltd</p> <p>Major submission</p>	<p>Anti-HIV drug</p>	<p>Replace the current Section 100 (Highly Specialised Drugs Program) listing with: Treatment, in combination with other antiretroviral agents, and co-administered with 100 mg ritonavir twice daily, of HIV infection in antiretroviral experienced patients with</p> <p>(a) evidence of HIV replication (viral load greater than 10,000 copies per mL); and/or</p> <p>(b) CD4 cell counts of less than 500 per cubic millimetre.</p> <p>A patient must have failed previous treatment with, or have resistance to, 1 antiretroviral regimen.</p>	<p>The PBAC recommended listing on a cost-minimisation basis with lopinavir with ritonavir (Kaletra<sup>®</sup>). The equi-effective doses are darunavir 600 mg twice daily in combination with ritonavir 100 mg twice daily and lopinavir 400 mg with ritonavir 100 mg twice daily.</p> <p>The PBAC had previously also recommended out-of-session the listing of a new strength of darunavir, a 150 mg tablet.</p>
<p>Docetaxel, injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL and 1 single use vial solvent 1.5 mL and injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL and 1 single</p>	<p>Anti-cancer drug</p>	<p>Extend the current Authority Required listing to include adjuvant treatment of operable breast cancer in combination with cyclophosphamide.</p>	<p>The PBAC recommended listing on the basis of an uncertain but acceptable cost-effectiveness ratio compared with the chemotherapy regimen doxorubicin with cyclophosphamide.</p>

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use vial solvent 6 mL, Taxotere <sup>®</sup> Sanofi-Aventis Australia Pty Ltd. Major submission			
Dutasteride, capsule, 0.5 mg, Avodart <sup>®</sup> GlaxoSmithkline Australia Pty Ltd Minor submission	Benign prostatic hyperplasia	Authority Required (STREAMLINED) listing for the treatment, in combination with an alpha-antagonist, of lower urinary tract symptoms due to benign prostatic hyperplasia where treatment has been initiated by a urologist.	Recommended for listing as requested on the basis of an acceptable cost-effectiveness ratio compared with alpha-antagonist alone.
Essential amino acid formula, powder, 200 g, Essential Amino Acid Mix <sup>®</sup> Nutricia Australia Pty Ltd Minor submission	Medicinal food	Restricted Benefit listing for gyrate atrophy of the choroid and retina; and urea cycle disorders.	Recommended for listing at the same price per gram of protein as Dialamine <sup>®</sup> (essential amino acids formula with minerals and vitamin C)
Everolimus, tablet, 1 mg, Certican <sup>®</sup> Novartis Pharmaceuticals Australia Pty Ltd Minor submission	Transplant-rejection drug	Section 100 (Highly Specialised Drugs Program) and Section 85 Authority Required listings of a new strength of everolimus for the management of renal or cardiac rejection.	Recommended

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<p>Fentanyl, transdermal patches, 2.063 mg (releasing approximately 12 micrograms per hour), Fenpatch 12<sup>®</sup>; 4.125 mg (releasing approximately 25 micrograms per hour), Fenpatch 25<sup>®</sup>; 8.25 mg (releasing approximately 50 micrograms per hour), Fenpatch 50<sup>®</sup>; 12.375 mg (releasing approximately 75 micrograms per hour), Fenpatch 75<sup>®</sup> and 16.5 mg (releasing approximately 100 micrograms per hour), Fenpatch 100<sup>®</sup></p> <p>Spirit Pharmaceuticals Pty Ltd</p> <p>Minor submission</p>	<p>Opioid analgesic</p>	<p>Request for listing of an additional brand of fentanyl transdermal patches.</p>	<p>The PBAC recommended listing out-of-session noting that bioequivalence has been demonstrated between the respective strengths of Fenpatch and Durogesic<sup>®</sup> patches (eg Fenpatch 25 and Durogesic 25) but that a separate listing was required due to minor differences in formulation.</p>
<p>Ganirelix, solution for injection, 250 micrograms in 0.5 mL (as acetate), single use pre-filled syringe, single use pre-filled syringe and 5 pre-filled syringes, Orgalutran<sup>®</sup></p> <p>Schering-Plough Pty Ltd</p> <p>Major submission</p>	<p>Fertility drug</p>	<p>Section 100 (IVF/GIFT Treatment Program) listing for prevention of premature luteinisation and ovulation in patients undergoing controlled ovarian stimulation, followed by oocyte pick-up and assisted reproductive techniques.</p>	<p>The PBAC considered there is a clinical need for such products on the IVF/GIFT Treatment Program and recommended listing as requested at the same price per IVF cycle as a 2-month course of nafarelin for endometriosis.</p>
<p>Gefitinib, tablet 250 mg, Iressa<sup>®</sup></p> <p>AstraZeneca Pty Ltd</p> <p>Minor submission</p>	<p>Anti-cancer drug</p>	<p>Requests a change to the current restriction wording so that the specific method used to detect mutations in the EGFR gene is not specified, and therefore newer technologies are not excluded</p>	<p>Recommended.</p>

