



Pharmaceutical Benefits Scheme – Biosimilar Rituximab

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

Brand name	Date listed on PBS
Riximyo®	1 October 2019
Truxima®	1 January 2020
Ruxience®	1 June 2022

These brands are listed under the [Section 100 Highly Specialised Drugs Program](#) (HSD Program), and the [Efficient Funding of Chemotherapy](#) (EFC) 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.

Riximyo, Ruxience and Truxima have been assessed by the TGA on the basis of comparability and clinical studies to be highly similar to the reference brand, MabThera®. This means that Riximyo, Ruxience and Truxima provide the same health outcomes and are as safe and effective as MabThera.

MabThera was removed from the PBS at the request of the pharmaceutical company which supplies this brand on 1 April 2021.

What is rituximab?

Rituximab is used to treat severe autoimmune inflammatory diseases such as severe active rheumatoid arthritis, severe active microscopic polyangiitis, polyangiitis (Wegeners granulomatosis), and the cancers, follicular B-cell non-Hodgkin's lymphoma, CD20 positive lymphoid cancer and CD20 positive acute lymphoblastic leukaemia.

More information about this medicine is available by entering 'rituximab' at the [NPS MedicineWise Medicine Finder](#).

Can PBS brands of rituximab be substituted?

The Pharmaceutical Benefits Advisory Committee (PBAC), an independent, expert advisory body, recommended that Riximyo, Ruxience and Truxima be listed on the PBS as substitutable biosimilars of MabThera for all approved indications. Following the removal of MabThera from the PBS, Riximyo, Ruxience and Truxima 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 rituximab?

Following a recommendation of the PBAC, PBS listings for Riximyo, Ruxience and Truxima became Unrestricted on 1 September 2022. Previously these brands were either [Authority Required \(Written\)](#) or [Authority Required \(STREAMLINED\)](#).

The brands continue to be supplied under the HSD and EFC Programs.

Following these listing changes, Supply Only arrangements were applied to enable repeat dispensing of some forms and strengths of rituximab on the PBS for a limited time.

Read the Schedule of Pharmaceutical Benefits for the [rituximab](#) listings. The Schedule is also available via the [PBS publications page](#). The prescribing software contains further details. Over time PBS listing details may change – please consult the Schedule for current information.

Do biosimilar uptake drivers apply to rituximab?

The Government has implemented policies to encourage greater use of biosimilar brands. Further information about the biosimilar uptake drivers is available on the [PBS website](#).

Following the removal from the PBS of the reference brand MabThera on 1 April 2021, biosimilar uptake drivers are no longer required for rituximab.

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 [Riximyo](#).
- PBS website – PBAC Public summary document for [Ruxience](#).
- PBS website – PBAC Public summary document for [Truxima](#).
- 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.