

MONTH YEAR PBAC OUTCOMES – 1ST TIME DECISIONS NOT TO RECOMMEND

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>ATEZOLIZUMAB</p> <p>Solution concentrate for I.V. infusion 1200 mg in 20 mL</p> <p>Tecentriq®</p> <p>Roche Products Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Small cell lung cancer (SCLC)</p>	<p>To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the first-line treatment of patients with extensive-stage small cell lung cancer (SCLC).</p>	<p>The PBAC did not recommend atezolizumab for the treatment of previously untreated extensive-stage SCLC. The PBAC noted the high clinical need for effective treatments in this therapeutic area.</p> <p>The PBAC considered the evidence presented demonstrated there was a modest improvement in overall survival with atezolizumab. Although the PBAC considered this change to be clinically meaningful, the PBAC noted the magnitude and durability of this benefit was uncertain and the impact on patient quality of life was unclear.</p> <p>The PBAC also considered the incremental cost effectiveness ratio in this setting was uncertain and unacceptably high at the proposed price.</p>
<p>BUDESONIDE WITH FORMOTEROL</p> <p>Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses</p> <p>Pressurised inhalation containing budesonide 100 micrograms with formoterol fumarate dihydrate 3 micrograms per dose, 120 doses</p>	<p>Asthma</p>	<p>To request an Authority Required (STREAMLINED) listing for use as first-line treatment of mild asthma.</p>	<p>The PBAC did not recommend an extension of the current Authority Required (STREAMLINED) listing for budesonide with formoterol fixed dose combination (Symbicort) for asthma to include use as an anti-inflammatory reliever therapy administered as needed for adolescent and adult patients with mild asthma.</p> <p>The PBAC considered that inhaled corticosteroid (ICS) maintenance plus short-acting beta2-agonist (SABA) as needed was the appropriate main comparator. However, the PBAC considered the results reported for severe asthma exacerbations and well-controlled asthma weeks meant the claim of non-inferior comparative effectiveness versus ICS plus SABA was uncertain.</p> <p>The PBAC considered that the cost-minimisation analysis presented did not support the claim that, at the price requested, the cost of Symbicort to the health system is, at most, equivalent to ICS plus SABA. In addition, the PBAC considered the financial estimates provided in the submission to be uncertain, with use likely to be high and beyond the proposed estimates.</p>
<p align="center">Sponsor's Comment:</p>			<p>Roche is disappointed with the outcome given the genuine unmet need for a new treatment option that can prolong survival in patients with extensive-stage small cell lung cancer. Roche is committed to working with the PBAC to ensure that Australian patients with extensive-stage SCLC can access atezolizumab at the earliest opportunity.</p>

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<p>Symbicort® Turbuhaler® 200/6 Symbicort® Rapihaler® 100/3</p> <p>AstraZeneca Pty Ltd</p> <p>Change to listing (Major Submission)</p>		<p align="center">Sponsor's Comment:</p>	<p>No comment</p>
<p>CABOZANTINIB</p> <p>Tablet 20 mg Tablet 40 mg Tablet 60 mg</p> <p>Cabometyx®</p> <p>Ipsen Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Hepatocellular carcinoma</p>	<p>To request an Authority Required (STREAMLINED) listing for the treatment of patients with hepatocellular carcinoma who have previously been treated with sorafenib for this condition.</p>	<p>The PBAC did not recommend cabozantinib for the treatment of patients with Barcelona-Clinic Liver Cancer B or C advanced hepatocellular carcinoma who have been previously treated with sorafenib. The PBAC considered the clinical benefits of cabozantinib were modest with considerable toxicity.</p> <p>The PBAC considered at the proposed price the Incremental Cost-Effectiveness Ratio (ICER) per quality adjusted life year was unacceptably high for the level of potential benefit in this setting and substantial cost reductions would be required to bring the ICER into an acceptable range. The PBAC was also concerned that the financial impact of listing cabozantinib is uncertain.</p>
		<p align="center">Sponsor's Comment:</p>	<p>No comment</p>
<p>DURVALUMAB</p> <p>Solution concentrate for I.V. infusion 120 mg in 2.4 mL Solution concentrate for I.V. infusion 500 mg in 10 mL</p>	<p>Urothelial cancer</p>	<p>To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the treatment of locally advanced or metastatic urothelial cancer after the failure of a prior platinum-based chemotherapy.</p>	<p>The PBAC did not recommend durvalumab for the treatment of patients with locally advanced or metastatic urothelial cancer who have disease progression during or following platinum-based chemotherapy.</p> <p>The PBAC considered that the clinical need for durvalumab was limited, given the availability of pembrolizumab, which has a more robust evidence base. The PBAC considered the data presented did not adequately establish non-inferiority between durvalumab and the nominated comparator, pembrolizumab.</p>

