

NOVEMBER 2019 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>BELIMUMAB</p> <p>Injection 200 mg in 1 mL pre-filled pen</p> <p>Benlysta®</p> <p>GlaxoSmithKline Australia Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Systemic lupus erythematosus (SLE)</p>	<p>To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of patients with highly active auto-antibody positive SLE.</p>	<p>The PBAC did not recommend belimumab for the treatment of patients with active auto-antibody positive SLE with a high degree of disease activity, despite ongoing standard therapy. The PBAC considered there is a clinical need for effective and safe treatments for SLE, particularly for patients with severe active disease who have failed, or are intolerant to, other therapies. The PBAC considered that the evidence demonstrated a modest clinical benefit. However, the PBAC considered that the economic model presented in the submission did not provide a reliable basis for estimating the cost-effectiveness of belimumab, and the financial estimates were uncertain and likely overestimated.</p>
		<p align="center">Sponsor's Comment:</p>	<p>No comment</p>
<p>BROLUCIZUMAB</p> <p>Solution for intravitreal injection 19.8 mg in 0.165 mL pre-filled syringe</p> <p>Beovu®</p> <p>Novartis Pharmaceuticals Australia Pty Limited</p> <p>New listing (Major Submission)</p>	<p>Subfoveal choroidal neovascularisation (CNV)</p>	<p>To request an Authority Required listing for the treatment of patients with CNV due to age-related macular degeneration.</p>	<p>The PBAC did not recommend brolocizumab for the treatment of patients with CNV due to age-related macular degeneration. The PBAC noted the higher incidence of ocular serious adverse events reported for brolocizumab compared with aflibercept in the clinical studies and considered the claim of non-inferior safety was uncertain.</p>
		<p align="center">Sponsor's Comment:</p>	<p>Novartis is disappointed with the PBAC decision but will work collaboratively with the PBAC and the Department of Health to ensure that Australians with CNV due to age-related macular degeneration receive access to Beovu® (brolocizumab) through the PBS at the earliest opportunity.</p>

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<p>BUPRENORPHINE + NALOXONE</p> <p>Tablet (sublingual) containing 0.7 mg buprenorphine hydrochloride with 0.18 mg naloxone hydrochloride</p> <p>Tablet (sublingual) containing 1.4 mg buprenorphine hydrochloride and 0.36 mg naloxone hydrochloride</p> <p>Tablet (sublingual) containing 2.9 mg buprenorphine hydrochloride and 0.71mg naloxone hydrochloride</p> <p>Tablet (sublingual) containing 5.7 mg buprenorphine hydrochloride and 1.4 mg naloxone hydrochloride</p> <p>Tablet (sublingual) containing 8.6 mg and 2.1mg naloxone hydrochloride</p> <p>Tablet (sublingual) containing 11.4 mg buprenorphine hydrochloride and 2.9 mg naloxone hydrochloride</p> <p>Zubsolv®</p>	<p>Opiate dependence</p>	<p>To request a Section 100 (Opiate Dependence Treatment Program) Restricted Benefit listing for the treatment of patients with opiate dependence.</p>	<p>The PBAC did not recommend the listing of buprenorphine with naloxone sublingual tablets (Zubsolv®) for the treatment of patients with opioid dependence on the basis that the clinical need for an additional form of buprenorphine with naloxone was unclear, non-inferior clinical effectiveness of Zubsolv® to the nominated comparator (Suboxone® film) was not demonstrated and the equi-effective doses were uncertain. The PBAC further considered there were significant concerns relating to dose titration issues should patients switch therapies, as well as prescriber confusion regarding strengths leading to incorrect dosing of patients.</p>
		<p>Sponsor's Comment:</p>	<p>Mundipharma will continue to work with the PBAC and the Department of Health in pursuing PBS-subsidised access for an alternative opioid substitution therapy at the earliest opportunity.</p>

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Mundipharma Pty Limited New listing (Major Submission)			
CERTOLIZUMAB PEGOL Injection 200 mg in 1 mL single use pre-filled syringe Solution for injection 200 mg in 1 mL pre-filled pen Cimzia® UCB Australia Proprietary Limited Change to recommended listing (Minor Submission)	Chronic plaque psoriasis (CPP)	Resubmission to request reconsideration of the basis of the PBAC's March 2019 recommendation for the Authority Required listing for the treatment of patients with CPP.	The PBAC did not recommend a change to the basis of its March 2019 recommendation for the Authority Required listing of certolizumab pegol (CZP) for the treatment of patients with severe CPP. The PBAC reaffirmed its March 2019 recommendation that CZP 400 mg should be listed on a cost-minimisation basis with the least costly alternative biologic for this indication and that it would be appropriate to price CZP 200 mg on the same per mg basis as CZP 400 mg.
		Sponsor's Comment:	No comment

