Pharmaceutical Benefits Scheme – Biosimilar Infliximab

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

Brand name	Date listed on PBS
Inflectra®	1 December 2015
Renflexis®	1 August 2017
Remsima®	1 July 2021
Ixifi®	1 November 2025

These brands are 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.

Inflectra®, Renflexis®, Remsima® and Ixifi® have been assessed by the TGA on the basis of comparability and clinical studies to be highly similar to the reference brand, Remicade®.

This means that Inflectra®, Renflexis®, Remsima® and Ixifi® provide the same health outcomes and are as safe and effective as Remicade®.

Infliximab is also available on the PBS in the PBS General Schedule as the brand Remsima SC® (subcutaneous 120mg/mL injection formulation). There are no alternative biosimilar brands available on the PBS for this specific formulation in the General Schedule.

What is infliximab?

Infliximab is a biological medicine that is used to treat autoimmune conditions such as ankylosing spondylitis, Crohn disease, psoriatic arthritis, psoriasis, rheumatoid arthritis and ulcerative colitis.

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

Can PBS brands of infliximab be substituted?

The Pharmaceutical Benefits Advisory Committee (PBAC), an independent, expert advisory body, recommended that Inflectra®, Renflexis®, Remsima® and Ixifi® be listed on the PBS as substitutable biosimilars of Remicade®, the reference brand of infliximab. Substitutable brands are marked in the Schedule 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.

Authority requirements for infliximab

Authority Requirements for prescribing infliximab 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.

For a number of PBS indications prescribers may use the relevant Authority Required (STREAMLINED) code for the *subsequent continuing* treatment phase when prescribing the biosimilar brands Inflectra®, Renflexis®, Remsima® and Ixifi®. Biosimilars are also Authority Required (STREAMLINED) for some indications for the *first continuing* treatment phase.

Read the Schedule of Pharmaceutical Benefits for the complete restrictions for infliximab. The Schedule is also available via the PBS publications page. Prescribing software also contains details of initial, continuing, first continuing, and subsequent continuing treatment phases criteria and eligibility details. Please select item codes carefully. Over time PBS listing details may change – please consult the Schedule for current information.

Do biosimilar uptake drivers apply to infliximab?

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:

> **Biosimilar Prescribing Policy**
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> Prescribing of the 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.

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 Inflectra.
- PBS website – PBAC Public summary document for Renflexis.
- PBS website – PBAC Public Summary Document for Remsima®
- PBS website – PBAC Public Summary Document for Ixifi®
- 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.