Pharmaceutical Benefits Scheme – Biosimilar Filgrastim

Nivestim® and Zarzio® are biosimilars brand of filgrastim which were listed on the Pharmaceutical Benefits Scheme (PBS) on 1 April 2011 and 1 September 2013 respectively. These brands are listed under the Section 100 Highly Specialised Drugs Program (HSD Program).

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.

Nivestim and Zarzio have been assessed by the TGA on the basis of comparability and clinical studies to be highly similar to the reference brand, Neupogen®. This means that Nivestim and Zarzio provide the same health outcomes and are as safe and effective as Neupogen.

Nivestim was approved by the TGA and listed on the PBS prior to the TGA's updated biosimilar registration process in December 2015. It was approved on the basis of the European Union Guideline for Similar Biological Medicinal Products adopted by the TGA. Zarzio was also subsequently approved on this basis.

What is filgrastim?

Filgrastim is a biological medicine in the granulocyte colony stimulating agents (G-CSF) class and acts to stimulate bone marrow to produce white blood cells. It is used to treat neutropenia resulting from reduced white blood cell counts in patients undergoing chemotherapy or receiving bone marrow transplants. It is also used to stimulate the release of stem cells in the blood for subsequent stem cell collection and transplantation.

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

Can PBS brands of filgrastim be substituted?

The Pharmaceutical Benefits Advisory Committee (PBAC), an independent, expert advisory body, recommended that from 1 October 2019 Nivestim and Zarzio be listed on the PBS as substitutable biosimilars of Neupogen 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 filgrastim?

Authority levels for both HSD Program – Private and Public Hospital (s100) PBS listings are Authority Required (STREAMLINED).

Read the Schedule of Pharmaceutical Benefits for the restrictions for filgrastim. The Schedule is also available via the PBS publications page. The prescribing software contains further eligibility details. Over time PBS listing details may change – please consult the Schedule for current information.

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 Nivestim.
- 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.