

MARCH 2020 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>ATEZOLIZUMAB</p> <p>Solution concentrate for I.V. infusion 840 mg in 14 mL</p> <p>Tecentriq®</p> <p>Roche Products Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Breast cancer</p>	<p>To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the first-line treatment of patients with unresectable locally advanced or metastatic triple-negative breast cancer who are programmed death-ligand 1 (PD-L1)-positive.</p>	<p>The PBAC did not recommend atezolizumab for the first-line treatment of patients with unresectable locally advanced or metastatic triple-negative breast cancer who are PD-L1 positive. The PBAC considered that there was a high clinical need for effective treatments for these patients, but considered that the applicability of the clinical evidence to the relevant patient population was limited and the magnitude of the overall survival benefit claimed was uncertain. The PBAC also noted that the incremental cost-effectiveness ratio was high and likely to be underestimated due to reliance on optimistic assumptions regarding overall survival, which were not sufficiently supported by the clinical evidence. The PBAC also noted that the cost-effectiveness of atezolizumab was likely to be affected by the choice of PD-L1 assay used to determine eligibility to treatment.</p>
		<p>Sponsor's comment:</p>	<p>Roche is disappointed with the outcome given the genuine unmet need for a new treatment option in patients with unresectable locally advanced or metastatic triple-negative breast cancer. Roche is committed to working with the PBAC to ensure that Australian patients with unresectable locally advanced or metastatic triple-negative breast cancer who are PD-L1-positive can access atezolizumab at the earliest opportunity.</p>
<p>AVELUMAB</p> <p>Solution concentrate for I.V. infusion 200 mg in 10 mL</p> <p>Bavencio®</p> <p>Merck Healthcare Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Renal cell carcinoma (RCC)</p>	<p>To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED), in combination with axitinib, for the first-line treatment of patients with advanced (Stage IV) clear cell variant RCC.</p>	<p>The PBAC did not recommend the listing of avelumab in combination with axitinib (AVE + AXI) for the first-line treatment of advanced clear cell variant RCC. The PBAC noted that AVE + AXI did not demonstrate a statistically significant difference in overall survival versus sunitinib, which was in contrast to the statistically significant overall survival gains reported for the comparator, nivolumab plus ipilimumab (NIVO + IPI), versus sunitinib. Further, the PBAC considered that progression free survival may not be a reliable measure of the clinical effectiveness of immunotherapies in this setting, and noted that AVE + AXI was not associated with an improvement in quality of life versus sunitinib. Overall, the PBAC considered that the submission had not adequately demonstrated non-inferiority versus NIVO + IPI, but noted that updated overall survival data are likely to be available in the near future.</p>
		<p>Sponsor's comment:</p>	<p>Merck Healthcare is disappointed with the PBAC decision and will continue to work with the PBAC and the Department of Health to pursue access for Australian patients with advanced RCC.</p>