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Glucose indicator – blood, electrode strips, 50, Accu-Chek Mobile®  Roche Diagnostics Australia Pty Ltd.  Minor submission	Monitor blood glucose	Restricted Benefit listing for diabetic patients on insulin therapy only.	The PBAC recommended a restricted benefit listing as requested at the same price as currently listed products, and to reduce potential wastage associated with use by type 2 diabetes on oral treatment only.
Glucose indicator – blood, electrode strips, 50, Bionime Rightest®  CS Pharma Australia Pty Ltd  Minor submission	Monitor blood glucose	Unrestricted benefit	Recommended
Glucose indicator - blood, electrode strips, Clever Chek TD-3250®, Clever Chek TD-3217® & TD4227®  DTS Diagnostic & Technical Services Pty Ltd  Minor submission	Monitor blood glucose	Unrestricted benefit	Recommended
Glucose indicator – blood, electrode strips, LifeLine Attest®  Boian Surgical Pty Ltd  Minor submission	Monitor blood glucose	Unrestricted benefit	Recommended
Goserelin acetate, subcutaneous implant 3.6 mg (base) in pre-filled injection syringe, Zoladex Implant®  AstraZeneca Pty Ltd	Anti-cancer drug	Extend the current Authority Required listing to include use in early breast cancer in peri- or pre-menopausal women.	The PBAC recommended listing for the treatment of hormone-dependent breast cancer as an alternative to adjuvant chemotherapy in peri or pre-menopausal women.on the basis of clinical need and an acceptable cost-effectiveness ratio.

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Minor submission			
Hydromorphone hydrochloride, tablet 4 mg (modified release), <b>Jurnista<sup>®</sup></b>  Janssen-Cilag Pty Ltd  Minor submission	Analgesics	Restricted benefit listings in the general and dental schedules, of a new, lower dose.	Recommended for listing in accordance with the pricing of the comparative strengths of the comparator, oxycodone.
Ibuprofen, tablet, 800 mg (sustained release), <b>Brufen SR<sup>®</sup></b>  Abbott Australasia Pty Ltd  Minor submission	Non-steroidal anti-inflammatory drug.	Request for listing of a new formulation and strength of ibuprofen as: <ol style="list-style-type: none"> <li>1) Restricted benefit in the General and Dental Schedules for chronic arthropathies (including osteoarthritis) with an inflammatory component and bone pain due to malignant disease.</li> <li>2) Authority required in the Palliative Care Schedule for patients where severe pain is a problem.</li> </ol>	Recommended for listing as requested on a per mg cost-minimisation basis with ibuprofen 400 mg tablet.
Influenza vaccine, injection (trivalent) 0.5 mL (containing A/Brisbane/59/2007, A/Brisbane/10/2007 and B/Florida/4/2006 like strains), <b>Agrippal<sup>®</sup></b>  Novartis Vaccines and Diagnostics Pty Ltd.  Minor submission	Vaccine for Influenza	Restricted Benefit listing of a new brand of seasonal influenza vaccine on the PBS for persons at special risk of adverse consequences from infections of the lower respiratory tract.  Request the PBAC recommend that Agrippal be designated as a vaccine pursuant to Section 9B (7) of the National Health Act 1953 to allow the sponsor to participate in future national tenders for supply via the National Immunisation Program (NIP).	Recommended

