Factsheet for Healthcare Professionals

Biosimilar etanercept on the Pharmaceutical Benefits Scheme

Listing of etanercept (Brenzys®) on the PBS from 1 April 2017

Brenzys® is a new brand on the Pharmaceutical Benefits Scheme (PBS) from 1 April 2017. It is a biosimilar to the reference biological medicine Enbrel®. Both brands contain etanercept and have been assessed by the Therapeutic Goods Administration (TGA) on the basis of comparability and clinical studies to be highly similar. Brenzys® provides the same health outcome and is as safe and effective as Enbrel®.

What is etanercept used for?

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). Details of the PBS prescribing restrictions are available in the online Schedule of Pharmacuetical Benefits, or in prescribing software.

What is a biological medicine?

Biological medicines, including biosimilar medicines, contain one or more active substances that are derived from living cells or organisms.

What is a biosimilar medicine?

Biosimilar medicines are highly similar, but not identical, versions of an already registered reference biological medicine. They are not referred to as generic medicines (although like generics they are competitor brands). Inherent variability of the biological systems used in the manufacturing process means that the resulting product is also variable. No two batches of a biological medicine, including biosimilar medicines, are ever exactly the same (even from the same manufacturer).

For a biosimilar medicine to be approved, its structural variability must not be greater than the acceptable limits of batch variation for the reference biological medicine, and all critical quality attributes (i.e. those important for the function of the molecule) must be highly similar.

Biosimilar medicines that are approved for marketing have been assessed to have no clinically meaningful differences and to be therapeutically equivalent to the reference biological medicine.

Community Pharmacy Dispensing

Brenzys® is 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.

Etanercept Brands and Pharmacy Substitution

The two brands are highly similar and can be substituted at the point of dispensing by the pharmacist, as with generic brands. The TGA has determined that Brenzys® is as safe and effective as Enbrel® and can be used to treat the same conditions. The independent expert Pharmaceutical Benefits Advisory Committee (PBAC) recommended that the brands Enbrel® and Brenzys® could be marked as equivalent in the Schedule of Pharmaceutical Benefits ('a' flagged) for the purposes of substitution by the pharmacist at the point of dispensing for all the circumstances (restrictions) for which both brands are listed. This recommendation was given after individual consideration of the evidence for Brenzys®.

Who chooses whether the biosimilar medicine is used?

The medicine used for treatment is a choice that is made by doctors in consultation with their patients. Healthcare professionals are encouraged to talk through these choices with their patients.

One 'a' flagged brand of a medicine can be exchanged for another by the pharmacist in consultation with the patient but without needing to refer back to the doctor.

Even if a medicine is substitutable, the doctor can tick the 'brand substitution not permitted' box when writing a prescription. If this box is ticked, by law the pharmacist cannot dispense a brand other than that prescribed.

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 again putting pressure on the sustainability of the PBS. Six of the ten most expensive medicines subsidised by the PBS in 2015-16 were biological medicines with a combined cost of $1.28 billion.

Biosimilar medicines provide an opportunity to reduce the cost to the PBS for subsidising biological medicines based on price competition in the market when different brands are used.

Good uptake of biosimilar medicines is expected to deliver significant savings which can be reinvested into other areas of the Australian health system, expand access to biologic medicines when they become more affordable, and reduce the risk of medicine shortages.

Where can I find more information?

Australian Government Department of Health: www.health.gov.au/biosimilars

Therapeutic Goods Administration: www.tga.gov.au/publication/evaluation-biosimilars

The PBAC Public Summary Document for Brenzys®: www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/pbac-public-summary-documents-july-2016