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Imfinzi™ AstraZeneca Pty Ltd New listing (Major Submission)		Sponsor's Comment:	No comment
LANADELUMAB Solution for injection 300 mg in 2 mL Takhzyro® Shire Australia Pty Ltd New listing (Major Submission)	Hereditary angioedema (HAE)	To request an Authority Required listing for the prevention of recurrent attacks of HAE (C1-esterase-inhibitor deficiency or dysfunction) in patients aged 12 years and older for whom the use of danazol is not clinically appropriate or not effective. Sponsor's Comment:	The PBAC did not recommend the listing of lanadelumab as routine prophylaxis of recurrent attacks of HAE. The PBAC noted the debilitating nature of HAE attacks and also acknowledged the consumer comments outlining that there is a clinical need for effective and tolerable prophylactic therapies in patients who experience fewer than eight attacks per year (i.e. patients who do not meet the current National Blood Authority criteria for intravenous (IV) C1-esterase-inhibitor (C1-INH)). Thus, the PBAC considered the clinical need, and appropriate clinical role of lanadelumab, to be broader than that for IV C1-IHN, and as such, the cost-minimisation analysis versus C1-INH presented in the submission was uninformative. The PBAC further considered the number of patients meeting the National Blood Authority criteria for prophylactic treatment with C1-INH, as well as the size of the broader population, to be uncertain. Shire (now part of Takeda) will work with the Department of Health and the PBAC so that patients with this rare disease are able to access lanadelumab prophylaxis in Australia.
LEUPRORELIN Subcutaneous implant 3.6 mg (as acetate) in pre-filled syringe Subcutaneous implant 5 mg (as acetate) in pre-filled syringe	Prostate cancer	To request a Restricted Benefit listing for the treatment of patients with locally advanced and metastatic prostate cancer.	The PBAC did not recommend the Section 85, Restricted Benefit listing of the low dose gonadotropin-releasing hormone (GnRH) analogue leuprorelin subcutaneous implant (LERIN) for the treatment of locally advanced and metastatic prostate cancer on the basis of an uncertain clinical need and an uncertain effectiveness compared with PBS-listed high dose GnRH analogues. The PBAC considered that the different dosing and treatment durations of LERIN compared with the comparator and other PBS-listed alternatives could be confusing to prescribers and constitute a potential quality use of medicines issue.

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Lerin® Sandoz Pty Ltd New listing (Major Submission)		Sponsor's Comment:	No comment
OSIMERTINIB Tablet 40 mg Tablet 80 mg Tagrisso® AstraZeneca Pty Ltd Change to listing (Major Submission)	Non-small cell lung cancer (NSCLC)	To request an Authority Required listing for the first-line treatment of patients with Stage IIIB (locally advanced) or Stage IV (metastatic), epidermal growth factor receptor (EGFR) mutation positive (M+) NSCLC.	<p>The PBAC did not recommend osimertinib for the first-line treatment of locally advanced or metastatic EGFR M+ NSCLC. The PBAC noted the improvement in progression free survival associated with treatment with osimertinib compared with treatment with erlotinib or gefitinib. However, the magnitude of benefit in overall survival was uncertain, as the data provided were still immature.</p> <p>The PBAC considered the incremental cost effectiveness ratio per quality adjusted life years was unacceptably high and uncertain at the proposed price. The PBAC also considered that the estimated PBS population for first-line use was likely to be overestimated and the length of treatment was uncertain, resulting in a high overall financial opportunity cost.</p>
		Sponsor's Comment:	No comment

