| **DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION** | **TGA INDICATION** | **CURRENT PBS LISTING** | **LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION** | **PBAC OUTCOME** |
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| **ALEMTUZUMAB**  10 mg/mL injection, 1 x 2 mL vial,  Lemtrada®  Genzyme (A Sanofi company) Pty Ltd  Change to recommended listing  (Minor submission) | Treatment of relapsing forms of multiple sclerosis (MS) for patients with active disease defined by clinical or imaging features to slow the accumulation of physical disability and reduce the frequency of clinical relapses. | Not currently PBS listed  At the July 2014 PBAC meeting, alemtuzumab was recommended for the treatment of relapsing-remitting multiple sclerosis | Re-submission to amend the July 2014 PBAC recommendation to list alemtuzumab on a cost-minimisation basis with natalizumab and fingolimod with regards to the claimed dosing durability, at a higher price than recommended by the PBAC in July 2014. | The PBAC reaffirmed its previous recommendation for the Authority Required Section 100 (Highly Specialised Drugs Program) listing of alemtuzumab for the treatment of relapsing-remitting multiple sclerosis. |
| Comparator:  fingolimod and natalizumab | Accepted, as previously accepted with the recommendation for listing by the PBAC at the July 2014 meeting. |
| Clinical claim:  Alemtuzumab was non-inferior to both natalizumab and fingolimod in terms of comparative effectiveness | Accepted, as previously accepted with the recommendation for listing by the PBAC at the July 2014 meeting. |
| Economic claim:  Cost-minimisation analysis based on a longer duration of treatment with fingolimod and natalizumab than recommended by the PBAC in July 2014. | Not accepted. The PBAC reiterated its July 2014 recommendation, and noted that no new data were presented in the submission to justify revising the dosing durability compared to the comparators. |
| Sponsor’s comments: | Sanofi is working with the Department towards achieving the PBS listing of Lemtrada for patients with relapsing-remitting multiple scleroisis. |
| **TALIGLUCERASE ALFA**  200 units injection, 1 vial    Elelyso®  Pfizer Australia Pty Ltd  New listing  (Major submission) | Long-term enzyme replacement therapy for adult and paediatric patients with a confirmed diagnosis of Type 1 Gaucher disease associated with at least one of the following: splenomegaly, hepatomegaly, anaemia, thrombocytopaenia. | Not currently PBS listed | Section 100 (Highly Specialised Drugs Program) listing for type 1 Gaucher disease | The PBAC rejected the submission to list taliglucerase alfa on the PBS on the basis that although the PBAC accepted that taliglucerase alfa provides a clinical benefit to patients, the clinical claim that taliglucerase alfa provides equivalent health outcomes to imiglucerase and velaglucerase alfa was weakened by the limited comparability of the results between the trials. |
| Comparator:  Imiglucerase and velaglucerase alfa. | The PBAC recognised that imiglucerase and velaglucerase alfa are not listed on the PBS and have not been considered to be cost-effective for listing on the PBS but agreed that these two treatments were the appropriate comparators. |
| Clinical claim:  The resubmission claimed that taliglucerase alfa achieves similar efficacy outcomes to imiglucerase and velaglucerase with a non-inferior safety and tolerability profile. | Differences in baseline values, outcome measurements and methods of measurement of organ volume in the clinical trial data limited the comparability of results between the trials and made it difficult to conclusively determine whether taliglucerase alfa is non-inferior to imiglucerase and velaglucerase alfa. As there were insufficient data available to allow a formal comparison of safety profiles of taliglucerase alfa, imiglucerase and velaglucerase alfa, the PBAC could not ascertain that taliglucerase alfa has a non-inferior safety profile compared to the other two treatments. |
| Economic claim:  Cost-minimisation analysis against imiglucerase and velaglucerase alfa. | Not accepted. |
| Sponsor’s comments: | The sponsor had no comment. |