Australian Government
Department of Health

Pharmaceutical Benefits Scheme
Biosimilar ADALIMUMAB

The following biosimilars brands of adalimumab are listed on the Pharmaceutical Benefits Scheme (PBS):

Brand name	Date listed on PBS
Amgevita®	1 April 2021
Hadlima®	
Hyrimoz®	
Idacio®	

These brands are listed under the PBS General Schedule and 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.

Amgevita, Hadlima, Hyrimoz and Idacio have been assessed by the TGA on the basis of comparability and clinical studies to be highly similar to the reference brand, Humira. This means that Amgevita, Hadlima, Hyrimoz and Idacio provide the same health outcomes and are as safe and effective as Humira.

What is adalimumab?

Adalimumab is a biological medicine that is used to treat a range of conditions such as rheumatoid arthritis, juvenile idiopathic arthritis, chronic plaque psoriasis, psoriatic arthritis, ankylosing spondylitis, Crohn disease, ulcerative colitis and hidradenitis suppurativa.

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

Can PBS brands of adalimumab be substituted?

The Pharmaceutical Benefits Advisory Committee (PBAC) recommended that Amgevita, Hadlima, Hyrimoz and Idacio be listed on the PBS as substitutable biosimilars of Humira, the reference brand of adalimumab. Substitutable 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 adalimumab?

From 1 April 2021, prescriptions for the biosimilar brands Amgevita, Hadlima, Hyrimoz and Idacio under the General Schedule and the HSD Program may use an Authority Required (STREAMLINED) code for prescriptions written for the Subsequent Continuing treatment phase. However, the reference brand Humira remains available as Authority Required (Written) listing for this treatment phase. A new reduced diluent formulation of Humira will be PBS listed and will be considered equivalent for substitution ('a'-flagged) with original formulations and all biosimilars.

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 the most up to date information.

Do biosimilar uptake drivers apply to adalimumab?

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

For subsequent continuing treatment, all biosimilar brands are available as Authority Required (STREAMLINED) prescription and are 'a'-flagged to allow substitution at a pharmacy level.

All brands of adalimumab for earlier treatment phases are prescribed as Authority Required (Written).

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 adalimumab:

Note

Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz and Idacio 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 Amgevita on the PBAC webpage of the PBS website

The PBAC Public Summary Document for Hadlima on the PBAC webpage of the PBS website

The PBAC Public Summary Document for Hyrimoz on the PBAC webpage of the PBS website

The PBAC Public Summary Document for Idacio 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’.