Pharmaceutical Benefits Scheme – Biosimilar Omalizumab

March 2026

Omlyclo® is a biosimilar brand of omalizumab which was listed on the Pharmaceutical Benefits Scheme (PBS) on 1 August 2025. Omlyclo® is 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.

Omlyclo® has been assessed by the TGA on the basis of comparability (through several quality, non-clinical and clinical studies) to be highly similar to the reference brand, Xolair®. This means that Omlyclo® provide the same health outcomes and is as safe and effective as Xolair®.

What is omalizumab?

Omalizumab is a monoclonal antibody which acts by binding and blocking the immunoglobulin E which is a protein of the immune system that plays an important role in the inflammatory response involved in signs and symptoms of allergic asthma, nasal polyps and chronic spontaneous urticaria.

Omalizumab is listed on the PBS for the treatment of uncontrolled severe asthma; severe chronic spontaneous urticaria and uncontrolled severe allergic asthma.

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

Can PBS brands of omalizumab be substituted?

The Pharmaceutical Benefits Advisory Committee (PBAC), and independent, expert advisory body to the Australian Government, recommended that Omlyclo® be listed on the PBS as a substitutable biosimilar of Xolair®, the reference brand of omalizumab. Substitutable brands are marked in the Schedule of Pharmaceutical Benefits with an ‘a’-flag. When PBS brands are ’a’-flagged with each other the pharmacist may dispense any of these brands in consultation with the patient and provided the prescriber has not indicated ‘brand substitution not permitted’ on the prescription.

Pharmacists can substitute a reference brand with a biosimilar brand, however, depending on the PBS item code prescribed, substituting a biosimilar brand with a reference brand may not be permitted.

Authority requirements for omalizumab

Authority Requirements for prescribing omalizumab vary between PBS items and need to be confirmed in the Schedule of Pharmaceutical Benefits. Depending on the item, authority approval may be obtained either in writing or via the Health Professionals Online Service (HPOS) form upload facility, or alternatively approval may be obtained in real time via telephone or online application via Services Australia’s Online PBS Authorities (OPA) system.

Prescribers may use the relevant Authority Required (STREAMLINED) code for the *continuing* treatment phase when prescribing the biosimilar brand Omlyclo®.

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

Do biosimilar uptake drivers apply to omalizumab?

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

For some items, prescribing the biosimilar brand is administratively easier than prescribing the reference brand as authority requirements may differ.

In line with the Government’s commitment to the uptake of biosimilars, prescribers are encouraged to prescribe a biosimilar brand for treatment-naïve patients where appropriate. The following administrative note is included in the Schedule for some items:

Biosimilar prescribing policy

Prescribing of a biosimilar brand where available 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 PBS subsidises a range of biological medicines to treat cancers, immunological and degenerative disorders, which significantly affect the quality of life for affected individuals. These are generally innovative treatments and their increasing cost and utilisation across a range of disease indications continue to put pressure on the PBS. In 2024-25, biological medicines represented seven of the ten PBS medicines which attracted the most Government subsidy, with a combined cost of over $3.18 billion. Biosimilar prescribing can help relieve this pressure.

In addition, availability of biosimilar medicines ensures that there are more brand options for prescribers and patients, reducing the risk of medicines shortages.

How can greater use of biosimilars benefit the PBS?

Brand competition can lead 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 timely, 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 Omlyclo
- 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.