5.22 ETANERCEPT, Injections 50 mg in 1 mL single use pre-filled syringes, 4, Nepexto®, Maxx Pharma Pty Ltd

1 Purpose of Submission

1.1 The Category 3 submission requested General Schedule Authority Required and Section 100 (Highly Specialised Drugs Program) Authority Required listings of a new etanercept biosimilar (Nepexto®) in the form of Injections 50 mg in 1 mL single use pre-filled syringe (PFS) under the same conditions as its reference biologic Enbrel® (Injections 50 mg in 1 mL single use PFS).

2 Background

TGA Registration

2.1 Nepexto was TGA registered on 30 September 2020 under the brand name Etera® as a biosimilar to the reference brand (Enbrel).

2.2 The sponsor will be applying to change the brand name from Etera to Nepexto in tandem with this submission.

Previous PBAC Considerations

2.3 In November 2021, Rymti® was recommended by the PBAC, however a pricing offer package was not submitted within the timeframe due to changes in market authorisation. Rymti is being resubmitted to the PBAC under the brand name Nepexto.

2.4 Etanercept (Nepexto), Injection 50 mg in 1 mL single use auto-injector, was recommended at the November 2022 PBAC meeting but is not yet listed on the PBS (paragraph 7.1, etanercept (Nepexto) Public Summary Document, November 2022 PBAC meeting).

3 Requested listing

3.1 The submission requested Nepexto PFS be listed for all indications for which the reference brand Enbrel is currently PBS-listed:

- Severe psoriatic arthritis
- Ankylosing spondylitis
- Severe active rheumatoid arthritis

- Severe chronic plaque psoriasis
- Severe active juvenile idiopathic arthritis

3.2 The submission also requested that the listings for Nepexto be consistent with the biosimilar uptake driver policy.

3.3 As the submission requested that the proposed listings be consistent with the existing etanercept PFS listings, the full restrictions have not been reproduced here, however an example has been included below (for 'Severe active rheumatoid arthritis', treatment phase: Initial treatment – Initial 1 (new patient)).

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
ETANERCEPT					
etanercept 50 mg/mL injection, 4 x 1 mL syringes	9089J	1	1	3	[a]Enbrel [a]Brenzys [a]Nepexto

3.4 The submission requested that Nepexto be considered equivalent ('a' flagged) to Enbrel and Brenzys for the purpose of substitution.

3.5 Nepexto will have the same drug, form and manner of administration as the existing etanercept (injections 50 mg in 1 mL single use pre-filled syringes) brands and, as such, will be required to have the same approved ex-manufacturer price (AEMP) as the existing etanercept brands as per Section 85C of the National Health Act 1953.

4 Consideration of the evidence

Sponsor hearing

4.1 There was no hearing for this item.

Consumer comments

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

Clinical evidence

4.3 As per the Prescription Medicine Decision Summary, the TGA has confirmed that "Rymti, Etera (etanercept) is a biosimilar medicine to Enbrel."

4.4 The submission stated that the equi-effective doses of Nepexto singe use PFS and PBS-listed etanercept are: Nepexto 50 mg single use PFS = Enbrel 50 mg single use PFS = Brenzys 50 mg single use PFS.

4.5 As a Category 3 submission, no evaluation of the clinical evidence was undertaken.

Estimated PBS usage and financial implications

4.6 Listing of biosimilar brands does not change overall utilisation of the drug.

4.7 The submission stated that Nepexto is expected to substitute for the other brands of etanercept, injections 50 mg in 1 mL single use pre-filled syringes, and, as such, there is expected to be nil financial impact to the PBS/RPBS with the proposed listing.

5 PBAC Outcome

5.1 The PBAC recommended General Schedule Authority Required and Section 100 (Highly Specialised Drugs Program) Authority Required listings of a new etanercept biosimilar (Nepexto®) in the form of Injections 50 mg in 1 mL single use pre-filled syringe on a cost-minimisation basis and under the same circumstances as its reference biologic Enbrel® (Injections 50 mg in 1 mL single use PFS).

5.2 The PBAC advised the equi-effective doses to be Nepexto 50 mg single use PFS = Enbrel 50 mg single use PFS = Brenzys 50 mg single use PFS.

5.3 The PBAC noted that the TGA has confirmed that Nepexto is a biosimilar medicine to Enbrel.

5.4 The PBAC advised that the listings for Nepexto should include the same indications as Enbrel including adding in the caution: 'Etanercept 50 mg/mL 1mL pen devices and prefilled syringes are intended for use in children and adolescents weighting 62.5kg or more' in the juvenile indications.

5.5 The PBAC noted that the submission requested for the Nepexto listings to be consistent with the biosimilar uptake driver policy, that is, to have an Authority Required (STREAMLINED) requirement for the subsequent continuing treatment listings and the inclusion of an administrative note across all Nepexto listings encouraging use of a biosimilar brand for treatment naïve patients. The PBAC considered that the application of biosimilar uptake drivers to Nepexto would be clinically appropriate and would not impact cost-effectiveness.

5.6 The PBAC advised that, under Section 101(4AACD) of the *National Health Act 1953*, Nepexto, Enbrel and Brenzys should be considered equivalent for the purpose of substitution at the pharmacy level (i.e., 'a' flagged in the Schedule of Pharmaceutical Benefits).

5.7 The PBAC considered that the listing of Nepexto would not result in a net cost to the PBS as it would likely substitute for the other brands of etanercept and not increase the overall market utilisation.

5.8 The PBAC noted its recommendation was on a cost-minimisation basis and advised that, because Nepexto is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity over the other brands of etanercept, or not expected to address a high and urgent unmet clinical need given the presence of alternative therapies, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* for Pricing Pathway A were not met.

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

Outcome:
Recommended

6 Recommended listing

6.1 The restrictions are complex due to the number of PBS item codes and indications requested for listing. As the submission requested the same restrictions as the existing PBS-listed reference biologic, Enbrel, the full restrictions have not been reproduced.

6.2 Add Nepexto biosimilar PFS brand with schedule equivalence ('a' flag) for the same indications as Enbrel and apply the biosimilar uptake policy to Nepexto PFS.

MEDICINAL PRODUCT **medicinal product pack**	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Available brands**
ETANERCEPT					
etanercept 50 mg/mL injection, 4 x 1 mL syringes	Multiple	-	-	-	[a]Enbrel [a]Brenzys [a]Nepexto

These restrictions may be subject to further review. Should there be any changes made to the restriction the sponsor will be informed.

7 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.

8 Sponsor's Comment

The sponsor had no comment.