

**NOVEMBER 2015 PBAC OUTCOMES – 1<sup>ST</sup> TIME DECISIONS NOT TO RECOMMEND**

<b>DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION</b>	<b>DRUG TYPE OR USE</b>	<b>LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION</b>	<b>PBAC OUTCOME</b>
<p>APREPITANT 165 mg capsule</p> <p>Emend®</p> <p>Merck Sharp &amp; Dohme (Australia) Pty Limited</p> <p>Change to listing  (Major Submission)</p>	<p>Chemotherapy induced nausea and vomiting</p>	<p>To request an extension to the current Section 100 and S85 PBS listing to include use with carboplatin/oxaliplatin regimens from the first chemotherapy cycle without having a prior episode of chemotherapy induced nausea and vomiting.</p>	<p>The PBAC rejected the request to extend the PBS listing of aprepitant to include prevention of acute and delayed chemotherapy induced nausea and vomiting (CINV) associated with carboplatin and oxaliplatin based chemotherapy regimens. In making its recommendation, the PBAC considered that the cost-effectiveness of aprepitant in the proposed population had not been adequately demonstrated by the submission.</p> <p>The PBAC noted that the submission did not present an economic evaluation of aprepitant for the requested indication. The PBAC considered that in the absence of an economic analysis, the cost-effectiveness of aprepitant in the broader population requested could not be determined.</p> <p>On the basis of meta-analysis evidence presented by the submission, for every 100 patients treated with aprepitant in comparison to standard therapy;</p> <ul style="list-style-type: none"> <li>• Approximately 11 additional patients would have complete response (no vomiting and no rescue therapy) over 120 hours post chemotherapy.</li> </ul>
		<p>Sponsor Comment:</p>	<p>The sponsor had no comment</p>

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<p>ARMODAFINIL 50 mg tablet, 30 150 mg tablet, 30 250 mg tablet, 30</p> <p>Nuvigil®</p> <p>Teva Pharma Australia Pty Ltd</p> <p>New listing</p> <p>(Major Submission)</p>	<p>Narcolepsy</p>	<p>To request an Authority Required listing for the treatment of narcolepsy.</p>	<p>The PBAC decided not to recommend the listing of armodafinil on the PBS for excessive daytime sleepiness associated with narcolepsy. In making its recommendation, the PBAC considered that there was no apparent unmet clinical need for armodafinil and the estimation of the equi-effective doses remained uncertain in the cost-minimisation analysis.</p>
		<p>Sponsor Comment:</p>	<p>Teva Pharma will work to resolve the issues identified by the PBAC.</p>
<p>BEVACIZUMAB 100 mg and 400 mg single dose vials containing 4 mL and 16 mL, respectively, of bevacizumab (25 mg/mL)</p> <p>Avastin®</p> <p>Roche Products Pty Ltd</p> <p>Change to listing</p> <p>(Major Submission)</p>	<p>Advanced cervical cancer</p>	<p>To request Section 100 Authority Required (STREAMLINED) listing for the treatment of patients with persistent, recurrent or metastatic cervical cancer not amenable to curative treatment with surgery and/or radiation, in combination with platinum-based chemotherapy or topotecan plus paclitaxel.</p>	<p>The PBAC rejected the request to list bevacizumab for the treatment of patients with advanced cervical cancer on the basis of high and unacceptable cost-effectiveness.</p> <p>On the basis of direct evidence presented by the submission, the comparison of bevacizumab plus chemotherapy and chemotherapy alone resulted in:</p> <ul style="list-style-type: none"> <li>• Approximately 3.5 months prolongation in median overall survival over a median follow-up of 61 weeks.</li> <li>• Approximately 2.3 months prolongation in median progression free survival for over a median follow-up of 52 weeks.</li> <li>• Approximately 15 additional patients would experience a serious adverse event, for every 100 patients treated with bevacizumab plus chemotherapy, over a median duration of exposure of 20.7 weeks.</li> <li>• Approximately 21 additional patients would experience serious adverse events of special interest, for every 100 patients treated with bevacizumab plus chemotherapy, over a median duration of exposure of 20.7 weeks.</li> </ul>

