

NOVEMBER 2018 PBAC OUTCOMES – OTHER MATTERS

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 DURVALUMAB NIVOLUMAB PEMBROLIZUMAB</p> <p>Tecentriq® Imfinzi® Opdivo® Keytruda®</p> <p>PBAC matter</p>	<p>Non-small cell lung cancer (NSCLC)</p>	<p>PBAC advice</p>	<p>The PBAC advised the Minister examine the potential for a broad PBS subsidy listing for PD-(L)1 inhibitors for non-small cell lung cancer (NSCLC), as substantial evidence and experience is now available for four PD-(L)1 medicines in this setting. The PBAC considered there is potential for a NSCLC listing that allows patients of WHO performance status 0 and 1 access to a single course of treatment with a PD-(L)1 inhibitor, irrespective of disease stage (unresectable stage III or IV), biomarker status, line of treatment (adjuvant, 1st or later line), and with or without concomitant cytotoxic therapy. This would allow the decision regarding timing the PD-(L)1 inhibitor to be determined by the clinician and patient.</p> <p>The PBAC noted a lack of robust evidence to support the efficacy of sequential courses of PD-(L)1 checkpoint inhibitors, and considered limiting treatment with a PD-(L)1 to once per lifetime appropriate at this time.</p> <p>The PBAC asked the Department to work with stakeholders to progress this matter for further consideration by the PBAC in 2019.</p>

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<p>Post-market Review of Pulmonary Arterial Hypertension (PAH) Medicines</p> <p>AMBRISENTAN</p> <p>BOSENTAN</p> <p>EPOPROSTENOL</p> <p>ILOPROST</p> <p>MACITENTAN</p> <p>RIOCIGUAT</p> <p>SILDENAFIL</p> <p>TADALAFIL</p> <p>(All forms, strengths and listed brands)</p>	<p>Medicines specifically used to treat PAH</p>	<p>To consider the findings from the Post-market Review of PAH medicines</p>	<p>The PBAC considered the Post-market Review of PAH Medicines draft Report, stakeholder submissions to the Review, sponsors' pre-sub-committee and pre-PBAC responses, and ESC and DUSC advice.</p> <p>Overall, the PBAC accepted the key findings presented in the Report. After consideration of the findings from Terms of Reference 1-4, the PBAC did not recommend a review of the cost-effectiveness of existing PBS listed PAH medicines, and in treatment of World Health Organization (WHO) Functional Class (FC) II and combination treatment in WHO FC III and WHO FC IV patients.</p> <p>The PBAC considered the six options presented in the Review Report and made the following recommendations:</p> <p>Option 1: Requested PBS subsidy of PAH therapies for patients presenting in WHO FC II (in monotherapy)</p> <p>The PBAC was of a mind to recommend the extension of PBS restrictions to patients in WHO FC II for monotherapy with targeted PAH medicines. Based on the evidence presented, subsidy should be restricted to PBS listed medicines within the endothelin receptor antagonist (ERA) and phosphodiesterase-5 (PDE-5) inhibitor classes. The PBAC requested the revised PBS restrictions for ERAs and PDE-5 inhibitors be presented to the PBAC again prior to a final recommendation. The estimates of cost to the PBS associated with the revised restrictions should also be provided.</p> <p>Option 2: Request PBS subsidy of dual combination PAH therapies for patients presenting in WHO FC II</p> <p>The PBAC did not recommend extending PBS restrictions to include dual combination therapy for patients with WHO FC II symptoms.</p> <p>Option 3: Request PBS subsidy of dual combination (initial and/or sequential combination) PAH therapy for patients in WHO FC III-IV classification</p> <p>The PBAC was of a mind to recommend initial combination therapy with PBS subsidised ERA and PDE-5 inhibitor medicines for patients with WHO FC III/IV symptoms with increased risk factors, and sequential combination therapy with ERA and add on PDE-5 inhibitor medicine for patients with WHO FCIII/IV symptoms with demonstrated inadequate response to monotherapy. Accordingly, the PBAC suggested a stakeholder meeting be</p>
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			<p>held with sponsors to progress PBS restrictions and prices for dual combination PAH therapy.</p> <p>Option 4: Align PBS restrictions for PAH medicines with clinical treatment guidelines</p> <p>The PBAC recommended that the current requirement for patients to ‘have failed to respond to six or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists’ be removed from the PBS restrictions for all PAH medicines.</p> <p>The PBAC also recommended that treating clinicians seeking an exemption from a right heart catheterisation (RHC) in specific patients, be required to provide a second opinion from an expert cardiologist or PAH physician to reconfirm the reasons why a RHC should not be performed.</p> <p>Option 5: Extend PBS restrictions to include the remaining WHO Group I PAH subtypes</p> <p>The PBAC recommended extending the PBS restrictions for all PAH medicines to include the remaining WHO Group 1 PAH subtypes associated with HIV infection; portal hypertension; and schistosomiasis.</p> <p>Option 6: Review the guidelines for PAH Designated Prescribing Centres with regard to patient numbers</p> <p>The PBAC recommended a review of the guidelines/criteria for establishing PAH Designated Prescribing Centres, particularly with regard to annual numbers of patients and available clinical expertise. Where possible, the criteria should be aligned with international clinical guidelines.</p>
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