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<p>NUSINERSEN</p> <p>Solution for injection 12 mg in 5 mL</p> <p>Spinraza®</p> <p>Biogen Australia Pty Ltd</p> <p>Change to listing (Matters Outstanding)</p>	<p>Spinal muscular atrophy (SMA)</p>	<p>Consider the deferred request for a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of patients with pre-symptomatic, infantile and childhood-onset, SMA.</p>	<p>The PBAC did not recommend extending the current listing of nusinersen to include the pre-symptomatic initiation of treatment of patients genetically diagnosed with a severe form of SMA. The PBAC noted the advice from the Medical Services Advisory Committee (MSAC) that Survival of motor neuron – 2 gene (SMN2) copy number variation offers some prognostic value for SMA severity and that the prognostic information indicated reduced risk of overtreatment of infants with ≤ 2 copies of SMN2 compared with 3 copies of SMN2.</p> <p>Based on additional advice from clinical experts, the PBAC considered that pre-symptomatic initiation of treatment with nusinersen would likely provide an additional benefit for some patients compared with waiting for symptoms to appear before initiating treatment. However, the PBAC maintained that the magnitude of incremental benefit compared with symptomatic treatment could not be determined from the available evidence. Further, the PBAC considered the economic model did not provide a reliable basis to inform the cost-effectiveness of pre-symptomatic initiation of treatment with nusinersen.</p> <p>The PBAC noted the advice from MSAC that the proportion of false positive patients (i.e. patients predicted based on the SMN2 result to progress to manifest SMA symptoms sufficient to qualify for the existing PBS listing, but who would not actually have progressed as predicted) who would be treated under a listing for pre-symptomatic initiation of treatment with nusinersen would be low. However, the PBAC considered the prospect of treating any such patient who would not sufficiently benefit from pre-symptomatic initiation of treatment was a risk given the long-term safety of repeated lumbar puncture in the context of a lifelong disease was unknown. The PBAC considered that it may be appropriate to restrict any future listing of nusinersen for the pre-symptomatic initiation of treatment for patients with SMA to those with ≤ 2 copies of SMN2.</p>
		<p align="center">Sponsor's Comment:</p>	<p>Biogen is disappointed with the decision and looks forward to working with the PBAC to make nusinersen available for all patients with SMA who could benefit from it.</p>