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<p>PERTUZUMAB</p> <p>Solution for I.V. infusion 420 mg in 14 mL</p> <p>Perjeta®</p> <p>Roche Products Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Breast cancer</p>	<p>To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing, in combination with trastuzumab and chemotherapy, for the neoadjuvant treatment of patients with human epidermal growth factor receptor-2 positive (HER2+) locally advanced, inflammatory or early stage breast cancer.</p>	<p>The PBAC did not recommend pertuzumab, in combination with trastuzumab and chemotherapy, for the neoadjuvant treatment of HER2+ locally advanced, inflammatory or early stage (≥2 cm in diameter or node positive) breast cancer. The PBAC considered that there was no evidence that neoadjuvant pertuzumab would improve patient outcomes if it were added to the current clinical algorithm which includes standard chemotherapy in the neoadjuvant setting and for patients who do not achieve a pathological complete response, trastuzumab emtansine (T-DM1) in the adjuvant setting. Given the uncertain clinical effectiveness, the PBAC considered that the cost-effectiveness of adding pertuzumab to current therapy was not able to be assessed.</p>
		<p align="center">Sponsor's comment:</p>	<p>Roche is disappointed with the outcome and is committed to working with the PBAC to ensure that Australian patients with early breast cancer can access the optimal anti-HER2 neoadjuvant therapy.</p>
<p>PROTEIN FORMULA WITH CARBOHYDRATE, FAT, VITAMINS, MINERALS AND TRANSFORMING GROWTH FACTOR BETA-2</p> <p>Powder for oral liquid, 400 g, 12</p> <p>Modulen IBD®</p> <p>Nestle Health Science</p> <p>New listing (Minor Submission)</p>	<p>Crohn disease (CD)</p>	<p>To request a Restricted Benefit listing of Modulen IBD® for the dietary management of CD in patients aged 5 years or older in the active or remission phase of disease.</p>	<p>The PBAC did not recommend the PBS listing of Modulen IBD® for the dietary management of CD. The PBAC considered there was an uncertain clinical need for Modulen IBD® (and enteral nutrition more broadly) on the PBS for the management of CD as there are a range of pharmacotherapy treatment options available on the PBS, as well as hospital access programs for enteral nutrition. The PBAC considered the nominated comparators to be inappropriate, and that the relevant comparators were standard enteral nutrition formulas for children and PBS-listed corticosteroids and other pharmacotherapies for CD for adults. The PBAC considered there to be uncertain evidence of clinical benefit and as such, considered it was not possible to evaluate the comparative effectiveness and safety of Modulen IBD® with relevant alternatives.</p>
		<p align="center">Sponsor's comment:</p>	<p>The sponsor had no comment.</p>

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<p>TRIGLYCERIDES MEDIUM CHAIN FORMULA</p> <p>Oral powder 400 g</p> <p>Peptamen Junior®</p> <p>Nestle Health Science</p> <p>Change to listing (Minor Submission)</p>	<p>Dietary management of conditions requiring a source of medium chain triglycerides</p>	<p>To request an extension of the current Restricted Benefit listing to include critically or chronically ill paediatric patients who are dependent on nutritional support therapy.</p>	<p>The PBAC did not recommend Peptamen Junior® for the dietary management of malnutrition and/or intolerance to conventional enteral nutrition formulas for critically or chronically ill paediatric patients who are dependent on nutritional therapy due to short bowel syndrome, neurological impairment (e.g. cerebral palsy), cystic fibrosis, Crohn’s disease, malabsorption, chronic diarrhoea, HIV/AIDS, burns or cancer. The PBAC considered that the population was poorly defined, and that the submission had nominated an inappropriate comparator and failed to demonstrate a clinical need for the requested listing.</p>
Sponsor’s comment:			<p>The sponsor had no comment.</p>
<p>VENETOCLAX</p> <p>Pack containing 14 tablets venetoclax 10 mg and 7 tablets venetoclax 50 mg and 7 tablets venetoclax 100 mg and 14 tablets venetoclax 100 mg</p> <p>Tablet 10 mg</p> <p>Tablet 50 mg</p> <p>Tablet 100 mg</p> <p>Venclexta®</p> <p>AbbVie Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Chronic lymphocytic leukaemia (CLL)</p>	<p>To request an Authority Required (STREAMLINED) listing, in combination with obinutuzumab, for the first-line treatment of patients with CLL who have coexisting conditions and are unsuitable for fludarabine based chemotherapy.</p>	<p>The PBAC did not recommend the listing of venetoclax in combination with obinutuzumab for the first-line treatment of patients with CLL who have coexisting conditions and are unsuitable for fludarabine based chemotherapy. The PBAC accepted that venetoclax + obinutuzumab was clinically superior to current first-line therapy for CLL in delaying progression. However, the PBAC considered that the incremental cost-effectiveness ratio was difficult to ascertain based on the model provided and would need to be revised. Additionally, the financial estimates were highly uncertain.</p>
Sponsor’s comment:			<p>AbbVie welcomes the PBAC’s acknowledgement that venetoclax + obinutuzumab is clinically superior to current first-line therapy for CLL however is disappointed with the recommendation to reject the submission. AbbVie will continue to work collaboratively with the PBAC to seek access for patients in need.</p>