

## 6.13 ETANERCEPT

### **Injection 50 mg in 1 mL single use auto-injector, 4 Injection 50 mg in 1 mL single use pre-filled syringe, 4 Brenzys<sup>®</sup>, Merck Sharp & Dohme (Australia) Pty Ltd**

#### **1 Purpose of Application**

- 1.1 The minor submission sought changes to the listing of the Brenzys<sup>®</sup> brand of etanercept with the intent of supporting further uptake of the biosimilar brand.

#### **2 Requested listing**

- 2.1 The submission requested three changes to the listing(s) of etanercept, including:
- Changing the authority level for initial 1, initial 2 and first continuing prescribing from a written authority to a telephone authority for the Brenzys brand of etanercept;
  - For bDMARD/biologic-naïve patients, having the use of a biosimilar in the first instance not count as a treatment failure as part of a treatment cycle, as one of five agents in rheumatoid arthritis (RA) or three agents in ankylosing spondylitis (AS), psoriatic arthritis (PsA) or chronic plaque psoriasis (CPP); and
  - Re-introduction of 'a' flagging the Brenzys and Enbrel<sup>®</sup> brands for the subsequent continuing treatment phase, such that written authority prescriptions for Enbrel can be substituted for biosimilars at the pharmacy level, in addition to the streamlined authority listing of Brenzys that currently exists.
- 2.2 Written authorities for etanercept include requirements for diagnostic test results and specific active joint counts and locations. These requirements cannot be verified by means of a telephone authority. As such, the implementation of a telephone authority for initial and first continuing prescriptions of etanercept would require a review of current restrictions to ensure they are assessable and auditable.
- 2.3 In its Pre-PBAC response, the sponsor provided a telephone authority checklist it considered may be an appropriate basis for administering a telephone authority listing of biosimilar etanercept on the PBS.
- 2.4 If a change to telephone authority was recommended for etanercept, it may also be appropriate for this to be extended to some or all of the other biosimilar medicines listed on the PBS currently or into the future.
- 2.5 The request for bDMARD-naïve patients to have use of a biosimilar brand in the first instance not counted as part of a treatment cycle (five treatments in a lifetime for RA, three treatments followed by a five year break for PsA, AS and CPP) would affect the basis on which bDMARDs (as a group of therapies) are currently listed for a range of

indications. The clinical and economic implications of this change have not been discussed in the submission.

- 2.6 The submission did not propose new restrictions for etanercept; however some of the requested changes would require amendments to the restrictions of etanercept to facilitate implementation.
- 2.7 The requested restriction changes are considered to be complex.

### **3 Background**

- 3.1 The reference brand of etanercept, Enbrel, is TGA registered for RA, PsA, CPP, AS, non-radiographic axial spondyloarthritis (NrAxSp), juvenile idiopathic arthritis (JIA) and juvenile plaque psoriasis (JPP) and is PBS-listed for all of these except NrAxSp. The Brenzys brand of etanercept is not TGA-registered or PBS-listed for juvenile indications.
- 3.2 At its August 2017 meeting, the PBAC considered an application from the sponsor of Brenzys which requested a range of biosimilar uptake drivers be applied to the listings for etanercept. The PBAC advised that there would not be clinical or other concerns about appropriate use of medicines if a policy decision were made to lower the authority requirement for only the biosimilar brand of etanercept under certain conditions. These conditions included<sup>1</sup>:
- All initial treatment restrictions for etanercept, including those for new patients, patients changing treatment and recommencing treatment, should remain Authority Required (in writing) listings;
  - Continuing restrictions for etanercept could be split into first continuing and subsequent continuing restrictions, with first continuing restrictions to remain Authority Required (in writing) and retaining the response to treatment criteria that currently exist in continuing restrictions, whilst subsequent continuing restrictions be Authority Required (STREAMLINED) listings;
  - The PBAC recommended that subsequent continuing restrictions for etanercept retain the requirement for patients to be responding to treatment. The PBAC noted that being an Authority Required (STREAMLINED) listing, no evidence of response would be provided to the Department of Human Services (DHS) at time of prescribing, rather that ongoing treatment response would be documented in the patient's medical notes.
- 3.3 A second biosimilar etanercept, Erelzi® (sponsored by Sandoz Pty Ltd), was recommended by the PBAC at its March 2018 meeting, including for the juvenile indications, but is yet to be listed on the PBS.

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<sup>1</sup> August 2017 PBAC, Etanercept (Brenzys) Public Summary Document. Available at [PBAC PSD website](#)

### ***Sponsor hearing***

3.4 There was no hearing for this item as it was a minor submission.

### ***Consumer comments***

3.5 The PBAC noted that no consumer comments were received for this item.

## **4 PBAC Outcome**

4.1 The PBAC deferred its consideration of the requested biosimilar uptake drivers on the basis that these matters had potentially broader biosimilar policy implications and considered that further discussions between the Department and key stakeholders regarding these requests was necessary to inform decision making.

4.2 In deferring its consideration, the PBAC was of the view that these requests were unlikely to be relevant solely to the Brenzys brand of etanercept, and should be considered in the context of all biosimilars for a range of indications.

4.3 The PBAC requested the Department engage in further discussions to determine the feasibility of the request for additional uptake drivers from a policy and implementation perspective.

4.4 The PBAC noted that this submission is not eligible for an Independent Review as the request was not for a different disease, condition, subtype, or patient population.

### **Outcome:**

Deferred

## **5 Context for Decision**

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

## **6 Sponsor's Comment**

MSD is encouraged that the PBAC finds there are no implications to the PBS of adding Brenzys as an 'a' flagged brand alternative to Enbrel for written authority at the subsequent continuing treatment phase. MSD is further encouraged by the PBAC's request for the Department to engage in broader biosimilar policy discussions. We will continue to work with both the Department and the PBAC towards the timely implementation of the proposed uptake drivers, which are intended to give clinicians and patients reasons to use biosimilars, whilst retaining prescriber choice, in support of government policy.