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<p>Lacosamide, tablets, 50 mg, 100 mg, 150 mg and 200 mg and oral solution, 15 mg per mL, 465 mL, Vimpat®</p> <p>UCB Australia Pty Ltd</p> <p>Major submission</p>	<p>Anti-epileptic drug</p>	<p>Authority required listing for treatment of partial epileptic seizures not controlled satisfactorily by other anti-epileptic drugs, in patients who meet certain criteria.</p>	<p>Recommended for listing where treatment is initiated by a neurologist for use in combination with two or more anti-epileptic drugs on the basis of an acceptable cost-effectiveness ratio compared to placebo plus standard background therapy.</p>
<p>Lansoprazole, capsule, 30 mg, Zopral®</p> <p>Alphapharm Pty Ltd</p> <p>Minor submission</p>	<p>Proton pump inhibitor</p>	<p>Request listing of a new brand of lansoprazole 30 mg capsules, "a" flagged to the orally disintegrating tablet 30 mg (Zoton FasTab®).</p>	<p>The PBAC recommended the listing of lansoprazole 30 mg capsules on the PBS on a cost minimisation basis compared with lansoprazole 30 mg tablet (orally disintegrating). The PBAC had no objection to bioequivalence marking for these pharmaceutical alternatives of lansoprazole 30 mg, on the basis that lansoprazole, Zoton Fastabs are bioequivalent to Zoton capsules.</p>
<p>Maraviroc, tablets, 150 mg and 300 mg, Celsentri®</p> <p>Pfizer Australia Pty Ltd</p> <p>Major submission</p>	<p>Anti-HIV drug</p>	<p>Section 100 (Highly Specialised Drugs Program) listing for treatment, in combination with other antiretrovirals, of an antiretroviral experienced adult patient infected only with CCR5-tropic HIV-1 and:</p> <p>(a) evidence of HIV replication (viral load greater than 1,000 copies per mL) and/or</p> <p>(b) CD4 cell counts of less than 500 per cubic millimetre.</p> <p>A patient must have failed previous treatment with, or have resistance to, 3 different antiretroviral regimens, including regimens with:</p> <p>(i) at least 1 non-nucleoside reverse transcriptase inhibitor; and</p> <p>(ii) at least 1 nucleoside reverse transcriptase inhibitor; and</p> <p>(iii) at least 2 protease inhibitors.</p>	<p>Recommended for listing as requested on the basis of an uncertain but acceptable cost-effectiveness ratio compared to optimised background therapy.</p>

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<p>Memantine hydrochloride, tablet, 20 mg, Ebixa<sup>®</sup></p> <p>Lundbeck Australia Pty Ltd.</p> <p>Minor submission</p>	<p>Alzheimer disease</p>	<p>Authority Required listing of a new 20 mg strength of memantine tablet.</p>	<p>Recommended</p>
<p>Mesalazine, suppositories, 1 g, and enemas, 1 g in 100 mL, Pentasa<sup>®</sup>, Ferring Pharmaceuticals Pty Ltd; enemas, 2 g in 60 mL and 4 g in 60 mL, and rectal foam, 1 g per applicatorful, Salofalk<sup>®</sup>, Orphan Australia Pty Ltd.</p> <p>Minor submission</p>	<p>Ulcerative colitis</p>	<p>The Gastroenterological Society of Australia requested an amendment to the listings for rectal formulations of mesalazine for patients with acute episodes of ulcerative colitis (currently Authority Required (STREAMLINED) and acute episodes of ulcerative proctitis (currently Restricted Benefit) to allow prescribing for patients who require a longer duration of therapy than one month.</p>	<p>The PBAC agreed to the request and recommended the listings be amended to allow for one repeat prescription.</p>
<p>Mesalazine, tablet, 1.2 g (prolonged release), Mezavant<sup>®</sup></p> <p>Shire Australia Pty Ltd</p> <p>Minor submission</p>	<p>Ulcerative colitis</p>	<p>Authority Required (STREAMLINED) listing for ulcerative colitis where hypersensitivity to sulfonamides exists or where intolerance to sulfasalazine exists.</p>	<p>Recommended for listing as requested at the same price per mg as currently listed mesalazineoral products for ulcerative colitis.</p>
<p>Methoxy-polyethylene glycol-epoetin beta, solution for injection, 30 micrograms in 0.3 mL, 50 micrograms in 0.3 mL, 75 micrograms in 0.3 mL, 100 micrograms in 0.3 mL, 120 micrograms in 0.3 mL, 200 micrograms in 0.3 mL and 360 micrograms in 0.6 mL, single use pre-filled syringe, Mircera<sup>®</sup></p> <p>Roche Products Pty Ltd</p>	<p>Treatment of anaemia</p>	<p>Section 100 (Highly Specialised Drugs Program) listing for treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per litre, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia.</p>	<p>Recommended for listing on a cost-minimisation basis compared with darbepoetin alfa and epoetin.</p>

