Pharmaceutical Benefits Scheme – Biosimilar Etanercept

Brenzys® is a biosimilar brand of etanercept which was listed on the Pharmaceutical Benefits Scheme (PBS) on 1 April 2017. This brand is listed under the Section 100 Highly Specialised Drugs Program (HSD Program).and the PBS General Schedule.

What are biological and biosimilar medicines?

Biological medicines, including biosimilars, contain substances made by living cells or organisms. They are more complex to make than synthetic chemical medicines.

A biosimilar medicine is a highly similar version of a reference biological medicine, which is invariably the first brand to market. Biosimilar medicines are used to treat the same diseases, in the same way, as the reference biological medicines.

Biosimilar medicines have been tested and shown to be as safe and effective as the reference biological medicines.

How is biosimilarity determined?

Biosimilar medicines are designed and engineered to be as similar as possible to the reference biological medicine. There may be minor differences (known as molecular microheterogeneity) due to natural variability and the more complex manufacturing processes required for biological medicines. Importantly, these minor differences do not affect the safety, quality or effectiveness of the biosimilar medicine.

For a biosimilar medicine to be approved by the Therapeutic Goods Administration (TGA), the structural variability of the biosimilar medicine and the reference biological medicine, and all critical quality attributes (i.e. those important for the function of the molecule) must be highly similar. There must also be no clinically meaningful differences identified in clinical studies comparing the biosimilar and reference products.

Brenzys has been assessed by the TGA on the basis of comparability and clinical studies to be highly similar to the reference brand, Enbrel®. This means that Brenzys provides the same health outcomes and is as safe and effective as Enbrel.

What is etanercept?

Etanercept is used on the PBS to treat severe active rheumatoid arthritis, ankylosing spondylitis, severe psoriatic arthritis, severe chronic plaque psoriasis and severe active juvenile idiopathic arthritis (Brenzys is available for these indications, with the exception of severe active juvenile idiopathic arthritis).

More information about this medicine is available by entering ‘etanercept’ at the NPS MedicineWise Medicine Finder.

Can PBS brands of etanercept be substituted?

The Pharmaceutical Benefits Advisory Committee (PBAC), an independent, expert advisory body, recommended that Brenzys be listed on the PBS as a substitutable biosimilar of Enbrel for all approved indications. The brands are marked in the Schedule with an ‘a’-flag.

When PBS brands are listed as substitutable with each other, the pharmacist may dispense any brand, provided the prescriber has not indicated 'brand substitution not permitted' on the prescription, and they have permission from the patient.

What are the PBS restrictions for etanercept?

Brenzys was the first biosimilar medicine in Australia to be available through community pharmacy as a General Schedule item, and it can be self-administered after training. The reference brand Enbrel is supplied under both the General Schedule and the HSD Program.

Brenzys is available as an Authority Required (STREAMLINED) prescription for subsequent continuing treatment when Enbrel is also available as a treatment choice, or as an Authority Required (Written) for initial and first continuing treatment.

The dosage for Brenzys is the same as for the reference brand Enbrel: 50mg of etanercept per week. It comes in single-use pre-filled syringes and pre-filled pens and is administered via subcutaneous (SC) injection.

Read the Schedule of Pharmaceutical Benefits for the restrictions for etanercept. The Schedule is also available via the PBS publications page. The prescribing software contains further details of initial, first continuing and subsequent continuing treatment phase criteria and eligibility details. Over time PBS listing details may change – please consult the Schedule for current information.

Do biosimilar uptake drivers apply to etanercept?

The Government has implemented policies to encourage greater use of biosimilar brands.

The PBS listings for etanercept were changed in December 2017 to provide for a simpler and faster approval process for prescribing Brenzys using the Authority Required (STREAMLINED) process for subsequent continuing treatment, while maintaining the Authority Required (Written) process for Enbrel. Prescriptions for the biosimilar brand in private hospitals can be written using online approval or Authority Required (telephone).

To further encourage uptake an administrative Note, applicable to all indications, has been added for prescribers in the Schedule. The Note is applicable for initial treatment with etanercept:

> **Note Biosimilar prescribing policy**
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> Prescribing of the biosimilar brand Brenzys is encouraged for treatment naïve patients. Encouraging biosimilar prescribing for treatment naïve patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments.

Further information about the biosimilar uptake drivers is available on the PBS website.

Why are biosimilar medicines important?

The growing cost of new and innovative medicines, including biological medicines, continues to put pressure on the financial sustainability of the PBS. Eight of the ten most expensive medicines subsidised by the PBS in 2020-21 were biological medicines with a combined cost of $2.41 billion. The introduction of biosimilars on the PBS can help relieve this pressure.

How can greater use of biosimilars benefit the PBS?

The introduction of brand competition into the market leads to lower PBS prices, due to Price Disclosure and other statutory price reductions to PBS medicines. Under Price Disclosure arrangements the PBS subsidy is adjusted twice a year to reflect average market prices. As these become lower through competition, the prices of medicines that have at least one other brand on the PBS can be reduced. A price reduction only occurs if the weighted average discounting across all brands of a drug is greater than set percentages.

Savings from statutory price reductions to PBS medicines are being re-invested in the PBS, ensuring all Australians continue to have the earliest possible access to new medicines. All Australian patients benefit from rapid, equitable and sustainable access to the most effective medicines through the PBS.

Detailed information about PBS pricing, including Price Disclosure, is available on the PBS website.

More Information

For more information, read:

- Department of Health and Aged Care website About medicines page.
- Therapeutic Goods Administration website biosimilars medicines regulation.
- PBS website – PBAC Public summary document for Brenzys.
- The Biosimilar Education Hub (Generic and Biosimilar Medicines Association Education website, originally funded by the Australian Government).

Further information for healthcare professionals regarding the use of PBS Authorities and claiming of PBS benefits is available at the Services Australia website.