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			<p>The PBAC considered the claim of superior comparative efficacy was adequately supported in terms of OS and PFS compared with chemotherapy alone. However, the claim of manageable and acceptable safety profile was not adequately supported. While bevacizumab has some clinical benefits to patients, these may be counter-balanced by clinical harms.</p> <p>The PBAC noted the cost utility analysis presented in the submission resulted in a base case ICER of \$75,000 - \$105,000/QALY. The PBAC, noting the clinical outcomes, considered that this base case ICER/QALY was unacceptably high and was not in the range usually accepted by the PBAC.</p>
		Sponsor Comment:	Given the high unmet need, Roche is committed to working with the PBAC to provide access at the earliest opportunity to bevacizumab for patients with advanced cervical cancer.
<p>BLINATUMOMAB 38.5 microgram injection [1 vial] (&amp;) inert substance solution [10 mL vial], 1 pack</p> <p>Blincyto®</p> <p>Amgen</p> <p>New listing</p> <p>(Major Submission)</p>	<p>Philadelphia chromosome-negative relapsed or refractory B-precursor acute lymphoblastic leukaemia</p>	<p>To request Section 100 HSD Authority Required for the treatment of relapsed or refractory acute lymphoblastic leukaemia in both in-patient and outpatient setting.</p>	<p>The PBAC did not recommend the listing of blinatumomab for the treatment of relapsed or refractory Ph- B-precursor acute lymphoblastic leukaemia (ALL) due to uncertainties in comparative clinical effectiveness and a high and uncertain ICER. The PBAC considered that the clinical claim of superior efficacy and superior safety was difficult to assess, noting that blinatumomab has clear efficacy in a minority of patients and appears superior to current salvage therapy, however the magnitude of improvement in long-term outcomes cannot be determined readily from the data presented and there were significant harms associated with blinatumomab treatment.</p>
		Sponsor Comment:	Amgen is disappointed with the PBAC's recommendation given the urgent need for effective therapies in this patient population, but will continue to seek reimbursed access at the earliest possible opportunity for relapsed and refractory Philadelphia negative, B-precursor, acute lymphoblastic leukaemia patients. Amgen agrees with the PBAC that an innovative solution may be the most expeditious alternative to provide access as soon as possible to patients in significant need.

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<p>BUPRENORPHINE 5 microgram/hour patch, 2 10 microgram/hour patch, 2 20 microgram/hour patch, 2</p> <p>Norspan®</p> <p>Mundipharma Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Chronic pain</p>	<p>To request a Streamlined Authority listing for patients requiring ongoing therapy.</p>	<p>The PBAC did not to recommend an additional Authority Required (STREAMLINED) listing for buprenorphine patches with an increased maximum quantity and number of repeats, considering that the current restriction remains appropriate from a quality use of medicines perspective.</p>
		<p>Sponsor Comment:</p>	<p>The sponsor had no comment</p>
<p>DARUNAVIR + COBICISTAT darunavir 800 mg + cobicistat 150 mg tablet, 30</p> <p>Prezcobix®</p> <p>Janssen Cilag Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>HIV infection</p>	<p>To request Section 100 HSD Authority Required (STREAMLINED) listing for the treatment of HIV infection in treatment experienced patients and in patients with no darunavir resistance associated mutations.</p>	<p>The PBAC rejected the request to list darunavir/cobicistat fixed-dose combination (FDC) tablets for the treatment of human immunodeficiency virus (HIV) on the basis that the submission incorrectly proposed treatment in treatment-experienced patients while the evidence presented for clinical efficacy and safety also supported use in treatment naïve patients. The PBAC noted that the submission's proposed listing was not consistent with the current Australian Commentary to the US Department of Health and Human Services Guidelines for the use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents (August 2015), which lists darunavir/ritonavir (with tenofovir disoproxil fumarate/emtricitabine) as a recommended regimen and darunavir/cobicistat (with tenofovir disoproxil fumarate/emtricitabine or abacavir/lamivudine) as an alternative option in first line therapy for treatment naïve patients.</p> <p>The PBAC accepted the two nominated comparators, darunavir and ritonavir, taken concomitantly and darunavir and cobicistat, taken concomitantly.</p>
		<p>Sponsor Comment:</p>	<p>The sponsor had no comment</p>

