# Pharmaceutical Benefits Scheme – Biosimilar Infliximab

Inflectra® and Renflexis® are biosimilars brand of infliximab which were listed on the Pharmaceutical Benefits Scheme (PBS) on 1 December 2015 and 1 August 2017 respectively. 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 and Renflexis 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 and Renflexis 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 and Renflexis be listed on the PBS as substitutable biosimilars of Remicade for all approved indications. The 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 infliximab?

A number of changes to PBS listings for infliximab have been made which support Australian Government initiatives to encourage the use of biosimilar brands of biological medicines. These include the application of biosimilar uptake drivers and certain changes in the availability of substitution between brands of infliximab on the PBS.

On 1 October 2019, the private hospital listings were amended to Authority Required (STREAMLINED) in the instances where the medicine is already listed with this authority level for public hospitals.

On 1 November 2019, further PBS listing amendments were made. These allow for brand substitution where prescriptions are Authority Required (Written) at the subsequent continuing treatment phase.

Read the Schedule of Pharmaceutical Benefits for the restrictions for infliximab. The Schedule is also available via the PBS publications page. The prescribing software contains further details of initial, first continuing and subsequent continuing treatment phase criteria and eligibility details. 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.

The PBS listings for infliximab were changed to provide for a simpler and faster approval process for prescribing Inflectra and Renflexis using the Authority Required (STREAMLINED) process for subsequent continuing treatment, while maintaining the Authority Required (Written) process for Remicade. Prescriptions for the biosimilar brands in private hospitals can be written using online approval or Authority Required (telephone).

These changes were implemented for each indication as follows:

| Implementation date | Indication |
|---|---|
| 1 July 2018 | Severe Crohn Disease |
| 1 August 2018 | Complex Refractory Fistulising Crohn Disease |
| 1 September 2018 | Paediatric Patients with Refractory Crohn Disease |
| 1 October 2018 | Moderate to Severe Ulcerative Colitis |
| 1 November 2018 | Ankylosing Spondylitis and Rheumatoid Arthritis |
| 1 December 2018 | Adult Patients with Severe Active Psoriatic Arthritis |
| 1 January 2019 | Severe Chronic Plaque Psoriasis |

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 infliximab:

**Note Biosimilar Prescribing Policy**

Prescribing of the biosimilar brand Inflectra or Renflexis 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

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.
- 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.