Changes have been made to this item. Details of the corrigendum are at the end of this document.

6.17 ETANERCEPT, Injection 50 mg in 1 mL single use dose-dispenser cartridges, 4, Enbrel®, Pfizer Australia Pty Ltd

1 Purpose of Application

1.1 The Category 4 submission sought to request General Schedule and Section 100 (Highly Specialised Drugs Program) listings of etanercept injection 50 mg in 1 mL single use dose-dispenser cartridges, 4, (herein referred to as etanercept DDC) under the same conditions as the currently listed etanercept injection 50 mg in 1 mL single use pre-filled syringes, 4 (herein referred to as etanercept PFS).

2 Background

Registration status

2.1 Etanercept DDC was listed on the ARTG on 21 May 2021. Etanercept DDC was TGA approved on the basis that the only differences between the DDC and the currently registered PFS and auto-injector are the introduction of a new container, i.e. a dose-dispenser cartridge (TGA approval letter).

Previous PBAC consideration

2.2 Etanercept DDC has not been previously considered by the PBAC.

3 Requested listing

3.1 The submission requested listing etanercept DDC for the same indications for which the reference etanercept PFS is currently PBS listed. Etanercept is currently listed on the PBS as an Authority Required listing for the following indications:

- Severe active rheumatoid arthritis
- Severe psoriatic arthritis
- Ankylosing spondylitis
- Severe chronic plaque psoriasis
- Severe active juvenile idiopathic arthritis

The submission requested a listing for non-radiographic axial spondyloarthritis, which is not a PBS-listed indication for etanercept. This request would not be considered in this submission because a Category 4 submission is not an appropriate pathway for this type of request.

3.2 The submission claimed etanercept DDC will allow patients to overcome barriers observed with self-injection, reduce treatment non-adherence and consequently improve clinical outcomes through automating the subcutaneous injection with the SmartClic device which is provided with the DDC.

3.3 An updated AMT form was provided by the AMT Team during the evaluation of this submission. The MPP was confirmed to be different to the current listing: etanercept 50 mg/mL injection, 4 x 1 mL cartridges, which was appropriate. The PBAC noted that etanercept DDC would likely be listed under new PBS item codes.

3.4 During the evaluation, the sponsor was requested to provide further information about the product labels and DDC instructions to provide clarity around how the DDC would be administered. In its pre-PBAC response, the sponsor confirmed that there would be training information and instructions available for users to safely administer the DDC via the SmartClic device. In addition to information being provided at the point of dispensing, there would be a nurse educator team available by appointment and a medicines information line available to assist users.

3.5 In July 2016, the PBAC noted the potential for a quality use of medicines issue relating to differences in auto injector presentations of two brands of etanercept, Brenzys® and Enbrel®, but noted that any differences are likely to be minor and can be managed through regular patient education and counselling on the use of the devices that is provided to patients by prescribers and pharmacists.

4 Comparator

4.1 The submission nominated the currently listed etanercept PFS as the comparator to the DCC. It was noted the etanercept auto-injector could have also been a comparator, however, the syringe was appropriate.

5 Consideration of the evidence

Sponsor hearing

5.1 There was no hearing for this item.

Consumer comments

5.2 The PBAC noted that this item received no consumer comments.

Clinical claim

5.3 The submission inferred non-inferior comparative effectiveness and non-inferior comparative safety of etanercept DDC in comparison with etanercept PFS.

5.4 The PBAC considered that etanercept DDC was non-inferior in terms of comparative effectiveness and safety to etanercept PFS based on the TGA approval.

Pricing Considerations

5.5 The sponsor proposed an approved ex-manufacturer price (AEMP) of $939.25 for etanercept DDC, which is equivalent to the price for etanercept PFS and auto-injector currently listed on the PBS.

Estimated PBS utilisation and financial implications

5.6 The submission predicted that listing the etanercept DDC on the PBS will most likely replace the PFS and auto-injector presentations of etanercept currently listed and therefore will not change the overall usage of etanercept on the PBS. The submission estimated there would be nil net financial impact to the PBS.

5.7 The submission overview noted that the DDC requires the SmartClic device and needles for etanercept to be administered. In its pre-PBAC response, the sponsor confirmed that the DDC contained both the needle and etanercept solution. The pre-PBAC response also noted that the SmartClic device and needles would be provided to patients free of charge. The sponsor confirmed that it does not anticipate the listing of the DDC on the PBS to result in any out of pocket expenses to the patient.

For more detail on PBAC's view, see section 6 PBAC outcome.

6 PBAC Outcome

6.1 The PBAC recommended the listing of etanercept injection 50 mg in 1 mL single use dose-dispenser cartridges, 4 (etanercept DDC) on the basis that it should be made available for the same indications under both General Schedule and Section 100 (Highly Specialised Drugs Program) as the currently listed etanercept injection 50 mg in 1 mL single use pre-filled syringes, 4 (etanercept PFS). The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of etanercept DDC would be acceptable if it were cost-minimised to etanercept PFS.

6.2 The PBAC advised the equi-effective doses of etanercept DDC and etanercept PFS are: 50 milligrams of etanercept DDC = 50 milligrams of etanercept PFS.

6.3 The PBAC noted that the etanercept DDC was TGA approved on the basis that the only differences between the DDC and the currently registered PFS and auto-injector are the introduction of a new container, i.e. a dose-dispenser cartridge.

6.4 The PBAC accepted the currently listed etanercept PFS as an appropriate comparator and noted that the auto-injector would also have been appropriate.

6.5 The PBAC advised that under Section 101(4AACD) of the *National Health Act 1953*, in the Schedule of Pharmaceutical Benefits, the same strengths of etanercept DDC, etanercept PFS and etanercept auto-injector should be considered equivalent at the

pharmacy level (i.e. 'a'-flagged in the Schedule) for the purpose of substitution. The PBAC was satisfied that the differences in administration techniques of the DDC, PFS and auto-injector would be appropriately managed based on the information provided at the point of dispensing as well as additional educational resources such as nurse educators and a medicines information line to assist patients to overcome any quality use of medicines issue and safely administer the devices.

6.6 The PBAC noted that the listing of etanercept DDC is expected to have no change in the overall net cost to the government as etanercept DDC would replace the PFS and auto-injector presentations of etanercept currently listed. The PBAC also noted that there would be no out of pocket expenses for patients as a result of listing etanercept DDC on the PBS.

6.7 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because etanercept DDC is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity over etanercept PFS or auto-injector, or not expected to address a high and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009* for Pricing Pathway A were not met.

6.8 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

7.1 Add new medicinal product pack (MPP)/trade product pack (TPP) based on existing listings for etanercept PFS: 11196G, 11208X, 11219L, 11224R, 1963H, 3446J, 3449M, 5733R, 9085E, 9086F, 9087G, 9088H, 9089J, 9090K, 9091L, 9431J, 9615C.

MEDICINAL PRODUCT **medicinal product pack**	**Proprietary Name, Manufacturer**
ETANERCEPT etanercept 50 mg/mL injection, 4 x 1 mL cartridges	Enbrel, Pfizer Australia Pty Ltd

This restriction may be subject to further review. Should there be any changes made to the restriction the Sponsor will be informed.

8 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.

9 Sponsor's Comment

The sponsor had no comment.

10 Corrigendum

The following changes were made to the public summary document:

Change made	Date of revision
• Para 6.5 – Updated paragraph to clarify PBAC recommendation that etanercept cartridge, PFS and auto-injector should all be considered equivalent for the purposes of substitution at the pharmacy level.	February 2022