Australian Government
Department of Health

Information for Healthcare Professionals
Pharmaceutical Benefits Scheme (PBS) – Listing Changes for Biosimilar RITUXIMAB

Amended PBS listings for rituximab

From 1 October 2019, following advice from the independent, expert Pharmaceutical Benefits Advisory Committee (PBAC), rituximab may be prescribed as an Authority Required (STREAMLINED) item. For continuing treatment of inflammatory conditions with rituximab, brands may be prescribed as either written or streamlined authorities.

A summary of the rituximab PBS listing amendments for each indication, updated to 1 February 2020, is provided in the **table below.**

Refer to the Schedule of Pharmaceutical Benefits, available online, in PDF and in prescribing software, for detailed information on the PBS prescribing restrictions.

Further information about the biosimilar uptake drivers, why they are important, and how they are being implemented, is available on the PBS website.

The listing updates will be notified through PBS News.

Why have the rituximab listings been amended?

Truxima® is a brand of rituximab listed in the PBS Schedule on 1 January 2020 through the Efficient Funding of Chemotherapy (EFC) Program. Further listing changes on 1 February 2020 enable availability of this brand through the Highly Specialised Drugs (HSD) Program, also known as s100 HSD supply. Truxima® is the second biosimilar brand on the PBS, and joins the following brands of rituximab listed in the Schedule:

Brand name	Date listed on PBS	Brand status
MabThera®	1 February 1999	Reference
Riximyo®	1 October 2019	Biosimilar

From 1 October 2019 the PBS listings for rituximab were amended as a part of Australian Government initiatives to encourage the use of biosimilar brands of biological medicines.

These changes follow from the listing in the PBS Schedule of the biosimilar brands of rituximab and include new authority required listing conditions which implement the Government's biosimilar uptake driver policy. An administrative Note has been added in the Schedule of Pharmaceutical Benefits encouraging the use of a biosimilar brand of rituximab for initial treatment or induction therapy. Further information is provided on the PBS webpage, Biosimilars on the PBS.

What is rituximab?

Rituximab is used to treat severe autoimmune inflammatory diseases such as rheumatoid arthritis and polyangiitis, and the cancers, lymphoma and leukaemia

Rituximab is subsidised under the HSD and EFC Programs of the PBS. Note also that the brand MabThera SC® of rituximab is also available under the General Schedule and the EFC for use in treating lymphoid cancer and non-Hodgkin's lymphoma.

What is a biological medicine?

Biological medicines, including biosimilars, contain active substances derived from living cells or organisms. Compared to synthetic chemical medicines, biological medicines are more complex and have an inherent degree of minor variability in the production process. This means no two batches of a biological medicine (even from the same manufacturer) are ever exactly the same.

What is a biosimilar medicine?

Biosimilar medicines are highly similar versions of an already registered reference brand of a biological medicine.

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, 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.

Prescriber choice and brand substitution

Following recommendations by the PBAC, the three brands of rituximab on both the HSD and EFC Programs are considered to be substitutable. In its recommendation the PBAC noted that the Therapeutic Goods Administration considered Riximyo® and Truxima® to be biosimilar to MabThera®, each brand having the same safety and efficacy and providing the same health outcomes.

Prescribers retain, in consultation with their patient, the choice of which brand to prescribe. 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', and they have permission from the patient.

Who chooses whether the biosimilar brand is used?

In Australia, infusions of rituximab are administered in a hospital or clinic. The choice of brand generally used in a hospital or clinic may be based on medicine purchasing decisions made by a clinician-led committee. Specific patient requirements will remain for discussion between a patient and treating clinician.

Prescribers are encouraged to discuss biosimilar medicines with patients. See "How do I talk to patients about biosimilar medicines?" in the 'Information for health care professionals' FAQs on the Australian Government Department of Health website.

Why are biosimilar medicines important?

The PBS is a key element of Australia's National Medicines Policy, which aims to deliver timely access to medicines at a cost that individuals and the community can afford.

