

MARCH 2011 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>Bevacizumab, solution for I.V. infusion, 100 mg in 4 mL and 400 mg in 16 mL, Avastin[®]</p> <p>Roche Products Pty Ltd</p> <p>Major submission</p>	<p>Anti-cancer drug</p>	<p>Authority Required Section 85 and Section 100 listing under the Chemotherapy Pharmaceuticals Access Program (CPAP) to include initial treatment in combination with carboplatin and paclitaxel of a patient with advanced or metastatic non – squamous non – small cell lung cancer (NSCLC) with a WHO performance status of 0 or 1, who has not previously received treatment for their metastatic disease. Continuing treatment as monotherapy in a patient who does not have progressive disease.</p> <p>Sponsor's comments:</p>	<p>The PBAC rejected the submission on the basis of an unacceptably high and uncertain cost-effectiveness ratio.</p> <p>The sponsor will be considering its position regarding any future course of action.</p>
<p>Cladribine, tablet, 10 mg, Movectro[®]</p> <p>Merck Serono Australia Pty Ltd</p> <p>Major submission</p>	<p>Multiple sclerosis</p>	<p>Section 100 listing for the initial and continuing treatment of relapsing – remitting multiple sclerosis (RRMS) initiated by a neurologist, 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.</p> <p>Sponsor's comments:</p>	<p>The PBAC rejected the submission because of use of an inappropriate comparator, uncertain clinical benefit and uncertain and unacceptable cost effectiveness in comparison with the appropriate comparator. The appropriate main comparator is interferon beta, the most commonly used first line treatment for multiple sclerosis.</p>
		<p>Sponsor's comments:</p>	<p>Merck Serono is encouraged to be working with the Department of Health and PBAC and is looking forward to presenting a resubmission for this short-course oral treatment for Multiple Sclerosis</p>

Colistimethate sodium, powder for nebuliser solution, 1 million IU (equivalent to 80 mg colistimethate sodium), Tadim [®] Phebra Pty Ltd Major submission	Inhaled antibiotic for the treatment of lung infections in patients with cystic fibrosis	Section 100 and Section 85 Authority Required listings for the treatment of colonisation and infections of the lung due to susceptible Pseudomonas aeruginosa in patients with cystic fibrosis.	The PBAC rejected the submission on the basis of uncertain clinical benefit, uncertain clinical place in therapy and extrapolating from that to uncertain cost-effectiveness.
		Sponsor's comments:	The sponsor has no comment.
Docetaxel, solution concentrate for IV infusion, 20 mg in 1 mL, 80 mg in 4 mL, 140 mg in 7 mL, Docetaxel Actavis [®] Generic Health Pty Ltd Minor submission	Anti-cancer drug	Authority required listing for <u>monotherapy</u> indications only.	The PBAC rejected the submission because the TGA registered indications include other indications, not just monotherapy, and therefore PBS listing should reflect the TGA registered indications.
		Sponsor's comments:	The sponsor has no comment.
Isotretinoin, capsule, 20 mg (30), 40 mg (60), Oratane [®] Ascent Pharma Pty Ltd Minor submission	Severe acne	Authority required (STREAMLINED) listing under the current listing conditions for two new pack sizes.	The PBAC rejected the submission due to lack of demonstrated clinical need and no convincing evidence of patient benefit.
		Sponsor's comments:	Ascent is disappointed with the PBAC decision and will consider its position regarding any further action.
Lenalidomide, capsules, 5 mg and 10 mg, Revlimid [®] Celgene Pty Ltd Major submission	Myelodysplastic syndrome	Section 100 (Highly Specialised Drugs) Authority Required listing for initial and continuing treatment of: - myelodysplastic syndrome (MDS) classified as low risk or Intermediate – 1 according to the International Prognostic Scoring System (IPSS); and - Who has a deletion 5q cytogenetic	The PBAC rejected the submission on the basis of a high and uncertain cost-effectiveness ratio.