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<p>OXYCODONE</p> <p>Tablet containing oxycodone hydrochloride 10 mg (controlled release)</p> <p>Tablet containing oxycodone hydrochloride 15 mg (controlled release)</p> <p>Tablet containing oxycodone hydrochloride 20 mg (controlled release)</p> <p>Tablet containing oxycodone hydrochloride 30 mg (controlled release)</p> <p>Tablet containing oxycodone hydrochloride 40 mg (controlled release)</p> <p>Tablet containing oxycodone hydrochloride 80 mg (controlled release)</p> <p>OxyContin®</p> <p>Mundipharma Pty Limited</p> <p>Change to listing (Major Submission)</p>	<p>The management of moderate to severe chronic pain unresponsive to non-narcotic analgesia.</p>	<p>To request changes to the authority level and restriction for the existing a-flagged listings for controlled release oxycodone for chronic severe disabling pain to differentiate the brands that are intended to be crush-deterrent.</p>	<p>The PBAC did not recommend the request for changes to the authority level and restriction for the existing a-flagged listings for controlled release oxycodone for chronic severe disabling pain to differentiate the brands that are intended to be crush-deterrent.</p> <p>The PBAC welcomes proposals for strategies to combat opioid misuse in Australia in the context of the Pharmaceutical Benefits Scheme subsidy arrangements. However, the PBAC considered the proposal put forward in the current submission would be highly unlikely to achieve this result; particularly as the PBAC was not satisfied the evidence presented in the submission supported the claim that crush-deterrent oxycodone has superior safety to other forms of oxycodone.</p> <p>In making its decision, the PBAC considered evidence from Australian epidemiological studies and surveys including the National Drug Strategy Household Survey and NOMAD studies, which did not indicate changes in overall population-level harms such as hospitalisation or ambulance attendances following the introduction of crush-deterrent oxycodone. Data in other Australian literature indicated there might have been changes to prescribing of some forms of oxycodone; however, the PBAC was concerned that patients may be switching to alternative forms of oxycodone or other opioids.</p> <p>The Committee noted the evidence presented may indicate injected oxycodone misuse has declined; however also considered much of the tampering of oxycodone was likely to be for misuse by means other than injection (such as by mouth). The PBAC noted there was limited evidence as to whether crush-deterrent forms of oxycodone had been effective in reducing misuse by means other than injection.</p> <p>The PBAC noted the submission did not attempt to quantify potential harms associated with attempting to inject crush-deterrent oxycodone, such as increased risk of thrombotic microangiopathy, or potential harms associated with oral misuse, including, in rare cases, intestinal obstruction.</p>
		<p align="center">Sponsor's Comment:</p>	<p>No comment</p>