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Major submission			
<p>Nebivolol hydrochloride, tablets, 1.25 mg, 5 mg and 10 mg (as hydrochloride), and titration pack containing 42 tablets 1.25 mg and 14 tablets 5 mg, Nebilet<sup>®</sup></p> <p>CSL Limited</p> <p>Major submission</p>	Heart failure	Authority Required (STREAMLINED) listing for moderate to severe heart failure stabilised on conventional therapy which must include an ACE inhibitor if tolerated.	The PBAC recommended listing for the treatment of moderate or severe heart failure in a patient stabilised on conventional therapy which must include an ACE-inhibitor or an Angiotensin II antagonist if tolerated. Listing was recommended on a cost-minimisation basis compared with carvedilol, bisoprolol and metoprolol.
<p>Nevirapine, oral liquid, 10 mg per mL, 240 mL, Viramune<sup>®</sup></p> <p>Boehringer-Ingelheim Pty Ltd</p> <p>Minor submission</p>	Anti-HIV drug	Request the PBAC reinstate the rescinded June 2000 recommendation for a Section 100 (Highly Specialised Drugs Program) listing for treatment of HIV infection for use in paediatric patients who meet certain criteria.	The PBAC recommended listing on the basis of comparable effectiveness with the solid dose form and clinical need.
<p>Quetiapine fumarate, tablets (modified release), 50 mg, 200 mg, 300 mg and 400 mg (base), Seroquel XR<sup>®</sup></p> <p>AstraZeneca Pty Ltd</p> <p>Minor submission</p>	Bipolar disorder	Request the “bipolar” PBS listings for immediate release quetiapine, be applied to the modified release quetiapine tablets.	Recommended
<p>Risperidone, powder for IM injection 25 mg, 37.5 mg and 50 mg (modified release) with 2 mL diluent in prefilled-syringe, Risperdal Consta<sup>®</sup></p> <p>Janssen-Cilag Pty Ltd</p> <p>Minor submission</p>	Anti-psychotic drug	Request to remove the NOTE stating no applications for increased maximum quantities and/or repeats will be authorised.	The PBAC recommended removal of NOTE for a period of six months.

