

JULY 2020 PBAC OUTCOMES - DEFERRALS

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>ARMODAFINIL and MODAFINIL</p> <p>modafinil Tablet 100 mg</p> <p>armodafinil Tablet 50 mg Tablet 150 mg Tablet 250 mg</p> <p>Various brands</p> <p>Australasian Sleep Association</p> <p>Change to listing (Minor Submission)</p>	<p>Narcolepsy</p>	<p>To request that the PBS listings of armodafinil and modafinil be changed to first-line treatment for narcolepsy in line with current clinical guidelines.</p>	<p>The PBAC deferred making a recommendation to change the listing of modafinil and armodafinil on the PBS to allow use as first-line therapy for the treatment of narcolepsy.</p> <p>The Committee considered that due to the significant cost difference between modafinil and armodafinil and dexamfetamine, permitting use of modafinil and armodafinil in the first line setting would have significant financial implications.</p> <p>The PBAC requested the Department seek further information on the available data to assess cost-effectiveness and financial implications of a first line listing of modafinil/armodafinil for the treatment of narcolepsy.</p> <p>The PBAC recommended that the restrictions clarify that sleep study reports need not be resubmitted when a patient is switched between drugs (modafinil/armodafinil). The PBAC further clarified that results for polysomnography, Multiple Sleep Latency Test or electroencephalographic test need not be provided to Services Australia for patients with a diagnosis of narcolepsy combined with a history of cataplexy.</p>
		<p align="center">Sponsor's comment:</p>	<p>The sponsor had no comment.</p>
<p>CANNABIDIOL</p> <p>Oral solution, 100 mg per mL, 100 mL</p> <p>Epidyolex®</p> <p>Emerge Health Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Lennox-Gastaut syndrome (LGS) Dravet syndrome (DS)</p>	<p>To request a Section 100 (Highly Specialised Drugs Program - Community Access) Authority Required (STREAMLINED) listing for the adjunctive treatment of seizures in patients with LGS or DS in patients aged 2 years or older.</p>	<p>The PBAC deferred making a recommendation for the listing of cannabidiol for the treatment of DS and LGS in combination with other anti-epileptic drugs on the PBS to enable consultation with stakeholders regarding the role of cannabidiol in the treatment of these rare forms of epilepsy. The PBAC considered further clarity on the clinical place of cannabidiol in therapy is required to inform the appropriate initial and continuing restriction criteria, cost-effectiveness and financial implications of listing cannabidiol.</p> <p>The PBAC considered there was a clinical need for additional effective and safe treatment options for people with DS and LGS and the clinical evidence presented in the submission demonstrated cannabidiol is likely to be beneficial; however, the magnitude of the benefit was uncertain.</p>

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		Sponsor's comment:	Chiesi Australia (formerly Emerge Health) will work collaboratively with the PBAC, the Department of Health, and the Federal Government to ensure patients living with DS and LGS receive access to Epidyolox® through the PBS at the earliest opportunity.
<p>INDACATEROL + GLYCOPYRRONIUM + MOMETASONE</p> <p>Capsule containing powder for oral inhalation mometasone furoate 80 micrograms with indacaterol 150 micrograms (as acetate) with glycopyrronium 50 micrograms (as bromide) (for use in Breezhaler)</p> <p>Capsule containing powder for oral inhalation mometasone furoate 160 micrograms with indacaterol 150 micrograms (as acetate) with glycopyrronium 50 micrograms (as bromide) (for use in Breezhaler)</p> <p>Energair Breezhaler®</p> <p>Novartis Pharmaceuticals Australia Pty Ltd</p> <p>New listing (Major Submission)</p>	Asthma	<p>To request an Authority Required (STREAMLINED) listing for the treatment of patients with severe asthma who are inadequately controlled on a long acting beta agonist in combination with an inhaled corticosteroid (LABA/ICS).</p> <p>Sponsor's comment:</p>	<p>The PBAC deferred making a recommendation for the listing of mometasone furoate (MF), with indacaterol acetate (IND) and glycopyrronium (GLY) fixed dose combination (FDC) for maintenance therapy of severe asthma as it was unclear if TGA registration would include medium dose MF/IND/GLY. However, the PBAC was of a mind to recommend the listing of high dose MF/IND/GLY for this indication on a cost-minimisation basis compared with the least costly combination of high dose ICS with LABA FDC plus long-acting muscarinic antagonist.</p> <p>The sponsor had no comment.</p>

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<p>LANADELUMAB</p> <p>Solution for subcutaneous injection 300 mg in 2 mL 300 mg in 2 mL pre-filled syringe</p> <p>Takhzyro®</p> <p>Shire Australia Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Hereditary angioedema (HAE)</p>	<p>Resubmission to request an Authority Required listing for the prevention of recurrent attacks of HAE (C1-esterase-inhibitor (C1-INH) deficiency or dysfunction) in patients aged 12 years and older.</p>	<p>The PBAC deferred making a recommendation for the listing of lanadelumab for routine (long-term) prophylaxis of recurrent attacks of HAE. The PBAC sought further information regarding the most appropriate patient population with regard to baseline HAE attack rate and continuation criteria. The PBAC also considered that the incremental cost-effectiveness ratio was high and uncertain and noted it was highly dependent on the baseline attack rate and the dosage regimen assumed to be used in practice.</p> <p>The PBAC considered that there is a high clinical need for effective and tolerable prophylactic therapies for HAE, particularly in patients who have a high burden of disease but do not meet the eligibility requirements for C1-INH through the National Blood Authority.</p>
		<p align="center">Sponsor's comment:</p>	<p>The sponsor had no comment.</p>
<p>RIBOCICLIB</p> <p>Tablet 200 mg</p> <p>Kisqali®</p> <p>Novartis Pharmaceuticals Australia Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Breast cancer</p>	<p>To request an Authority Required listing for the treatment of postmenopausal women with hormone receptor positive (HR+), human epidermal growth factor receptor 2 negative (HER2-) advanced or metastatic breast cancer in combination with fulvestrant.</p>	<p>The PBAC deferred making a recommendation to extend the listing of ribociclib to include use in combination with fulvestrant for the treatment of patients with (HR+ and HER2- unresectable advanced or metastatic breast cancer. The PBAC recognised the clinical need for this combination therapy. The PBAC considered recommending ribociclib in combination with fulvestrant, but considered that there remains a need to resolve the appropriate weighted price, financial impact and changes to risk sharing arrangements for ribociclib.</p>
		<p align="center">Sponsor's comment:</p>	<p>Novartis are committed to working with the PBAC to achieve sustainable PBS listing conditions and timely patient access to Kisqali® (ribociclib) in combination with fulvestrant.</p>
<p>RIFAMPICIN</p> <p>Capsule 150 mg Capsule 300 mg</p> <p>Rimycin 150®</p>	<p>For the treatment of Mycobacterium ulcerans infections (Buruli ulcer)</p>	<p>Request to extend the indication for rifampicin to include the treatment of Mycobacterium ulcerans infections (Buruli ulcer).</p>	<p>The PBAC deferred making a recommendation to extend the rifampicin listing pending receipt of the TGA Delegate's Overview, however was of a mind to recommend listing for the treatment of Mycobacterium ulcerans infections (Buruli ulcer).</p>

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Rymicin 300® Mylan Change to listing (Minor Submission)		Sponsor's comment:	The sponsor had no comment.