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<p>OLAPARIB</p> <p>Tablet 100 mg Tablet 150 mg</p> <p>Lynparza®</p> <p>AstraZeneca Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Ovarian, fallopian tube or primary peritoneal cancer</p>	<p>To request an Authority Required listing for the maintenance treatment of advanced high grade epithelial ovarian, fallopian tube or primary peritoneal cancer, in class 4 or 5 BRCA1/2 mutation positive patients who are in response to platinum-based chemotherapy.</p>	<p>The PBAC did not recommend the listing of olaparib (Lynparza®) for the first-line maintenance treatment of ovarian, fallopian tube or primary peritoneal cancer. The PBAC acknowledged the ongoing clinical need for effective first-line treatments for ovarian cancer. The PBAC considered that olaparib provided a substantial benefit to some patients in delaying recurrence, which it considered is likely to be a clinically important outcome. The PBAC considered that the modelled cost-effectiveness was uncertain due to an overly complex model including optimistic assumptions of the extent of the overall survival benefit which were not supported by the clinical evidence. The PBAC advised that the incremental cost-effectiveness ratio was high at the sponsor's proposed price. The PBAC considered the extent of use in the first-line setting was overestimated and the reduction in use in the second-line setting was underestimated.</p>
<p>PATIROMER (AS SORBITEX CALCIUM)</p> <p>Powder for oral liquid 8.4 g Powder for oral liquid 16.8 g</p> <p>Veltassa®</p> <p>Vifor Pharma Pty Limited</p> <p>New listing (Major Submission)</p>	<p>Hyperkalaemia</p>	<p>To request an Authority Required listing for the prevention of hyperkalaemia in patients with stage III or greater chronic kidney disease who have experienced a recent episode of hyperkalaemia requiring pharmacological intervention.</p>	<p>The PBAC did not recommend the listing of patiromer for the treatment of hyperkalaemia in patients with chronic kidney disease Stage 3+ who are receiving one or more renin angiotensin aldosterone system inhibitor (RAASi) medicines (or are indicated for a RAASi medicine but are unable to tolerate this due to complications of hyperkalaemia), have experienced a recent episode of hyperkalaemia requiring pharmacological intervention and need chronic management of serum potassium in order to prevent subsequent hyperkalaemia episodes.</p> <p>The PBAC considered the proposed population was not adequately defined and, in order to target patients with the highest clinical need, there would need to be better definition and a substantial narrowing of the eligible population. The PBAC also considered the incremental cost-effectiveness ratio and financial estimates were unacceptably high, uncertain and inadequately justified.</p>
		<p align="center">Sponsor's Comment:</p>	<p>No comment</p>
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<p>POLATUZUMAB VEDOTIN</p> <p>Powder for I.V. infusion 140 mg</p> <p>Polivy®</p> <p>Roche Products Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Diffuse large B-cell lymphoma (DLBCL)</p>	<p>To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of patients with relapsed or refractory (R/R) DLBCL who are ineligible for stem cell transplantation (SCT).</p>	<p>The PBAC did not recommend the listing of polatuzumab vedotin in combination with bendamustine and rituximab (Pola+BR) for the treatment of patients with R/R DLBCL who are ineligible for SCT. The PBAC did not accept bendamustine in combination with rituximab (BR), the nominated comparator, as an appropriate proxy for standard of care in R/R DLBCL because BR does not reflect current clinical practice in Australia as bendamustine is not TGA registered or PBS-listed for this indication. In addition, the PBAC considered that the validity of the clinical effectiveness data presented was highly uncertain as the results were likely confounded in favour of Pola+BR. Given these limitations with the clinical data, the PBAC considered the estimated cost-effectiveness ratio was very uncertain.</p>
<p>RUXOLITINIB</p> <p>Tablet 5 mg Tablet 10 mg Tablet 15 mg Tablet 20 mg</p> <p>Jakavi®</p> <p>Novartis Pharmaceuticals Australia Pty Limited</p> <p>Change to listing (Major Submission)</p>	<p>Polycythemia vera (PV)</p>	<p>To request an Authority Required listing for the treatment of patients with PV who are resistant to or intolerant of hydroxycarbamide (hydroxyurea).</p>	<p>The PBAC did not recommend the listing of ruxolitinib for the treatment of patients with PV who are resistant to, or intolerant of, hydroxyurea. The PBAC considered that the evidence from the key trial did not clearly support a benefit in terms of clinically relevant outcomes or overall survival. Further, the PBAC considered that the economic model did not provide a reliable basis for assessing the cost-effectiveness of ruxolitinib as the clinical benefits modelled were not supported by evidence.</p>
		<p align="center">Sponsor's Comment:</p>	<p align="center">No comment</p>
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<p>SIPONIMOD</p> <p>Tablet 250 micrograms Tablet 2 mg</p> <p>Mayzent®</p> <p>Novartis Pharmaceuticals Australia Pty Limited</p> <p>New listing (Major Submission)</p>	<p>Secondary progressive multiple sclerosis (SPMS)</p>	<p>To request an Authority Required listing for the treatment of patients with SPMS.</p>	<p>The PBAC did not recommend the listing of siponimod for the treatment of SPMS. The PBAC acknowledged the high clinical need for effective treatments in this therapeutic area. The PBAC considered the evidence presented supported the clinical claim that siponimod is superior compared with placebo with regards to confirmed disability progression and annualised relapse rate for patients with SPMS. However, the PBAC considered that the appropriate place of siponimod in the treatment algorithm for multiple sclerosis was uncertain, and the submission did not provide a reliable basis to assess the cost-effectiveness of siponimod. The PBAC also considered the financial estimates to be uncertain.</p>
<p>TALAZOPARIB</p> <p>Capsule 250 micrograms (as tosilate) Capsule 1 mg (as tosilate)</p> <p>Talzenna®</p> <p>Pfizer Australia Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Advanced breast cancer</p>	<p>To request an Authority Required listing for the treatment of patients with germline breast cancer susceptibility gene mutated (gBRCAm) human epidermal growth factor receptor negative (HER2-) advanced breast cancer who have been previously treated with a taxane and/or an anthracycline.</p>	<p>The PBAC did not recommend the Authority Required listing of talazoparib for the treatment of patients with gBRCAm HER2- locally advanced inoperable or metastatic breast cancer.</p> <p>The PBAC noted there was a moderate benefit in terms of progression free survival however it was unclear whether talazoparib would lead to any gains in overall survival as the data provided were still immature. The PBAC expressed interest in reviewing updated survival data when it becomes available.</p> <p>The PBAC considered that the incremental cost-effectiveness ratio per quality adjusted life year at the proposed price was unacceptably high and uncertain and potentially underestimated. Further, the PBAC considered that the financial impact of listing was underestimated as the submission did not account for gBRCA mutation testing costs for all patients who would be tested and underestimated the duration of treatment with talazoparib.</p>
		<p align="center">Sponsor's Comment:</p>	<p>Novartis is disappointed with the PBAC outcome but will continue to work collaboratively with the PBAC and the Department of Health to ensure that Australians with multiple sclerosis receive access to Mayzent® (siponimod) through the PBS at the earliest opportunity.</p>
		<p align="center">Sponsor's Comment:</p>	<p>No comment</p>