Australian Government

Department of Health

Pharmaceutical Benefits Scheme
Biosimilar RITUXIMAB

Riximyo® and Truxima® are biosimilars brands of rituximab which were listed on the Pharmaceutical Benefits Scheme (PBS) on 1 October 2019 and 1 January 2020 respectively. 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 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 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 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 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?

Prescriptions for Riximyo and Truxima under the HSD Program may use an Authority Required (STREAMLINED) code for re-induction of remission, maintenance therapy and subsequent continuing treatment.

Prescriptions remain Authority Required (Written) for Riximyo and Truxima when used in the following indications and treatment phases:

Indication	Treatment phase
Severe active granulomatosis with polyangiitis (Wegeners granulomatosis)	Induction of remission Re-induction of remission
Severe active microscopic polyangiitis	Induction of remission Re-induction of remission
Adult patients with severe active Rheumatoid Arthritis	Initial 1, Initial 2, Initial 3 First continuing Subsequent continuing

For Authority Required (Written) prescribing in the above circumstances, Riximyo and Truxima are substitutable, and are marked with an 'a'-flag in the Schedule of Pharmaceutical Benefits (the Schedule).

Note that for use of rituximab under the EFC Program, prescriptions are Authority Required (STREAMLINED) for all brands

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 current information.

Do biosimilar uptake drivers apply to rituximab?

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

The PBS listings for rituximab were changed from 1 October 2019 to provide for a simpler and faster approval process for prescribing the biosimilar brand Riximyo under the HSD Program. The biosimilar brands may use an Authority Required (STREAMLINED) code for re-induction of remission and subsequent continuing treatment. This prescribing process was also made available for Truxima from 1 February 2020.

To further encourage uptake an administrative Note, applicable to all indications, has been added for prescribers in the Schedule. The Note is reflected in the listing for initial treatment of severe active rheumatoid arthritis and for induction of remission for the polyangiitis indications with rituximab (ie. severe active granulomatosis with polyangiitis (Wegeners granulomatosis) and severe active microscopic polyangiitis):

> *Note*
>
> *Biosimilar prescribing policy*
>
> *Prescribing of the biosimilar brand Riximyo or Truxima 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 can be found on the Biosimilar Awareness Initiative webpage.*

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 Riximyo on the PBAC webpage of the PBS website

The PBAC Public Summary Document for Truxima 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’.