| **DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION** | **DRUG TYPE AND USE** | **LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION** | **PBAC OUTCOME** |
| --- | --- | --- | --- |
| OZANIMOD  Capsule 230 micrograms Capsule 460 micrograms Capsule 920 micrograms  Zeposia®  Celgene Pty Ltd  New listing  (Major Submission) | Relapsing-remitting multiple sclerosis (RRMS) | To request an Authority Required (STREAMLINED) listing for the treatment of patients with RRMS. | 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. |
| Sponsor’s Comment: | 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. |
| RIVAROXABAN  Tablet 2.5 mg  Xarelto®  Bayer Australia  New listing (Major Submission) | Coronary Artery Disease (CAD) and Peripheral Artery Disease (PAD) | 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. | 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. |
| Sponsor’s Comment: | Bayer will continue to work with the PBAC and the Department of Health on the listing of rivaroxaban 2.5mg. |
| TOFACITINIB  Tablet 5 mg  Xeljanz®  Pfizer Australia Pty Ltd  Change to recommended listing (Minor Submission) | Chronic plaque psoriasis Psoriatic arthritis Rheumatoid arthritis Ulcerative colitis | 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 *National Health Act 1953.* | The PBAC deferred the matter of the interchangeability of tofacitinib under Section 101(3BA) of the *National Health Act 1953* to a future meeting to allow further deliberation of the request. |
| Sponsor’s Comment: | 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. |