



Australian Government

Department of Health

Pharmaceutical Benefits Scheme Biosimilar BEVACIZUMAB

Mvasi[®] is a biosimilar brand of bevacizumab which was listed on the Pharmaceutical Benefits Scheme (PBS) on 1 June 2021. This brand is listed under the [Efficient Funding of Chemotherapy](#) (EFC) arrangements of 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.

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

Avastin was removed from the PBS at the request of the pharmaceutical company which supplies this brand on 1 June 2021.

What is bevacizumab?

Bevacizumab is a biological medicine that is used to treat cancers such as colorectal, lung, cervical, ovarian cancer and glioblastoma.

More information about this medicine is available by entering 'bevacizumab' at the [NPS MedicineWise Medicine Finder](#).

What are the PBS restrictions for bevacizumab?

From 1 June 2021, bevacizumab is available as an unrestricted benefit, ensuring that all patients needing this medicine have subsidised access to it, following the recommendation of the expert, independent Pharmaceutical Benefits Advisory Committee (PBAC). Prior to 1 June 2021, supply of bevacizumab on the PBS was on the basis of [Authority Required](#) or [Authority Required \(STREAMLINED\)](#) approval for a prescription.

The Schedule of Pharmaceutical Benefits, available [online](#), in [PDF](#) and in prescribing software. Note that 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

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 Mvasi 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'.