Pharmaceutical Benefits Scheme – Biosimilar Follitropin alfa

Bemfola® and Ovaleap® are biosimilar brands of follitropin alfa which were listed on the Pharmaceutical Benefits Scheme (PBS) on 1 August 2016 and 1 December 2021 respectively. These brands are listed under the Section 100 IVF Highly Specialised Drugs Program (HSD IVF 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.

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

What is follitropin alfa?

Follitropin alfa is a biological medicine that is used for the following treatments:

- women undergoing Assisted Reproductive Technology (ART);
- anovulatory infertility; and
- infertility due to hypogonadotrophic hypogonadism.

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

Can PBS brands of follitropin alfa be substituted?

The Pharmaceutical Benefits Advisory Committee (PBAC), an independent, expert advisory body, recommended that Ovaleap and Bemfola be listed on the PBS as substitutable biosimilars of Gonal-f for all approved indications. Ovaleap is marked in the Schedule with an ‘a’-flag.

While the PBAC noted the differences in administration techniques of Ovaleap and Gonal-f, it considered that patients with sufficient education and training resources would be able to administer different devices appropriately.

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.

The biosimilar brand Bemfola is not ‘a’-flagged with either Gonal-f or Ovaleap. In 2016, the PBAC did not recommend that Bemfola could be ‘a’-flagged with Gonal-f. This was due mainly to differences in the strengths, number of pens per pack and maximum quantities between the brands, which make substitution at the pharmacy level difficult from a practical perspective.

What are the PBS restrictions for follitropin alfa?

Prescriptions for follitropin alfa under the HSD IVF Program for use as an Assisted Reproductive Technology may use an Authority Required (STREAMLINED) code.

Prescriptions under the PBS General Schedule for anovulatory infertility and infertility resulting from hypogonadotrophic hypogonadism are available as a Restricted Benefit.

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

Read the Schedule of Pharmaceutical Benefits for the restrictions for follitropin alfa. 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.

Do biosimilar uptake drivers apply to follitropin alfa?

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

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

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Bemfola or Ovaleap 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 Bemfola.
- PBS website – PBAC Public summary document for Ovaleap.
- 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.