

**DECEMBER 2019 PBAC MEETING – OTHER MATTERS**

<b>DRUG, 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>November 2019 MSAC outcomes relevant to November 2019 PBAC recommendations: 5.02 Brigatinib 6.05 Olaparib 7.04 Ibrutinib (idelalisib and venetoclax)</p>	<p>Multiple indications</p>	<p>For the PBAC to note the outcomes of the November 2019 MSAC meeting in relation to these items and provide advice on their listings.</p>	<p>The PBAC noted the outcomes from the November 2019 Medical Services Advisory Committee (MSAC) meeting for three medicines considered by PBAC in November 2019: brigatinib (Alunbrig®), olaparib (Lynparza®) and ibrutinib (Imbruvica®) and considered its impact on related PBS listings.</p>
<p>Age restrictions on inhaled corticosteroid (ICS) + long-acting beta<sub>2</sub> agonist (LABA) fixed dose combination (FDC) products - Correspondence from Clinician</p>	<p>Asthma</p>	<p>For the PBAC to consider correspondence and provide advice on the appropriateness of the current PBS age restrictions specified for ICS+LABA FDC products.</p>	<p>The PBAC recommended that the existing PBS restrictions for inhaled corticosteroid (ICS) + long-acting beta<sub>2</sub> agonist (LABA) fixed dose combination (FDC) products should be retained, as they provide guidance for clinicians around the appropriate use of FDC products in children. However, the PBAC noted concerns raised by clinicians that treatment for children under the age of 12 who have failed on fluticasone propionate + salmeterol was not covered by the existing PBS restrictions, and considered that there was an unmet clinical need in this patient group. The PBAC therefore recommended a separate Authority Required (STREAMLINED) code for ICS+LABA FDC products other than fluticasone propionate + salmeterol that is silent on age and restricts use to those who have failed fluticasone propionate + salmeterol. The PBAC recommended that prescribing for this second-line listing would be limited to respiratory specialists and paediatricians.</p>

**DECEMBER 2019 PBAC MEETING – OTHER MATTERS**

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
Consideration of medicines for the treatment of epilepsy	Epilepsy	To seek the PBAC's advice on issues raised in correspondence to the PBAC on prescribing PBS-subsidised anti-epileptic drugs (AEDs) (ie. medicines) to treat epilepsy.	<p>The PBAC noted that the correspondence raised several issues:</p> <ol style="list-style-type: none"> <li>I. the use of valproate in women of child-bearing age is no longer recommended by the European Medicines Agency (EMA), however the preferred alternatives (lamotrigine and levetiracetam) are only PBS-listed as second line therapy options (i.e. patients must have failed less restricted first line AEDs like valproate before moving onto second line AEDs);</li> <li>II. the current PBS listings for newer AEDs restrict the choice of AEDs that can be prescribed as first line therapy through the PBS to certain conditions, contrary to current practice where prescribers are following international guidelines; and</li> <li>III. a positive recommendation made by the PBAC in November 2008 to extend the PBS restriction for levetiracetam to include patients with generalised epilepsies, providing more options for prescribers, was not progressed by the Sponsor.</li> </ol> <p>Issues I &amp; II – PBS listings and international guidelines on AED use</p> <p>The PBAC noted that the newer AEDs referenced in the article (lamotrigine, levetiracetam and topiramate) are PBS listed with an Authority Required (STREAMLINED) level of restriction and are limited to use in the second line setting. However, the PBAC acknowledged that there may be some PBS subsidised use outside of the PBS indication (second-line). The PBAC recalled that the basis of the recommendations for PBS listing of these medicines as second line AEDs, included the level of evidence available to justify a lower level of restriction or first line listing. The PBAC noted that in the absence of a successful submission to PBAC for first line listing for women of child-bearing age, this population is limited to using newer AEDs as second line treatment only.</p> <p>The PBAC recalled that the basis of its role in making recommendations to the Minister for Health about PBS listings under the National Health Act 1953, is based on Section 101 (3A), PBAC's consideration of the "effectiveness and cost of therapy involving the use of the drug, preparation or class, including by comparing the effectiveness and cost of that therapy with that of alternative therapies, whether or not involving the use of other drugs or preparations".</p>

