

4.02 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®**

Merck Sharp & Dohme (Australia) Pty Ltd

1 Purpose of Item

- 1.1 To seek the PBAC's advice on the sponsor's request to change the listing of etanercept biosimilar Brenzys® to support the uptake of the biosimilar brand:
- 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® 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 Background

- 2.1 At its August 2017 meeting, the PBAC did not recommend lowering the category of authority for the initial 2 and continuing restrictions for etanercept as proposed by the sponsor as it considered that changing the restrictions for these treatment phases to Authority required (STREAMLINED) was likely to result in use outside the intended PBS population to a wider population, such as patients who do not demonstrate the extent of response required for continuing treatment and use in patients with less severe disease. The PBAC noted that such extended use would likely affect the cost effectiveness of etanercept and represent use that is not consistent with the evidence of effectiveness considered by the PBAC when recommending listing on the PBS of etanercept for severe active RA, AS, severe PsA and severe CPP (para 4.8, etanercept Public Summary Document, August 2017 PBAC Meeting).
- 2.2 Biosimilar uptake drivers were first implemented in December 2017 when applied to etanercept. As agreed under the Strategic Agreements with Medicines Australia and the Generic and Biosimilar Medicines Association (GBMA) (the Strategic Agreements), two biosimilar uptake drivers were implemented by:

- encouraging prescribing of a biosimilar brand rather than the reference biological brand for treatment naïve patients by the addition of a Note in the Schedule of Pharmaceutical Benefits; and
- providing for a simpler and faster approval process for prescribing biosimilar brands (for example, streamlined authority) while maintaining an existing higher-level authority requirement for the reference biological brand (for example, written authority).

2.3 Initially, an approach to implementation was taken to remove the ‘a’-flags between Enbrel and Brenzys where the authority level differed between the two brands. While encouraging prescribing of the biosimilar brand, through differentiating listings for subsequent continuing treatment as written authority for Enbrel and streamlined authority for Brenzys, the removal of ‘a’ flagging precluded the possibility of dispensing Brenzys in accordance with a written authority. On 1 June 2019, ‘a’-flagging between Enbrel and Brenzys was reinstated at the subsequent continuing treatment phase for written authority prescriptions. The listing changes also had the effect of creating consistency with the listings for initial and first continuing treatment phases. On 1 November 2019 the approach to ‘a’-flagging of etanercept brands was also taken to infliximab brands.

2.4 In November 2018, the PBAC considered a submission from the sponsor that sought changes to the listing of the Brenzys brand of etanercept with the intent of supporting further uptake of the biosimilar brand. The PBAC deferred making a recommendation regarding 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.

For more detail on PBAC’s view, see section 4 PBAC outcome.

3 Current Situation

3.1 Five brands of etanercept have been approved for use in Australia. Of these, Enbrel (reference) and Brenzys (biosimilar) are currently listed on the PBS. Brenzys was listed on 1 April 2017.

3.2 The Department has been monitoring uptake of Brenzys through PBS dispensing claims data supplied by Services Australia. These data have shown a moderate but steady trend in market share growth of the biosimilar.

3.3 Prior to its December 2020 meeting, the PBAC sought policy advice from the Department regarding the requested uptake drivers.

3.4 The PBAC noted that, at present, prescribers can use the Online PBS Authorities (OPA) system on Health Professional Online Services (HPOS) to self-serve for authority approval of Authority Required (Telephone/electronic) items. Prescribers receive a

real time ‘immediate’ assessment response to these requests and the patient can leave with the prescription.

Committee-In-Confidence information

- 3.5 Most recent data indicate a growth in market share of Brenzys, from ■■■ per cent following implementation of the biosimilar uptake drivers to ■■■ per cent by the end of the 24 months following implementation.

End Committee-In-Confidence information

For more detail on PBAC’s view, see section 4 PBAC outcome.

4 PBAC Outcome

- 4.1 The PBAC did not recommend changing the authority level for initial 1, initial 2 and first continuing prescribing from Authority Required (Written) to Authority Required (Telephone) for Brenzys. The PBAC considered that a full assessment (written) is appropriate for Brenzys on the basis that the restrictions are complex and require prescribers to provide detailed clinical information to support the relevant PBS authority application. With a telephone authority, the PBAC considered it may be difficult and time consuming for Services Australia administrators to ensure that the specific entry criteria are explicitly addressed.
- 4.2 The PBAC noted that recent data showed that market share of Brenzys had increased from ■■■ per cent following implementation of the biosimilar uptake drivers to ■■■ per cent by the end of the 24 months following implementation.
- 4.3 The PBAC acknowledged that the Government is committed to promoting the greater use of biosimilar medicines in Australia and will support the introduction of measures that improve the uptake of biosimilar medicines as recommended by the Committee on a case-by-case basis. The PBAC noted that the Department is working with Services Australia to assess the requirements of PBS items which require paper based evidence (such as Brenzys) and will seek the PBAC’s advice for change where appropriate.
- 4.4 For bDMARD/biologic-naïve patients, the PBAC noted the sponsor’s request for 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 RA or three agents in AS, PsA or CPP. The PBAC reiterated that this request fell outside of the biosimilar uptake measures as agreed under the Strategic Agreements with Medicines Australia (the Strategic Agreement) and acknowledged by GBMA, and would require further consideration by these stakeholders, as well as the Joint Oversight Committee (composed of Department of Health and Medicines Australia representatives) established under the Medicines Australia Strategic Agreement. The PBAC did not support this request on the basis that a biosimilar medicine is a highly similar version of a reference biological medicine and contemporary clinical evidence does not support that the biosimilar be exempt from the treatment failure rule.

- 4.5 The PBAC noted that the request to re-introduce ‘a’ flagging for the Brenzys and Enbrel brands of etanercept in the subsequent continuing treatment phase was implemented on 1 June 2019.

Outcome:

Rejected

5 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

6 Sponsor’s Comment

MSD is disappointed the PBAC has rejected additional biosimilar uptake drivers proposed to support patient and clinician use of biosimilars. We remain ready to engage productively in discussions with the government, PBAC and relevant stakeholders to deliver benefits to patients and the health system.