

MONTH YEAR PBAC OUTCOMES - DEFERRALS

JULY 2019 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>DOLUTEGRAVIR WITH LAMIVUDINE</p> <p>Tablet containing dolutegravir 50 mg (as sodium) with lamivudine 300 mg Dovato®</p> <p>ViiV Healthcare Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Human immunodeficiency virus (HIV) infection</p>	<p>To request a Section 100 (Highly Specialised Drugs Program - Community Access) Authority Required (STREAMLINED) listing for the treatment of patients with HIV infection.</p>	<p>The PBAC deferred making a recommendation for a fixed-dose combination of dolutegravir with lamivudine (Dovato®) for the treatment of HIV infection, pending further clarity about the parameters of the TGA registration. The Committee was of a mind to recommend Dovato® for treatment-naïve patients, however considered it was appropriate to await further clarity about the TGA decision prior to making a recommendation.</p> <p>The PBAC agreed the Product Information documents adequately outline age and weight restrictions for therapies containing dolutegravir and recommended this information be removed from current PBS listings, including the listings of abacavir/lamivudine/dolutegravir (Triumeq®).</p>
		<p align="center">Sponsor's Comments:</p>	<p>No comment</p>
<p>EVOLOCUMAB</p> <p>Injection 420 mg in 3.5 mL single use prefilled cartridge Injection 140 mg in 1 mL single use pre-filled pen</p> <p>Repatha®</p> <p>Amgen Australia Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Hypercholesterolaemia</p>	<p>Resubmission to request an Authority Required listing for the treatment of patients with hypercholesterolaemia who are very high risk and symptomatic for atherosclerotic cardiovascular disease (ASCVD) and who are inadequately controlled on optimal doses of high potency statins and ezetimibe.</p>	<p>The PBAC deferred making a recommendation on the listing of evolocumab for the treatment of non-familial hypercholesterolaemia (non-FH) in patients with ASCVD and additional high-risk factors.</p> <p>The PBAC considered there were important clinical benefits associated with evolocumab therapy in appropriate high-risk patient groups. However, the PBAC considered that the incremental cost-effectiveness ratio (ICER) was high and sufficiently uncertain that a price reduction would be required to bring the ICER into an acceptable range. Further, the PBAC considered that the total financial impact was high and represented a significant opportunity cost for the Commonwealth.</p> <p>The PBAC also deferred making a recommendation on the resubmission's request to extend the existing familial hypercholesterolaemia (FH) listing in the ASCVD population to include patients with low-density lipoprotein (LDL) levels between 2.6 mmol/L and 3.3 mmol/L. The PBAC considered that patients with FH who have symptomatic ASCVD and LDL-c levels over 2.6 mmol/L would likely have at least an equivalent lifetime risk as the non-FH population identified in the revised restriction. As such, the PBAC considered that, should evolocumab be considered cost-effective in the non-FH population, then the cost-effectiveness of evolocumab could be inferred for the expanded FH listing, at the same price as accepted for non-FH.</p>