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<p>Rizatriptan benzoate, tablets, 5 mg and 10 mg (base), wafers, 5 mg and 10 mg (base), Maxalt®</p> <p>Merck Sharp &amp; Dohme (Australia) Pty Ltd</p> <p>Major submission</p>	<p>Migraine</p>	<p>Authority Required (STREAMLINED) listing for treatment of a patient with a migraine attack.</p>	<p>The PBAC recommended an Authority Required (Streamlined) listing for migraine attacks in a patient where attacks in the past have usually failed to respond to analgesics. Listing was recommended on a cost-minimisation basis with sumatriptan succinate where the equi-effective doses are rizatriptan benzoate 10 mg tablets and wafers to sumatriptan succinate 50 mg tablets.</p>
<p>Tenofovir disoproxil fumarate with emtricitabine and efavirenz, tablet, 300 mg – 200 mg – 600 mg Atripla®</p> <p>Gilead Sciences Pty Ltd</p> <p>Major submission</p>	<p>Anti-HIV drug</p>	<p>Section 100 (Highly Specialised Drugs Program) listing for treatment of HIV infection in patients with:</p> <p>(a) CD4 cell counts of less than 500 per cubic millimetre; or</p> <p>(b) viral load of greater than 10,000 copies per mL.</p>	<p>Recommended for listing on a cost-minimisation basis compared with the corresponding strengths of the individual components taken concomitantly.</p>
<p>Terbinafine hydrochloride, cream, 10 mg per g (1%) Lamisil® Novartis Consumer Health</p> <p>Terbinafine hydrochloride, tablets, 250 mg (base), Lamisil®, Novartis Pharmaceuticals Australia Pty Ltd;</p> <p>GenRx Terbinafine®, Apotex Pty Ltd;</p> <p>Sebifin 250®, Ranbaxy Australia Pty Ltd;</p> <p>Tamsil®, Sigma Pharmaceuticals (Australia) Pty Ltd;</p> <p>Terbihexal®, Sandoz Pty Ltd;</p> <p>Terbinafine 250®, Pharmacor Limited;</p> <p>Terbinafine-DP®, Genepharma Pty</p>	<p>Fungal infections</p>	<p>The Paediatric Medicines Working Group requested amendment to the restriction for terbinafine cream to include 'Treatment of a fungal or a yeast infection in a patient aged up to 18 years inclusive' and amendment to the restriction for terbinafine tablets to include 'Treatment of a dermatophyte infection in a patient aged up to 18 years inclusive where topical treatment and griseofulvin have failed'</p>	<p>The PBAC agreed to the request on the basis of clinical need in the paediatric patient population.</p>

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Ltd; Zabel <sup>®</sup> , Alphapharm Pty Ltd.  Minor submission			
Tocilizumab, solution for IV infusion, 80 mg in 4 mL, 200 mg in 10 mL and 400 mg in 20 mL, Actemra <sup>®</sup>  Roche Products Pty Ltd  Major submission	Rheumatoid arthritis	Extend the Section 100 (Highly Specialised Drugs Program) listing recommended by PBAC at the July 2009 meeting to include initial and continuing treatment with tocilizumab as monotherapy, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis of adults who meet certain criteria.	The PBAC recommended tocilizumab be available for use as monotherapy for the treatment of severe active rheumatoid arthritis patients who have failed to demonstrate a response to a TNF-alfa antagonist. Listing was on a cost-minimisation basis compared to etanercept, where the equi-effective doses are tocilizumab 8 mg/kg every 4 weeks and etanercept 50 mg weekly.
Triglycerides – medium chain, emulsion, 250 mL, Liquigen <sup>®</sup>  Nutricia 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; Intractable childhood epilepsy requiring a ketogenic diet; Long chain fatty acid oxidation disorders.	Recommended as an Authority Required listing at an equivalent price per gram of fat to MCT ProCal <sup>®</sup> (medium chain triglycerides formula).
Triglycerides, long chain with glucose polymer, oral liquid, 250 mL and 1 L, ProZero <sup>®</sup>  Vitaflo Australia Pty Ltd  Minor Submission	Medicinal food	Restricted Benefit listing for patients with proven inborn errors of protein metabolism who are unable to meet their energy requirements with permitted food and formulae.  Restricted benefit listing for children with chronic renal disease who are unable to meet their energy requirements with permitted food and formulae where a low protein and low phosphorus diet (+/- potassium restriction) is required.	The PBAC recommended listing for patients with proven inborn errors of metabolism at the same price per gram of protein as Duocal <sup>®</sup> (medium chain and long chain triglycerides with glucose polymer)  Listing for children with the chronic renal disease was not recommended because of uncertain clinical need and inappropriate choice of comparator.

