



Australian Government

Department of Health

Factsheet for Healthcare Professionals

Pharmaceutical Benefits Scheme - Biosimilar ETANERCEPT

Brenzys[®] is a brand of etanercept that was listed on the Pharmaceutical Benefits Scheme (PBS) on 1 April 2017. It is a biosimilar to the reference biological medicine Enbrel[®].

Brenzys[®] has been assessed by the Therapeutic Goods Administration (using comparability and clinical studies) to be highly similar to the reference brand, Enbrel[®]. This means that Brenzys[®] and Enbrel[®] provide the same health outcomes and are as safe and effective as each other.

Refer to the Schedule of Pharmaceutical Benefits, available [online](#), in [PDF](#) and in prescribing software, for detailed information on the PBS prescribing restrictions.

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). Refer to the Schedule of Pharmaceutical Benefits, available [online](#), in [PDF](#) and in prescribing software, for detailed information on the PBS prescribing restrictions for etanercept.

What is a biological medicine?

Biological medicines, including biosimilars, contain active substances derived from living cells or organisms. Compared to synthetic chemical medicines, biological medicines are more complex and have an inherent degree of minor variability in the production process. This means no two batches of a biological medicine (even from the same manufacturer) are ever exactly the same.

What is a biosimilar medicine?

Biosimilar medicines are highly similar versions of an already registered reference brand of a biological medicine.

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, 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.

Community Pharmacy Dispensing

Brenzys[®] was the first biosimilar medicine in Australia to be available through community pharmacy, and it can be self-administered after training.

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.

The independent expert Pharmaceutical Benefits Advisory Committee (PBAC) recommended that Brenzys[®] be listed on the PBS as a substitutable biosimilar of the Enbrel[®] brand of etanercept. This means the two brands of etanercept can be substituted by the pharmacist in consultation with the patient. This recommendation was based on individual consideration of the evidence for Brenzys[®].

Prescriber choice and brand substitution

Prescribers retain, in consultation with their patient, the choice of which brand to prescribe. When PBS brands are listed as substitutable with each other, the pharmacist may dispense any brand, provided they have permission from the patient and the prescriber has not indicated 'brand substitution not permitted'.

Prescribers are encouraged to discuss biosimilar medicines with patients. See "[How do I talk to patients about biosimilar medicines?](#)" in the 'Information for health care professionals' FAQs on the Australian Government Department of Health website.

Why are biosimilar medicines important?

The PBS is a key element of Australia's National Medicines Policy, which aims to deliver timely access to medicines at a cost that individuals and the community can afford.

Increasing costs associated with very expensive new health technologies, and the increasing prevalence of chronic conditions, is putting pressure on the sustainability of the PBS. Eight of the ten most expensive medicines subsidised by the PBS in 2018–19 were biological medicines with a combined cost of \$1.87 billion. The cost to taxpayers for etanercept alone in 2018–19 was \$105.7 million.

Increasing the use of biosimilar medicines is expected to deliver significant reductions in the cost of the PBS, due to price competition in the market. This can improve the Government's capacity to fund expanded access to biological medicines as they become more affordable, and reduce the risk of medicine shortages.

Where can I find more information?

The biosimilars page on the [Australian Government Department of Health website](#)

The biosimilars regulation page on the [Therapeutic Goods Administration website](#)

The PBAC Public Summary Document for Brenzys[®] on the [PBS website](#)

The [Biosimilar Education Hub](#) (for consumers and carers)