



Australian Government

Department of Health

Pharmaceutical Benefits Scheme Biosimilar BEVACIZUMAB

Mvasi[®], a biosimilar brand of bevacizumab will be listed on the Pharmaceutical Benefits Scheme (PBS) from 1 June 2021. It will be listed under Section 100, as a medicine funded through the Efficient Funding of Chemotherapy (EFC) Program.

Medicines listed on the PBS are subsidised by the Commonwealth of Australia where they are priced above the PBS co-payment amount, as is the case for bevacizumab.

Mvasi[®] has been assessed by the Therapeutic Goods Administration (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 the reference brand, Avastin[®].

From 1 June 2021 Avastin[®] will no longer be available on the PBS, and Mvasi[®] will be the sole brand available on the PBS. The Australian Government has been working with the manufacturers of this medicine to ensure continuity of supply on the PBS.

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 will be 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 is on the basis of Authority Required or Authority Required (STREAMLINED) approval for a prescription.

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 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.

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. Seven of the ten most expensive medicines subsidised by the PBS in 2019-20 were biological medicines with a combined cost of \$2.01 billion. The introduction of biosimilar medicines generally encourages brand competition in the Australian market. This will lead to a reduction in the cost of biological medicines, improving the Government's capacity to subsidise access to new and innovative treatments for seriously ill patients.

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 PBAC Outcome recommending bevacizumab as an unrestricted benefit on the PBS on the PBAC webpage of the [PBS website](#)

The [Biosimilar Education Hub](#)

Further information about the biosimilar uptake drivers, why they are important, and how they are implemented, is available on the [PBS website](#)