

JULY 2010 PBAC MEETING OUTCOMES – 1st time decisions not to recommend

DRUG AND FORM	DRUG USE AND TYPE	LISTING REQUESTED BY SPONSOR	PBAC OUTCOME AND COMMENTS
<p>Aliskiren, tablets, 150 mg and 300 mg (as hemifumarate), Rasilez[®]</p> <p>Novartis Pharmaceuticals Australia Pty Ltd</p> <p>Major submission</p>	<p>Antihypertensive</p>	<p>Unrestricted Benefit listing for the treatment of hypertension.</p>	<p>The PBAC rejected the submission on the basis of uncertain cost-effectiveness and lack of a clear clinical need for an anti-hypertensive that has demonstrated similar effects on a surrogate outcome, but has not yet demonstrated long term benefits on clinical endpoints or long term safety compared with other agents in similar therapeutic classes.</p>
		<p>Sponsor's comments:</p>	<p>The sponsor had no comment.</p>
<p>Darunavir, tablet, 400 mg (as ethanolate), Prezista[®]</p> <p>Janssen-Cilag Pty Ltd</p> <p>Major submission</p>	<p>HIV-infection</p>	<p>Section 100 (Highly Specialised Drugs Program) listing for treatment in combination with other antiretroviral agents, and co-administered with 100 mg ritonavir daily, of HIV infection in a protease inhibitor naïve patient 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>The PBAC rejected the submission because of the choice of comparator. The appropriate comparator is atazanavir with or without ritonavir.</p>
		<p>Sponsor's comments:</p>	<p>Janssen-Cilag is committed to ongoing interaction with the PBAC with a view to ensuring access to darunavir through the PBS for protease inhibitor naïve patients with HIV.</p>
<p>Icatibant, injection, 30 mg in 3 mL(as acetate), single use pre-filled syringe, Firazyr[®]</p> <p>Shire Australia Pty Limited</p> <p>Major submission</p>	<p>Acute hereditary angioedema</p>	<p>Authority Required listing for anticipated emergency treatment, initiated by a specialist immunologist or other relevant specialist, of laryngeal/oro-pharyngeal and severe abdominal attacks of acute hereditary angioedema in patients with confirmed diagnosis of C1-esterase inhibitor deficiency.</p>	<p>The PBAC rejected the submission because of insufficient evidence in the proposed setting to support the clinical place of the therapy and uncertain cost-effectiveness.</p>
		<p>Sponsor's comments:</p>	<p>Shire will continue to work with the PBAC to achieve reimbursement for Firazyr.</p>

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<p>Miglustat, capsule, 100 mg, Zavesca[®]</p> <p>Actelion Pharmaceuticals Australia Pty Ltd</p> <p>Major submission</p>	<p>Niemann-Pick type C disease</p>	<p>Inclusion on the Life Saving Drugs Program (LSDP) for the treatment of progressive neurological manifestations in adults and paediatric patients with Niemann-Pick type C (NPC) disease.</p>	<p>The PBAC hence rejected the application on the basis of uncertain clinical efficacy and a very high and uncertain cost effectiveness ratio</p> <p>The PBAC also rejected the submission for inclusion on the LSDP as it does not meet the criteria for inclusion on this program.</p>
		<p>Sponsor's comments:</p>	<p>Actelion Pharmaceuticals Australia Pty Ltd will continue to work with the PBAC and LSDP to make this important medicine available for patients suffering from NPC.</p>
<p>Oxycodone hydrochloride and naloxone hydrochloride dihydrate, tablets, 5 mg-2.5 mg, 10 mg-5 mg, 20 mg-10 mg and 40 mg-20 mg (controlled release), Targin[®]</p> <p>Mundipharma Pty Ltd</p> <p>Major submission</p>	<p>Pain relief</p>	<p>Restricted Benefit listing for the treatment of chronic severe disabling pain not responding to non-narcotic analgesics.</p>	<p>The PBAC rejected the submission on the basis of an uncertain and high cost-effectiveness ratio.</p>
		<p>Sponsor's comments:</p>	<p>The sponsor had no comment.</p>
<p>Pazopanib, tablets, 200 mg and 400 mg (as hydrochloride), Votrient[®]</p> <p>GlaxoSmithKline Australia Pty Ltd</p> <p>Major submission</p>	<p>Anti-cancer drug</p>	<p>Authority Required listing for the initial and continuing treatment of Stage IV clear cell variant renal cell carcinoma in an adult patient who meets certain criteria and who has not previously been issued with a PBS authority prescription for sunitinib maleate.</p>	<p>The PBAC rejected the submission because based on the currently available data, there is significant uncertainty as to whether pazopanib is non-inferior to sunitinib in the treatment of stage IV advanced and/or metastatic, clear cell variant, renal cell carcinoma. Additionally, the proposed PBS-restriction is clinically inappropriate and does not reflect the treatment algorithm which would result if pazopanib were to be PBS-listed.</p>
		<p>Sponsor's comments:</p>	<p>GlaxoSmithKline is disappointed by the decision but will continue to work with the PBAC to make the product available for this patient population.</p>

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<p>Psyllium hydrophilic mucilloid, oral powder (orange-flavoured, sugar-free), 283 g and 425 g, Metamucil Orange Smooth[®]</p> <p>Psyllium hydrophilic mucilloid, oral powder, (non-flavoured), 336 g and 504 g, Metamucil Natural Regular[®]</p> <p>Procter & Gamble Australia Pty Ltd</p> <p>Minor submission</p>	<p>Laxative.</p>	<p>Restricted Benefit listing for the following: Hypercholesterolemic patients who suffer from chronic constipation. Patients who suffer from chronic constipation but experience adverse effects with chemical laxatives. Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function not responding to other oral therapies. Patients who are receiving long term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities. Patients receiving palliative care. Constipation in patients with malignant neoplasia. Anorectal congenital abnormalities. Megacolon.</p> <p>Sponsor's comments:</p>	<p>The PBAC rejected the submission because insufficient information was provided to allow the Committee to form a view about the effectiveness and cost of this treatment compared to other treatments for constipation in patients with or without hypercholesterolaemia.</p> <p>The sponsor will be working to address the comments raised by the Committee.</p>
<p>Topotecan, capsules, 0.25 mg and 1 mg (as hydrochloride), Hycamtin[®]</p> <p>GlaxoSmithKline Australia Pty Ltd</p> <p>Major submission</p>	<p>Anti-cancer drug</p>	<p>Authority Required (STREAMLINED) listing for the treatment of relapsed small cell lung cancer where intravenous therapy is inappropriate.</p> <p>Sponsor's comments:</p>	<p>The PBAC rejected the submission on the basis of uncertain clinical benefit and a high and uncertain incremental cost-effectiveness ratio.</p> <p>The sponsor had no comment.</p>