**NOVEMBER 2009 PBAC MEETING OUTCOMES – Positive Recommendations**

<b>DRUG AND FORM</b>	<b>DRUG USE AND TYPE</b>	<b>LISTING REQUESTED BY SPONSOR</b>	<b>PBAC RECCOMENDATION</b>
<p>Ustekinumab (rmc), solution for injection, 45 mg in 0.5 mL, Stelara®</p> <p>Janssen-Cilag Pty Ltd</p> <p>Major submission</p>	<p>Chronic plaque psoriasis</p>	<p>Authority Required listing for initial and continuing treatment by a dermatologist for adults 18 years of age and over who have severe chronic plaque psoriasis who meet certain criteria.</p>	<p>The PBAC recommended listing for the treatment of severe chronic plaque psoriasis in patients who meet certain criteria on the basis of an acceptable cost-effectiveness ratio compared with etanercept.</p>
<p>Varenicline, tablet, 1 mg (as tartrate), Champix®</p> <p>Pfizer Australia Pty Ltd</p> <p>Major submission</p>	<p>Anti-nicotine dependence</p>	<p>Request the addition of a second continuing treatment restriction to the current authority required listing to allow a further 12 weeks of treatment for responders.</p>	<p>The PBAC recommended extending the listing to allow for a further 12 weeks treatment of responders on the basis of an acceptable cost-effectiveness ratio.</p>
<p>Vitamins, minerals and trace elements with carbohydrate, powder, 200 g, Paediatric Seravit®</p> <p>Nutricia Australia Pty Ltd</p> <p>Minor submission</p>	<p>Medicinal food</p>	<p>Restricted Benefit listing for children where vitamin and mineral intake is insufficient due to restrictive therapeutic diets for the management of inborn errors of metabolism, multiple food allergies and gastrointestinal disorders.</p>	<p>Recommended as an Authority Required listing for use in infants and children where vitamin and mineral intake is insufficient due to highly restrictive therapeutic diets and that a dietician and a paediatrician be involved in the management of patients using Paediatric Seravit.</p>
<p>Zoledronic acid, solution for I.V. infusion 5 mg (as monohydrate) in 100 mL, Aclasta®</p> <p>Novartis Pharmaceuticals Australia Pty Ltd</p> <p>Major submission</p>	<p>Bone conditions eg osteoporosis and Paget disease of bone.</p>	<p>Extend the current Authority Required listing to include treatment as the sole PBS-subsidised anti-resorptive agent for corticosteroid-induced osteoporosis in a patient currently on long-term (at least 3 months), high dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy with a Bone Mineral Density (BMD) T-score of -1.5 or less.</p> <p>The submission also requests a Streamlined Authority listing.</p>	<p>The PBAC recommended an Authority Required listing for corticosteroid-induced osteoporosis in the requested patient group on a cost-minimisation basis with risedronate. The equi-effective doses are zoledronic acid 5 mg annually and risedronate 5 mg daily.</p>

**NOVEMBER 2009 PBAC MEETING OUTCOMES – Positive Recommendations**

<b>DRUG AND FORM</b>	<b>DRUG USE AND TYPE</b>	<b>LISTING REQUESTED BY SPONSOR</b>	<b>PBAC RECCOMENDATION</b>
<p>Zoledronic acid, solution for I.V. infusion 5 mg (as monohydrate) in 100 mL, Aclasta®</p> <p>Novartis Pharmaceuticals Australia Pty Ltd</p> <p>Major submission</p>	<p>Bone conditions eg osteoporosis and Paget disease of bone.</p>	<p>Extend the current Authority Required listing to include symptomatic Paget's disease of bone.</p> <p>The submission also requests a Streamlined Authority listing.</p>	<p>The PBAC recommended an Authority Required listing on a cost-minimisation basis compared to disodium pamidronate. The equi-effective doses were considered to be one infusion of zoledronic acid 5 mg was equivalent to two infusions of disodium pamidronate 60 mg.</p>
<p>Zoledronic acid, solution for IV infusion, 5 mg (as monohydrate), in 100 mL, Aclasta®</p> <p>Novartis Pharmaceuticals Australia Pty Ltd</p> <p>Minor submission</p>	<p>Bone conditions eg osteoporosis and Paget disease of bone.</p>	<p>Extend the current primary and secondary prevention osteoporosis listings to include male patients.</p>	<p>Recommended.</p>