

**MARCH 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>OZANIMOD</p> <p>Capsule 230 micrograms Capsule 460 micrograms Capsule 920 micrograms</p> <p>Zeposia®</p> <p>Celgene Pty Ltd</p> <p>New listing (Major Submission)</p>	<p>Relapsing-remitting multiple sclerosis (RRMS)</p>	<p>To request an Authority Required (STREAMLINED) listing for the treatment of patients with RRMS.</p>	<p>The PBAC deferred recommending the listing of ozanimod pending receipt of the TGA Delegate's Overview, however was of a mind to recommend listing on a cost minimisation basis with fingolimod.</p>
		<p>Sponsor's Comment:</p>	<p>The Sponsor is pleased that the PBAC was of a mind to recommend ozanimod as a treatment for RRMS and will work with the Department to progress PBS listing as soon as possible following TGA registration.</p>
<p>RIVAROXABAN</p> <p>Tablet 2.5 mg</p> <p>Xarelto®</p> <p>Bayer Australia</p> <p>New listing (Major Submission)</p>	<p>Coronary Artery Disease (CAD) and Peripheral Artery Disease (PAD)</p>	<p>Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of patients at high risk of recurrent cardiovascular events with CAD or PAD who meet certain conditions.</p>	<p>The PBAC deferred making a recommendation for rivaroxaban for the prevention of recurrent cardiovascular events in patients with atherosclerotic cardiovascular disease and additional high-risk factors. The PBAC considered there were important clinical benefits associated with rivaroxaban and that the resubmission had appropriately targeted use to a group of patients who are likely to achieve the most favourable risk-benefit profile. The PBAC considered that the claim of superior comparative effectiveness of rivaroxaban in combination with aspirin versus aspirin alone was reasonable. However, the incremental cost-effectiveness ratio was unacceptably high and revision of the financial estimates was required.</p>
		<p>Sponsor's Comment:</p>	<p>Bayer will continue to work with the PBAC and the Department of Health on the listing of rivaroxaban 2.5mg.</p>

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<p>TOFACITINIB</p> <p>Tablet 5 mg</p> <p>Xeljanz®</p> <p>Pfizer Australia Pty Ltd</p> <p>Change to recommended listing (Minor Submission)</p>	<p>Chronic plaque psoriasis</p> <p>Psoriatic arthritis</p> <p>Rheumatoid arthritis</p> <p>Ulcerative colitis</p>	<p>To request that the PBAC review its advice on the interchangeability of tofacitinib on an individual patient basis with other biological disease modifying antirheumatic drugs under Section 101(3BA) of the <i>National Health Act 1953</i>.</p>	<p>The PBAC deferred the matter of the interchangeability of tofacitinib under Section 101(3BA) of the <i>National Health Act 1953</i> to a future meeting to allow further deliberation of the request.</p>
		<p align="center">Sponsor's Comment:</p>	<p>Pfizer recognises that this important issue of interchangeability of drugs on an individual patient basis (as opposed to a population basis) necessitates a thorough consideration by the PBAC and looks forward to receiving a timely recommendation in due course.</p>