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<p>ENZALUTAMIDE 40 mg capsule, 112</p> <p>Xtandi®</p> <p>Astellas Pharma Australia Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Metastatic castration resistant prostate cancer</p>	<p>To request an Authority Required listing for the treatment of metastatic castration-resistant prostate cancer in chemotherapy-naïve patients.</p>	<p>The PBAC decided not to recommend extending the PBS listing of enzalutamide to include treatment of metastatic castration-resistant prostate cancer (mCRPC) in patients who have not had prior docetaxel because the submission was focused on a claim of survival advantage, which was small and uncertain, rather than on outcomes that clinicians and patients considered to be of most value.</p> <p>The purpose of using enzalutamide earlier in the disease pathway would be 1) to delay symptoms from developing and maintaining a better quality of life for longer in asymptomatic patients for whom placebo, or watchful waiting, is the appropriate comparator; and 2) delaying the toxicities of chemotherapy in symptomatic patients considered suitable for docetaxel.</p> <p>The PBAC noted the median time to initiation of cytotoxic chemotherapy in the PREVAIL trial was 28.0 months in the enzalutamide group versus 10.8 months in the placebo group, a median difference of 17.2 months, which was clinically meaningful. In contrast the overall survival gain of 4 months for enzalutamide in the same trial compared to enzalutamide in the post-docetaxel setting (4.8 months from the AFFIRM trial) highlighted the minimal impact of earlier enzalutamide treatment on overall survival.</p> <p>The PBAC therefore rejected the application because it did not appropriately reflect the value of early enzalutamide treatment. The PBAC encouraged a resubmission to evaluate the potential gains in quality of life based on the patient populations and outcomes described above.</p>
		<p>Sponsor Comment:</p>	<p>Astellas is disappointed not to have secured an extended PBS listing for patients with mCRPC who have not had prior docetaxel, but is grateful to the PBAC for their helpful feedback and advice.</p>

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<p>EVEROLIMUS 250 microgram tablet, 60 500 microgram tablet, 60 750 microgram tablet, 60 1 mg tablet, 60</p> <p>Certican®</p> <p>Novartis Pharmaceuticals Australia Pty Ltd</p> <p>Change to listing  (Minor Submission)</p>	<p>Prophylaxis of organ rejection</p>	<p>To request a change from an Authority Required listing to an Unrestricted listing for transplant indications under the General Schedule.</p> <p>Sponsor Comment:</p>	<p>The PBAC rejected the general listing request of everolimus for transplant indications.</p> <p>The PBAC noted that the listings for everolimus referred to in the minor submission are also being considered in the context of the Post Market Review of PBS Authorities. The PBAC therefore declined to recommend any changes to these listings until the Review is complete and its recommendations have been implemented.</p> <p>Novartis understands that as part of the Post Market Review of PBS Authorities the recommendations for transplant medicines were made in Tranche 1, and were consistent for all transplant medicines. Novartis looks forward to working with the DoH and PBAC to implement a consistent PBS listing for patients on everolimus and their physicians.</p>
<p>LANREOTIDE ACETATE 60 mg injection, 1 syringe 90 mg injection, 1 syringe 120 mg injection ,1 syringe</p> <p>SomatulinAutogel®</p> <p>Ipsen Pty Ltd</p> <p>Change to listing  (Major Submission)</p>	<p>Gastroenteropancreatic neuroendocrine tumours</p>	<p>To request an Authority Required (STREAMLINED) listing for the treatment for patients with gastroenteropancreatic neuroendocrine tumours with unresectable locally advanced or metastatic disease.</p>	<p>The PBAC rejected the request to list lanreotide on the PBS for the treatment of gastroenteropancreatic neuroendocrine tumours (GEP- NETs) on the basis of uncertainty around the clinical significance of the progression free survival results from the CLARINET study; and that the economic model used to estimate the ICER was not reliable given fundamental issues with the model structure.</p> <p>On the basis of the direct evidence presented in the submission, lanreotide compared with placebo (for watchful waiting) resulted in:</p> <ul style="list-style-type: none"> <li>• A statistically significant and substantial increase in progression free survival. However, this increase in progression free survival was unable to be accurately quantified as insufficient patients treated with lanreotide had experienced disease progression by the end of the trial (at 96-weeks);</li> <li>• No statistically significant difference in overall survival;</li> <li>• Approximately 17 additional patients experiencing gastrointestinal disorders for every 100 patients treated;</li> <li>• Approximately 7 patients experiencing injection site pain for every 100 patients treated; and</li> <li>• Approximately 12 additional patients experiencing cholelithiasis (gallstones) for every 100 patients with an intact gallbladder.</li> </ul>

