**July 2014 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 Recommendation** |
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| ANTIDIABETEC MEDICINES, thiazolidinediones, glucagon-like peptide-1, and sodium-glucose co-transporter 2 inhibitors Pharmaceutical Evaluation Branch, Department of HealthChange to listing(Minor submission) | For the treatment of type 2 diabetes mellitus | To inform the Pharmaceutical Benefits Advisory Committee (PBAC) of responses from the sponsors of thiazolidinediones (glitazones), glucagon-like peptide-1 (GLP-1) and sodium-glucose co-transporter 2 (SGLT2) inhibitors (gliflozins)regarding the Department’s proposed changes to the restriction wordings (listings/circumstances) of PBS-subsidised third line treatment options for type 2 diabetes mellitus to take into account the change in the PBS availability of the dipeptidyl peptidase 4 inhibitors (gliptins).  | The PBAC deferred its decision on the restrictions for current third line diabetes agents and indicated that further sponsor consultation is required. |
| GOLIMUMAB, 50 mg/0.5 mL injection, 1 x 0.5 mL syringe, Simponi® INFLIXIMAB, 100 mg injection, 1 x 100 mg vial, Remicade® USTEKINUMAB, 45 mg/0.5 mL injection, 1 x 0.5 mL vial, Stelara®Janssen-Cilag Pty LtdChange to listings(Minor submission) | Rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, chronic plaque psoriasis, Crohn disease, ulcerative colitis | Change to the second and subsequent continuing treatment authorities for golimumab, infliximab, and ustekinumab for all of their PBS-reimbursed indications from complex written authority to telephone authority items. The submission also requests that the Department of Human Services provide electronic PBS authority application forms for electronic completion and record keeping purposes. | The PBAC deferred the submission, noting that this matter would be considered in the context of the Post Market Review of PBS Authorities. The PBAC agreed that the points raised by the sponsor merited further exploration, but considered that addressing these in a consolidated fashion in the context of the Review would be the most efficient approach.  |
|  |  | Sponsor Comment: | The sponsor had no comment.  |
| RUXOLITINIB, tablets, 5 mg, 15 mg and 20 mg, Jakavi®Novartis Pharmaceuticals Australia Pty LtdNew listing(Major submission) | Myelofibrosis | Authority required listing for the treatment of disease related symptoms or splenomegaly in patients with intermediate to high risk primary (idiopathic) myelofibrosis (MF), post-polycythemia MF and post-essential thrombocythemia MF who are resistant to, refractory to, intolerant of or not candidates for available therapy. | The PBAC deferred the proposed Authority Required listing for ruxolitinib for second line management of myelofibrosis in patients satisfying certain clinical criteria due to a lack of clarity around the appropriate clinical place of ruxolitinib in Australian practice, concerns regarding the proposed restriction, and an unacceptably high price. Each of these matters precluded the committee from reaching a conclusion that ruxolitinib was cost-effective.Based on the direct evidence presented by the resubmission, for every 100 patients treated with ruxolitinib in comparison to placebo (PBO) or best available therapy (BAT): * Approximately 41 additional patients who are intolerant or irresponsive to BAT would experience a spleen response over a maximum duration of follow-up of 24 weeks.
* Approximately 28 additional patients would experience a spleen response over the maximum duration of follow-up of 48 weeks, compared to BAT.
* Approximately 27 additional patients would experience at least one episode of anaemia over a median duration of follow-up of 144 weeks, compared to PBO or BAT.
* Approximately 39 additional patients would experience at least one episode of thrombocytopenia episode over a median duration of follow-up of 144 weeks, compared to PBO.
* Approximately 32 additional patients would experience at least one thrombocytopenia episode over a median duration of follow-up of 144 weeks, compared to BAT.
* Approximately 7 additional patients will be alive after 48 weeks and 9 additional patients at 112 weeks compared with PBO. Due to crossover of patients from PBO to ruxolitinib the degree of improvement in overall survival is uncertain, and may be greater than the observed estimates which are based on the intention-to-treat analyses.
* Approximately 8 additional patients will be alive after 112 weeks and 10 additional patients at 144 weeks compared with BAT. Due to crossover of patients from BAT to ruxolitinib the degree of improvement in overall survival is uncertain, and may be greater than the observed estimates which are based on the intention-to-treat analyses.
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|  |  | Sponsor Comment: | The sponsor had no comment.  |