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		Sponsor's Comment:	Amgen intends to continue to work with the PBAC to enable subsidised access to evolocumab for patients with high cardiovascular risk factors.
<p>FERRIC DERISOMALTOSE</p> <p>Injection 1000 mg (iron) in 10 mL Injection 500 mg (iron) in 5 mL</p> <p>Monofer®</p> <p>Pfizer Australia Pty Ltd</p> <p>New listing (Minor Submission)</p>	Iron deficiency anaemia	<p>To request an unrestricted benefit listing for a new strength of ferric derisomaltose and to request a change in the maximum quantity and repeats for the currently listed 500 mg strength of ferric derisomaltose.</p> <p>Sponsor's Comment:</p>	<p>The PBAC deferred making a recommendation on the unrestricted Section 85 listing for ferric derisomaltose, pending negotiations with the Department regarding financial arrangements. However, the PBAC was of the mind to recommend the request for a new strength of ferric derisomaltose, 1000 mg/10 mL solution for injection; and the requested changes to the maximum quantity and repeats for the current listing of the 500 mg/5 mL vial of ferric derisomaltose.</p> <p>No comment</p>
<p>INFLUENZA QUADRIVALENT ADJUVANTED VACCINE</p> <p>Injection 0.5 mL Fluad® Quad</p> <p>INFLUENZA TRIVALENT ADJUVANTED VACCINE</p> <p>Injection 0.5 mL Fluad®</p> <p>Seqirus (Australia) Pty Ltd</p> <p>New listing and change to listing (Major Submission)</p>	Prevention of seasonal influenza	<p>To request National Immunisation Program (NIP) listing for the prevention of seasonal influenza in patients aged 65 years and over; and to request that the PBAC review the circumstances of its March 2018 recommendation for NIP listing for Fluad® adjuvanted trivalent influenza vaccine (aTIV) for the prevention of seasonal influenza in patients aged 65 years and over.</p> <p>Sponsor's Comments:</p>	<p>The PBAC did not recommend the requested price increase for aTIV (Fluad®) on the NIP for vaccination against influenza in adults aged 65 years and above. This was on the basis that the extent of benefit of the aTIV over non-adjuvanted QIV was uncertain, given that the impact of the loss of the additional B strain differed across influenza seasons. The PBAC considered that this uncertainty made it difficult to assess the cost-effectiveness of the aTIV, and that although a small price premium for the aTIV over QIV may be reasonable, the proposed price premium was not justified.</p> <p>The PBAC deferred making a recommendation for a new listing for aQIV (Fluad Quad®) on the NIP for vaccination against influenza in adults aged 65 years and above, pending provision of the TGA Delegate's Overview. The PBAC considered that aQIV would provide additional clinical effectiveness to QIV, and the magnitude of the benefit would not be different to that for aTIV over a trivalent influenza vaccine (TIV). As such, the economic analysis provided in the submission for aTIV versus TIV could be relied upon to determine the cost-effectiveness of aQIV versus QIV.</p> <p>No comment</p>
<p>NIVOLUMAB</p> <p>Injection concentrate for I.V. infusion 40 mg in 4 mL</p>	Melanoma	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program), Authority Required	The PBAC deferred making a recommendation for nivolumab for the adjuvant treatment of patients who have had completely surgically resected Stage IIIB, IIIC, IIID or Stage IV malignant melanoma to allow for further discussions regarding an acceptable price and Risk Sharing Arrangement.

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Injection concentrate for I.V. infusion 100 mg in 10 mL Opdivo® Bristol-Myers Squibb Australia Pty Ltd Change to listing (Minor Submission)		(STREAMLINED) listing for the adjuvant treatment of patients who have had completely surgically resected Stage III or Stage IV malignant melanoma.	
		Sponsor's Comment:	No comment
NUSINERSEN Solution for injection 12 mg in 5 mL Spinraza® Biogen Australia Pty Ltd Change to listing (Major Submission)	Spinal muscular atrophy (SMA)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of patients with pre-symptomatic, infantile and childhood-onset SMA.	The PBAC deferred making a recommendation to extend the current listing of nusinersen to include the pre-symptomatic initiation of treatment of patients who have up to three copies of the survival-of-motor-neuron 2 (SMN2) gene, pending advice from the Medical Services Advisory Committee (MSAC) on the prognostic value of SMN2 copy number for the severity of SMA to help determine eligibility for nusinersen in pre-symptomatic patients. The PBAC considered it would be appropriate to await the advice it sought from the MSAC prior to making a recommendation. However, the PBAC was of a mind to not recommend extending the current listing of nusinersen on the basis there was insufficient evidence to demonstrate pre-symptomatic initiation of treatment with nusinersen would be more effective than treatment with nusinersen following the onset of symptoms of SMA. Further, the PBAC considered that the magnitude of incremental benefit if any, could not be determined from the available evidence.
		Sponsor's Comment:	No comment