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		Sponsor Comment:	Ipsen is disappointed with the PBAC's decision but will work with the PBAC and clinical community to address the issues raised.
<p>NAB-PACLITAXEL paclitaxel nanoparticle albumin bound 100 mg injection, vial</p> <p>Abraxane®</p> <p>Specialised Therapeutics Australia</p> <p>Change to listing (Minor Submission)</p>	Breast cancer	<p>To request that the PBAC reconsider the exclusion of nab-paclitaxel from use in combination with PBS-subsidised trastuzumab for the treatment of HER2 positive metastatic breast cancer.</p>	<p>The PBAC rejected the request for PBS subsidy of the use of nab-paclitaxel in combination with trastuzumab, in the treatment of patients with human epidermal growth factor receptor 2 (HER-2) positive metastatic breast cancer.</p> <p>The PBAC rejected the resubmission because there was no basis to justify, in terms of clinical benefits, the price advantage remaining with the reduced price offered for nab-paclitaxel when this was compared with the corresponding price of solvent-based paclitaxel.</p> <p>The PBAC instead recommended that the nab-paclitaxel restriction "Treatment of HER2 positive breast cancer in combination with trastuzumab" be changed to "HER2 positive breast cancer".</p>
<p>NALMEFENE 18 mg tablet, 28</p> <p>Selincro®</p> <p>Lundbeck Australia Pty Ltd</p> <p>New listing (Major Submission)</p>	Alcohol dependence	<p>To request Authority required listing for the treatment of patients with alcohol dependence.</p>	<p>The PBAC did not recommend the listing of nalmefene for the treatment of alcohol dependence. In reaching this conclusion, the PBAC considered that the clinical place of therapy was not well defined and therefore the comparator was uncertain. The PBAC also considered that it was not clear whether the demonstrated effect was clinically meaningful. Without clarity around these issues, the cost effectiveness of nalmefene in the proposed population could not be determined.</p>
		Sponsor Comment:	Lundbeck Australia is disappointed with the PBAC's decision as we believe there is a clear clinical role for Selincro and that new treatment options are needed to address alcohol-related harm in Australia.

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<p>NIVOLUMAB and IPILIMUMAB nivolumab 40 mg/4 mL concentrate solution for infusion, 4 mL vial nivolumab 100 mg/10 mL concentrate solution for infusion, 10 mL vial ipilimumab 200 mg/40 mL concentrate solution for infusion, 40 mL vial ipilimumab 50 mg/10 mL concentrate solution for infusion, 10 mL vial</p> <p>Opdivo® + Yervoy®</p> <p>Bristol-Myers Squibb Australia Pty Ltd</p> <p>New listing</p> <p>(Major Submission)</p>	<p>Melanoma</p>	<p>To request Section 100 Authority Required (STREAMLINED) listing for the treatment of patients with unresectable metastatic melanoma.</p>	<p>The PBAC decided not to recommend the combination of nivolumab and ipilimumab for the treatment of unresectable or metastatic (Stage III or Stage IV) melanoma for listing on the PBS. In reaching this conclusion, the PBAC noted that the use of combination immunotherapy was associated with a modest improvement in progression-free survival, but a substantial increase in adverse events. The net clinical benefit of combination treatment was therefore uncertain.</p> <p>On the basis of the direct comparison presented by the submission, the comparison of nivolumab plus ipilimumab and nivolumab monotherapy resulted in:</p> <ul style="list-style-type: none"> <li>• no conclusions regarding differences in overall survival</li> <li>• a statistically significant difference in progression-free survival, with a median difference of approximately 4.60 months favouring nivolumab plus ipilimumab.</li> </ul> <p>On the basis of the direct comparison presented by the submission, for every 100 patients treated with nivolumab plus ipilimumab compared to nivolumab monotherapy:</p> <ul style="list-style-type: none"> <li>• approximately 40 more patients experienced serious drug-related adverse events</li> <li>• approximately 39 more patients experienced severe (grade three or higher) adverse events</li> <li>• approximately 29 more patients experienced adverse events leading to discontinuation of treatment.</li> </ul>
		<p>Sponsor Comment:</p>	<p>The sponsor will work with the PBAC to resolve the outstanding matters and looks forward to bringing this treatment option to Australian patients.</p>

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<p>PIRFENIDONE 267 mg capsule, 270</p> <p>Esbriet®</p> <p>Roche Products Pty Ltd</p> <p>New listing</p> <p>(Major Submission)</p>	<p>Idiopathic pulmonary fibrosis (IPF)</p>	<p>To request Section 100 HSD Authority Required listing for the treatment of patients with IPF</p>	<p>The PBAC decided not to recommend pirfenidone for PBS listing for IPF on the basis of unacceptably high and uncertain cost-effectiveness.</p> <p>The PBAC recognised the high clinical need for an effective treatment for IPF and the significant debilitating effects of the disease on quality of life, as noted in the consumer comments received for this item.</p> <p>On the basis of direct evidence presented by the submission, in comparison to placebo, pirfenidone was associated with:</p> <ul style="list-style-type: none"> <li>• Approximately a 4.0% reduction in absolute change in FVC%Pred from baseline to week 52.</li> <li>• No significant difference for overall survival, as reported in the vital status-end of study analysis, which was considered by the FDA cross discipline team leader review for pirfenidone to be most representative of the efficacy of a drug in terms of disease modification/survival.</li> </ul> <p>On the basis of direct evidence presented by the submission, for every 100 patients treated with pirfenidone in comparison to placebo:</p> <ul style="list-style-type: none"> <li>• Approximately 8 additional patients would have a photosensitivity reaction over 52-72 week duration of follow-up.</li> <li>• Approximately 20 additional patients would have a rash over 52-72 week duration of follow-up.</li> </ul> <p>Approximately 6 additional patients would have stomach discomfort over 52-72 week duration of follow-up.</p>