**DECEMBER 2019 PBAC MEETING – OTHER MATTERS**

<p align="center"><b>DRUG, SPONSOR, TYPE OF SUBMISSION</b></p>	<p align="center"><b>DRUG TYPE OR USE</b></p>	<p align="center"><b>LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION</b></p>	<p align="center"><b>PBAC OUTCOME</b></p>
			<p>The PBAC noted that a recommendation for listing cannot be based on current prescribing practice unless there is current clinical evidence to support the listing. The PBAC noted that the cost of existing first line AEDs was lower than for second line AEDs, and that listing of new AEDs first line would need to be at a reduced price or would need to have demonstrated superior benefit. The PBAC recalled that the current listings for AEDs were also influenced by the design of the original trials, and accordingly which line of treatment they supported, and/or whether these submissions requested first line listings.</p> <p>Issue III – levetiracetam recommendation for use in generalised epilepsies</p> <p>The PBAC recalled its November 2008 recommendation to extend the Authority Required listing of levetiracetam to include generalised seizures. The Sponsor of levetiracetam did not accept that lamotrigine, rather than topiramate, was the appropriate comparator (section 14, levetiracetam, PSD, November 2008 PBAC meeting) and stated that it was re-evaluating its options.</p> <p>The PBAC noted that a positive PBAC recommendation is a very important step in the listing process. However, other steps generally need to be taken before a listing is achieved, such as pricing negotiations with the product’s sponsor, finalisation of the conditions for listing, quality and availability checks and consideration by the Government.</p> <p>In consideration of the issues identified in the article, the PBAC noted it would accept submissions to extend the PBS listings of any of the medications used to treat epilepsy at any time, but that Sponsors cannot be compelled to apply for expansions of the scope of existing PBS listings. Sponsors also cannot be compelled to progress recommended listings to become PBS listings.</p>

**DECEMBER 2019 PBAC MEETING – OTHER MATTERS**

<b>DRUG, SPONSOR, TYPE OF SUBMISSION</b>	<b>DRUG TYPE OR USE</b>	<b>LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION</b>	<b>PBAC OUTCOME</b>
TGA prescription opioid regulatory reform	Pain	For PBAC to consider changes to opioid indications and potential changes to PBS restrictions resulting from the TGA Opioid Review.	<p>The Pharmaceutical Benefits Advisory Committee (PBAC) considered the current restrictions for opioids on the Pharmaceutical Benefits Scheme (PBS) in the context of the regulatory measures being undertaken by the Therapeutic Goods Administration (TGA). The PBAC expressed its concern regarding the high number of deaths and hospitalisations caused by prescription opioids in Australia, and acknowledged the significant work being undertaken by the TGA to help tackle the problem.</p> <p>The PBAC noted that the TGA would be requiring sponsors to register new smaller pack sizes for some immediate-release opioid analgesics. The PBAC recommended new Restricted Benefit listings for smaller maximum quantities (MQs) of those immediate release opioids listed on the PBS (codeine, codeine with paracetamol, hydromorphone, morphine, oxycodone, and tramadol), with no increased quantities or repeats, for patients requiring short-term relief of acute severe pain that is unresponsive to non-opioid analgesics. The PBAC considered that additional PBS listings with smaller MQs could reduce the number of patients being prescribed a greater quantity of opioids than required for acute severe pain.</p> <p>The PBAC noted that the TGA had revised the indications of several opioid analgesics to broadly categorise them into opioids for acute severe pain and for chronic severe pain. The PBAC recommended that the PBS restrictions for immediate- and modified-release opioids should be changed in the following manner to align with the TGA indication changes:</p> <ul style="list-style-type: none"> <li>• Opioids for short-term use in the first-line setting (codeine tablets, codeine + paracetamol tablets, tramadol capsule, injection, and oral drops, and oxycodone tablets, capsules, suppository, and oral solution) to be Restricted Benefits limited to patients who have not responded to, are intolerant to or whose condition would not respond to non-opioid analgesics;</li> <li>• Opioids for short-term use in the second-line setting (hydromorphone tablets, injections, and oral liquid, morphine tablets, oral solution and injections) to be Restricted Benefits for patients who have not responded to, are intolerant to or whose condition would not respond to non-opioid nor other opioid</li> </ul>

**DECEMBER 2019 PBAC MEETING – OTHER MATTERS**

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
			<p>analgesics.</p> <ul style="list-style-type: none"> <li>• Opioids for long-term use in the first-line setting (buprenorphine transdermal patches, morphine capsules, tablets and granules, oxycodone tablets, oxycodone with naloxone tablets, tapentadol tablets, and tramadol tablets) to have authority level increased to Authority Required (STREAMLINED) for daily, continuous, long-term management of pain due to cancer or who have not responded to, are intolerant to or who experience inadequate pain management at maximum doses of non-opioid or other opioid analgesics.</li> <li>• Opioids for long-term use in the second-line setting (hydromorphone tablets, methadone tablets and injection, fentanyl transdermal patches) to have authority level increased to Authority Required (STREAMLINED) with the same restrictions as opioids in the long-term first-line setting with the additional requirement that the patient must not be opioid-naïve.</li> </ul> <p>The PBAC considered that its recommended changes to opioid listings on the PBS would complement the TGA's efforts to support the safe and clinically appropriate use of opioids while recognising the important role they play in providing pain relief for many people.</p> <p>The PBAC noted that the regulatory changes and recommended changes to PBS listings will be implemented as part of a broader suite of measures intended to support appropriate use of opioids, including education and awareness campaigns, changes to clinical guidelines and ongoing prescription and compliance monitoring.</p>