

NOVEMBER 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>DARATUMUMAB</p> <p>Solution concentrate for I.V. infusion 100 mg in 5 mL Solution concentrate for I.V. infusion 400 mg in 20 mL</p> <p>Darzalex®</p> <p>Janssen-Cilag Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Multiple myeloma (MM)</p>	<p>Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing, in combination with bortezomib and dexamethasone (Bd), for the treatment of patients with relapsed or refractory multiple myeloma (RRMM) who have progressive disease after at least one prior therapy.</p> <p>Sponsor's Comments:</p>	<p>The PBAC deferred making a recommendation for daratumumab in combination with bortezomib and dexamethasone (DBd), as a second-line treatment in patients with RRMM. The PBAC considered that there were important clinical benefits associated with DBd therapy, but requested revisions to the economic model, the estimated financial implications and the proposed a Risk Sharing Arrangement.</p> <p>The PBAC considered that the evidence presented in the submission supported the claim that DBd was superior to the nominated comparator, Bd, in the second-line setting. However, the PBAC considered that the proposed incremental cost-effectiveness ratio (ICER) at the proposed price remained unacceptably high and advised that the economic model be revised to a 15 year time horizon which incorporated appropriate survival estimates. The PBAC reiterated that it would consider an ICER within the range of \$45,000/QALY to \$75,000/QALY appropriate, as this is what was previously accepted in its consideration of carfilzomib (Public Summary Document, July 2017 PBAC meeting).</p> <p>The PBAC remained concerned that based on the financial estimates the opportunity cost of listing DBd remained very high, although considered the number of patients on which this was based to be overestimated.</p> <p>Janssen is disappointed with the outcome for Darzalex® (daratumumab), but welcomes the PBAC's acknowledgment that daratumumab would provide clinical benefit for the treatment of MM in Australia. While this is an evolving and complex treatment area, and further addressing the remaining issues identified by the PBAC is challenging, Janssen will continue to work with the PBAC and the Department of Health toward mutually agreeable solutions that reflect the innovation that daratumumab offers for the treatment of MM.</p>

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<p>DULAGLUTIDE</p> <p>Injection 1.5 mg in 0.5 mL single dose pre-filled pen</p> <p>Trulicity®</p> <p>Eli Lilly Australia Pty Ltd</p> <p>Change to listing (Major Submission)</p>	<p>Type 2 diabetes mellitus (T2DM)</p>	<p>To request an Authority Required (STREAMLINED) listing for use in combination with insulin and metformin for the treatment of patients with T2DM.</p>	<p>The PBAC deferred making a recommendation to extend the existing listing of dulaglutide 1.5 mg once weekly (QW) to include the treatment of T2DM in combination with insulin and metformin unless contraindicated or not tolerated. This was to request revision of the financial estimates as the PBAC considered the estimated financial impact of extending the current listing of dulaglutide to include use in combination with insulin was substantially underestimated due to underestimated patient numbers, market share and market growth.</p> <p>The PBAC considered that the price advantage over exenatide 10 mcg twice daily (BID) requested in the submission was not justified. However, the PBAC advised that a small price advantage may be appropriate for a proportion of the patient population with high clinical needs for which there are potential health benefits associated with the simplified QW dosing regimen of dulaglutide, compared with exenatide BID.</p>
		<p align="center">Sponsor's Comment:</p>	<p>No comment</p>
<p>FREMANEZUMAB</p> <p>Injection 225 mg in 1.5 mL pre-filled syringe</p> <p>Ajovy®</p> <p>Teva Pharma Australia Pty Limited</p> <p>New listing (Major Submission)</p>	<p>Chronic migraine</p>	<p>To request an Authority Required (STREAMLINED) listing for the prophylactic treatment of adult patients with chronic migraine who have experienced inadequate response, intolerance or a contraindication to at least three prior preventive migraine medications.</p>	<p>The PBAC deferred making a recommendation for fremanezumab for the treatment of chronic migraine in patients who have experienced an inadequate response, intolerance or a contraindication to at least three prior prophylactic migraine medications. The PBAC considered fremanezumab was an alternative treatment to Botox and galcanezumab for patients with chronic migraine and provided a similar reduction in monthly migraine days. The PBAC was of a mind to recommend fremanezumab for listing on the basis of cost-minimisation to Botox or galcanezumab. However, the PBAC deferred making a recommendation to address the uncertainties regarding the number of patients who would be treated and the net financial cost of listing fremanezumab on the PBS.</p>
		<p align="center">Sponsor's Comment:</p>	<p>Teva is pleased that the PBAC acknowledged the clinical need for effective treatment of chronic migraine in patients who have failed at least three prior prophylactic migraine medications. Teva will continue to work with the PBAC and the Department of Health with the aim of making fremanezumab available on the PBS for these patients.</p>

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<p>PEMBROLIZUMAB</p> <p>Solution concentrate for I.V. infusion 100 mg in 4 mL</p> <p>Keytruda®</p> <p>Merck Sharp & Dohme (Australia) Pty Ltd</p> <p>Change to listing (Minor Submission)</p>	<p>Melanoma</p>	<p>Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the adjuvant treatment of patients who have had completely surgically resected Stage IIIB-D malignant melanoma.</p>	<p>The PBAC deferred making a recommendation regarding the Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing of pembrolizumab as adjuvant treatment for patients with completely resected Stage IIIB, IIIC or IIID malignant melanoma. The PBAC considered it would be appropriate for pembrolizumab to be listed on a cost minimisation basis to nivolumab, noting that a listing for pembrolizumab would be unable to proceed until a listing was agreed for nivolumab.</p> <p>The PBAC considered that the proposal of a Risk Sharing Arrangement consisting of programmed cell death-1 (PD-1) inhibitor subsidisation caps across both the adjuvant and unresectable or metastatic settings, beyond which 100% rebates would apply, was appropriate to manage the uncertainty around uptake in the adjuvant setting and the changes in use in the unresectable or metastatic setting. Changes in the unresectable or metastatic setting would be due to patients no longer requiring (due to cure in the adjuvant setting) or no longer being eligible to receive treatment (due to relapse whilst receiving, or within six months of completing adjuvant treatment).</p>
		<p>Sponsor's Comments:</p>	<p>Merck Sharp & Dohme (MSD) is disappointed with the outcome of the third PBS submission for Keytruda® as adjuvant treatment for patients with completely resected Stage III malignant melanoma. MSD welcomes that the PBAC has acknowledged that there is a high clinical need for effective treatment to reduce the risk of recurrence in eligible melanoma patients. While treatments are now available for patients who display a specific BRAF mutation, approximately 62% of patients are not eligible for PBS-subsidised access to adjuvant treatment in this setting. MSD will continue to work with the PBAC and the Department of Health on a positive recommendation and PBS listing for this indication.</p>