Australian Government

Department of Health

Pharmaceutical Benefits Scheme
Biosimilar TERIPARATIDE

Terrosa® is a biosimilar brand of teriparatide which was listed on the Pharmaceutical Benefits Scheme (PBS) on 1 October 2021. This brand is listed under 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.

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

What is teriparatide?

Teriparatide is a biological medicine, produced in *Escherichia coli (E.coli)* using recombinant deoxyribonucleic acid (DNA) technology. It is used to treat:

- osteoporosis in postmenopausal women;
- primary osteoporosis in men when other agents are considered unsuitable and when there is a high risk of fracture; and

- osteoporosis associated with sustained systemic glucocorticoid therapy in women and men at high risk for fracture.

More information about this medicine is available by entering 'teriparatide' at the NPS MedicineWise Medicine Finder.

Can PBS brands of teriparatide be substituted?

The Pharmaceutical Benefits Advisory Committee (PBAC), an independent, expert advisory body, recommended that Terrosa be listed on the PBS as a substitutable biosimilar of Forteo for all approved indications. In its recommendation, the PBAC considered while there are differences in administration techniques between the two brands, this could be appropriately managed by the education plan proposed by the manufacturer of Terrosa. The brands are marked in the Schedule of Pharmaceutical Benefits (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 teriparatide?

Teriparatide is available on the PBS as initial and continuing treatment for severe established osteoporosis under certain conditions. Treatment is limited to a maximum of 18 months therapy in a patient's lifetime.

The Schedule, available online, in PDF and in prescribing software, contains the details of initial and continuing treatment phase criteria and eligibility details. Note that over time PBS listing details may change – please consult the Schedule for current information.

Listing changes from 1 January 2022 – 'Supply Only'

From 1 November 2020 when a product is deleted from the Schedule it may then be available under Supply Only rules. Supply Only items/brands are available on the Schedule for dispensing but not for prescribing

From 1 January 2022, the Forteo formulation of 250 microgram/mL injection, 2.4 mL pen device will remain available on the PBS for a period of five months under Supply Only arrangements until 31 May 2021. As such, this formulation will no longer be available to prescribe, however all prescriptions written prior to 1 January 2022 may still be dispensed. The biosimilar brand Terrosa will continue to be available on the PBS, and will be the sole brand available on the PBS from 1 June 2022.

Do biosimilar uptake drivers apply to teriparatide?

The Government has implemented policies to encourage greater use of biosimilar brands. The PBS listings for teriparatide have been changed to provide for a simpler and faster approval process for prescribing Terrosa using the Authority Required (STREAMLINED) process for initial and continuing treatment, while maintaining the Authority Required (Written) process for Forteo.

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 teriparatide:

Note

Biosimilar prescribing policy

Prescribing of the biosimilar brand Terrosa, 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

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 Terrosa on the PBAC webpage of the PBS website

The Biosimilar Education Hub (Generic and Biosimilar Medicines Association Education website funded by the Commonwealth)

Further information for healthcare professionals regarding the use of PBS authorities and claiming of PBS benefits is available at the Services Australia website, using the search terms ‘PBS Authorities’ and ‘Claim a benefit – Medicare benefits for health professionals’.