		<p>abnormality with or without additional cytogenic abnormalities; and</p> <p>- Who is red blood cell transfusion dependent, and who meets certain criteria.</p>	
		Sponsor's comments:	Celgene will continue to work with the PBAC to achieve a positive recommendation.
<p>Mannitol, capsule containing powder for oral inhalation, 40 mg (for use in inhaler device), Bronchitol®</p> <p>Pharmaxis Ltd</p> <p>Major submission</p>	Cystic fibrosis	<p>Section 100 (Highly Specialised Drugs) Authority Required listing for the treatment of cystic fibrosis (CF) in paediatric (six years and above) and adult patients as either add on therapy to dornase alpha or in patients intolerant or in patients inadequately responsive to dornase alpha.</p>	The PBAC rejected the submission because of uncertainties in where mannitol will fit in clinical practice and consequent difficulties in identifying the right comparator in one clinical setting that leads to uncertain cost-effectiveness.
		Sponsor's comments:	Pharmaxis is committed to an ongoing interaction with the PBAC to achieve access to mannitol via the PBS for cystic fibrosis patients."
<p>Pregabalin, capsules, 25 mg, 75 mg, 150 mg and 300 mg, Lyrica®</p> <p>Pfizer Australia Pty Ltd</p> <p>Major submission</p>	Neuropathic (nerve) pain	<p>Authority Required (STREAMLINED) listing for the initial and continuing treatment of neuropathic pain including patients requiring dosage reduction due to renal impairment.</p>	The PBAC rejected the submission because of uncertain cost effectiveness.
		Sponsor's comments:	Pfizer Australia acknowledges that the approval of new treatments for neuropathic pain is difficult as there is inherent uncertainty in the available evidence and agrees that there is a high unmet need. Therefore, the company will continue to work with the PBAC to make Lyrica available for this population of patients.

<p>Quadrivalent human papillomavirus (Types 6, 11, 16, 18) recombinant vaccine, suspension for injection, 0.5 mL, suspension for injection, pre-filled syringe single dose, Gardasil[®]</p> <p>CSL Limited</p> <p>Major submission</p>	<p>Vaccine for prevention of human papillomavirus (HPV)</p>	<p>National Immunisation Program (NIP) for prevention of human papillomavirus (HPV) in males 12 – 13 years of age and a catch-up program over 2 years for Year 9 males.</p>	<p>The PBAC rejected the submission because of unacceptably high and uncertain cost-effectiveness.</p>
		<p>Sponsor's comments:</p>	<p>CSL believes extending HPV vaccination to males is an important public health initiative and is committed to working with the PBAC to secure a positive recommendation for the NIP .</p>
<p>Sertindole, tablets, 4 mg, 12 mg, 16 mg and 20 mg, Serdolect[®]</p> <p>Lundbeck Australia Pty Ltd</p> <p>Major submission</p>	<p>Schizophrenia</p>	<p>Authority Required (STREAMLINED) listing for the treatment of schizophrenia in people who have had prior treatment with one other anti- psychotic.</p>	<p>The PBAC rejected the submission on the basis of uncertain clinical need, and concerns regarding relative efficacy.</p>
		<p>Sponsor's comments:</p>	<p>The sponsor has no comment.</p>
<p>Tapentadol, tablets, 50 mg, 100 mg, 150 mg, 200 mg and 250 mg (as hydrochloride) (sustained release), Palexia SR[®]</p> <p>CSL Biotherapies</p> <p>Major submission</p>	<p>Severe pain</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 because of uncertain clinical benefit and uncertain cost effectiveness.</p>
		<p>Sponsor's comment:</p>	<p>CSL is working with the PBAC to ensure that this medication is available for patients with chronic severe disabling pain not responding to non-narcotic analgesics.</p>
<p>Vorinostat, capsule, 100 mg, Zolinza[®]</p> <p>Merck Sharp & Dohme (Australia) Pty Ltd</p> <p>Major submission</p>	<p>Anti-cancer drug</p>	<p>Authority Required listing for the initial and continuing treatment as monotherapy of advanced (stage IIB – IV) Cutaneous T - Cell Lymphoma (CTCL) where treatment failure has occurred with four systemic therapies, unless contraindicated. At least one of these therapies should be a chemotherapy regimen.</p>	<p>The PBAC rejected the submission on the basis of unacceptably high and uncertain cost-effectiveness ratios.</p>

		Sponsor's comment	MSD believes vorinostat meets an important therapeutic need for patients with advanced Cutaneous T-Cell Lymphoma (CTCL) and will continue to work with the PBAC to investigate how this important medicine can be made available to this patient group.
--	--	-------------------	---