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		Sponsor Comment:	Given the high unmet need, Roche is committed to working with the PBAC to provide access at the earliest opportunity to pirfenidone for patients with idiopathic pulmonary fibrosis.
<p>PRALATREXATE 20 mg/mL injection, 1 mL vial</p> <p>Folotyn®</p> <p>Mundipharma Pty Ltd</p> <p>New listing</p> <p>(Major Submission)</p>	Peripheral T-cell lymphoma	<p>To request Section 100 Authority Required listing for the treatment of patients with peripheral T-cell lymphoma.</p> <p>Sponsor Comment:</p>	<p>The PBAC did not recommend Authority Required, listing for pralatrexate for treatment of relapsed or refractory peripheral T-Cell lymphoma. In reaching this conclusion, the PBAC considered that there was insufficient evidence of the incremental clinical benefit against currently available treatments, concerns regarding a high burden of adverse events, and economic modelling was not reliable to enable the Committee to determine the cost-effectiveness of the pralatrexate in the Australian context.</p> <p>The PBAC considered that there is a clinical need for new effective treatments for the relapsed or refractory peripheral T-Cell lymphoma. The PBAC considered that the incremental benefit of pralatrexate was uncertain, based on evidence from study PDX-008 and a meta-analysis of fourteen single arm comparisons. Overall, the PBAC considered that the claim of superior comparative effectiveness was not adequately supported by the data in the submission, and that pralatrexate was not cost-effective at the price requested in the submission.</p> <p>The sponsor had no comment</p>

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<p>PROTEIN FORMULA WITH CARBOHYDRATE, FAT, FIBRE, VITAMINS AND MINERALS oral liquid, 8 x 500 mL pouches</p> <p>Nutrini Low Energy Multi Fibre®</p> <p>Nutricia Australia Pty Ltd</p> <p>New listing</p> <p>(Major Submission)</p>	<p>Dietary management of disease related malnutrition</p>	<p>To request a Restricted benefit listing for the dietary management of disease related malnutrition in children with low energy tube feeding requirements.</p> <p>Sponsor Comment:</p>	<p>The PBAC did not recommend the listing of Nutrini Low Energy Multi Fibre on the PBS for children with cerebral palsy aged 1-12 years due to an uncertain definition of patient group likely to benefit from this product and an uncertain clinical need. The PBAC considered that non-modified feeds such as Nutrini Low Energy Multi Fibre are not appropriate for inclusion on the PBS.</p> <p>Whilst Nutricia is disappointed in the PBAC outcome, we will continue to work with the PBAC on demonstrating the value of Nutrini Low Energy Multi Fibre.</p> <p>Nutricia firmly believes that medical nutrition products, whether modified or non-modified, are important in the nutritional management of patients with a disease, disorder or medical condition and will continue to seek subsidised access for patients.</p>
<p>PROPRANOLOL 3.75 mg/mL oral liquid, 120 mL x 2</p> <p>Hemangirol ®</p> <p>Pierre Fabre Australia Pty Ltd</p> <p>Matters Outstanding</p> <p>(Minor Submission)</p>	<p>Infantile hemangioma</p>	<p>To provide a revised pricing proposal for an Authority Required listing as previously recommended in March 2015.</p> <p>Sponsor Comment:</p>	<p>The PBAC rejected the proposed price for Hemangirol and re-affirmed its decision in March 2015 regarding its pricing basis.</p> <p>Pierre Fabre is committed to ensuring that patients with infantile hemangioma have equitable access to treatment. We therefore will continue working with the Department to establish a price that reflects the value of Hemangirol as a safe and effective treatment in this vulnerable newborn population. The currently available option (compounded propranolol) does not provide the same standard of Quality Assurance as manufactured pharmaceutical goods like Hemangirol.</p>