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<p>PLITIDEPSIN</p> <p>Powder for I.V. infusion 2 mg with 4 mL solvent</p> <p>Aplidin®</p> <p>Specialised Therapeutics Pharma Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Multiple myeloma</p>	<p>To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required listing in combination with dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma (RRMM) who meet certain conditions.</p>	<p>The PBAC decided not to recommend plitidepsin in combination with dexamethasone for the treatment of patients with RRMM on the basis that the treatment comparison presented in the submission, plitidepsin plus dexamethasone versus dexamethasone alone, demonstrated only a marginal benefit in terms of progression free survival, and the overall survival gain was uncertain given it was statistically significant only when adjusted for cross-over.</p> <p>The PBAC considered that for the indirect comparison presented in the submission against pomalidomide plus dexamethasone, the claim of non-inferior efficacy was uncertain; and the claim of non-inferior safety could not be supported.</p> <p>The PBAC considered there may be a clinical place for plitidepsin as last-line treatment in RRMM, however its use offers a clinically meaningful effect in only a small and undefinable subgroup of patients, with a significant toxicity profile.</p>
		<p align="center">Sponsor's Comment:</p>	<p>No comment</p>
<p>POMALIDOMIDE</p> <p>Capsule 3 mg Capsule 4 mg</p> <p>Pomalyst®</p> <p>Celgene Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Multiple myeloma</p>	<p>To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing in combination with bortezomib and dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma (RRMM) who have received at least one prior treatment regimen (including lenalidomide).</p>	<p>The PBAC did not recommend listing pomalidomide Pomalyst® (pomalidomide) in combination with bortezomib and dexamethasone (PBd) for the treatment of patients with RRMM who have undergone or are ineligible for a stem cell transplant and who have been previously treated with lenalidomide.</p> <p>The PBAC considered, due to differences between the trials, that the indirect comparison with carfilzomib plus dexamethasone (Cd) was difficult to interpret and did not adequately demonstrate non-inferiority between the treatments. The PBAC was also concerned that, in contrast to Cd, PBd did not demonstrate an improvement in overall survival compared with bortezomib and dexamethasone treatment alone.</p>
		<p align="center">Sponsor's Comment:</p>	<p>Celgene is disappointed with the outcome but are committed to working with the PBAC in order to achieve a PBS listing for Pomalyst as a triplet regimen in rrMM, so patients with multiple myeloma have more options in the future.</p>

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<p>RAMUCIRUMAB</p> <p>100 mg in 10 mL vial, 500 mg in 50 mL vial</p> <p>Cyramza®</p> <p>Eli Lilly Australia Pty Ltd</p> <p>Change to recommended listing (Minor Submission)</p>	<p>Advanced metastatic gastric or gastro-oesophageal junction adenocarcinoma</p>	<p>Resubmission to request reconsideration of the basis of the PBAC's March 2018 recommendation for the Authority Required (STREAMLINED) listing in combination with paclitaxel for treatment of advanced or metastatic gastric or gastro-oesophageal junction adenocarcinoma.</p>	<p>The PBAC did not recommend a change to the basis of its March 2018 recommendation for ramucirumab in combination with paclitaxel for the treatment of patients with gastric or gastro-oesophageal junction adenocarcinoma.</p> <p>The PBAC reiterated its previous recommendation for ramucirumab, noting that a substantial price reduction would be required for it to be cost-effective in the proposed PBS population.</p>
		<p align="center">Sponsor's Comment:</p>	<p>Eli Lilly is disappointed with this PBAC decision given the company's substantial financial response to the conditions of the original recommendation. However, we will continue to work with PBAC and the Department of Health to ensure that Australian cancer patients get the best possible access to our medicines in the future.</p>
<p>RIFAXIMIN</p> <p>Tablet 550 mg</p> <p>Xifaxan®</p> <p>Norgine Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Prevention of hepatic encephalopathy</p>	<p>To request a change to the existing listing from Authority Required (Telephone) to Authority Required (STREAMLINED).</p>	<p>The PBAC did not recommend changing the current Authority Required listing of rifaximin to Authority Required (STREAMLINED) for prevention of the recurrence of hepatic encephalopathy. The PBAC advised the current authority should remain unchanged to assist in managing the risks of use outside the restriction and the potential for the development of antimicrobial resistance in the community associated with rifaximin use.</p> <p>The PBAC considered it was unlikely that the requirement for a telephone authority would prevent clinically appropriate prescribing of rifaximin to eligible patients.</p>
		<p align="center">Sponsor's Comment:</p>	<p>No comment</p>