Increasing costs associated with very expensive new health technologies, and the increasing prevalence of chronic conditions, is putting pressure on the sustainability of the PBS. Eight of the ten most expensive medicines subsidised by the PBS in 2018-19 were biological medicines with a combined cost of $1.87 billion. The cost to Government for rituximab alone in 2018-19 was $103.5 million.

Increasing the use of biosimilar medicines is expected to deliver significant reductions in the cost of the PBS, due to price competition in the market. This can improve the Government's capacity to fund expanded access to biological medicines as they become more affordable. It can also reduce the risk of medicine shortages.

Where can I find 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 PBS website

The PBAC Public Summary Document for Truxima® on the PBS website

The Biosimilar Education Hub

TABLES

Rituximab - Efficient Funding of Chemotherapy (EFC) (Public and Private) PBS Listings Summary

Background

The PBAC recommended at its March 2018 and March 2019 meetings respectively the listing on the PBS of the biosimilar brands of rituximab, Riximyo® and Truxima®. The PBAC considered all brands of rituximab on the PBS to be equivalent for the purposes of substitution.

Authority Required (STREAMLINED):

Form / Strength	Brand	PBS Indication	Treatment phase	Authority Code	PBS Item Code for Claiming
100 mg/10 mL injection, 2 x 10 mL vials 500 mg/50 mL injection, 50 mL vial 100 mg/10 mL injection, 2 x 10 mL vials 500 mg/50 mL injection, 50 mL vial 100 mg/10 mL injection, 2 x 10 mL vials 500 mg/50 mL injection, 50 mL vial	MabThera MabThera Riximyo Riximyo Truxima Truxima	Relapsed or refractory Stage III or IV CD20 positive follicular B-cell non-Hodgkin's lymphoma	Maintenance	9542	4613T (Public) 7258B (Private)
100 mg/10 mL injection, 2 x 10 mL vials 500 mg/50 mL injection, 50 mL vial 100 mg/10 mL injection, 2 x 10 mL vials 500 mg/50 mL injection, 50 mL vial 100 mg/10 mL injection, 2 x 10 mL vials 500 mg/50 mL injection, 50 mL vial	MabThera MabThera Riximyo Riximyo Truxima Truxima	Stage III or IV CD20 positive follicular B-cell non-Hodgkin's lymphoma	Maintenance	9451	10179R (Public) 10193L (Private)

Form / Strength	Brand	PBS Indication	Treatment phase	Authority Code	PBS Item Code for Claiming
100 mg/10 mL injection, 2 x 10 mL vials 500 mg/50 mL injection, 50 mL vial 100 mg/10 mL injection, 2 x 10 mL vials 500 mg/50 mL injection, 50 mL vial 100 mg/10 mL injection, 2 x 10 mL vials 500 mg/50 mL injection, 50 mL vial	MabThera MabThera Riximyo Riximyo Truxima Truxima	Previously untreated or relapsed/refractory CD20 positive lymphoid cancer	Induction or re-induction	7400	4614W (Public) 7257Y (Private)
100 mg/10 mL injection, 2 x 10 mL vials 500 mg/50 mL injection, 50 mL vial 100 mg/10 mL injection, 2 x 10 mL vials 500 mg/50 mL injection, 50 mL vial 100 mg/10 mL injection, 2 x 10 mL vials 500 mg/50 mL injection, 50 mL vial	MabThera MabThera Riximyo Riximyo Truxima Truxima	Previously untreated or Relapsed/refractory CD20 positive acute lymphoblastic leukaemia	Maintenance	7399	4615X (Public) 7259C (Private)

Note that under section 33(2) of the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011*, chemotherapy medicines supplied under the Efficient Funding of Chemotherapy program may be substituted with a different brand of the same chemotherapy medicine. These medicines are not marked with 'a'-flags in the Schedule of Pharmaceutical Benefits.

For more detailed information on prescribing conditions, please refer to the *Schedule of Pharmaceutical Benefits – Efficient Funding of Chemotherapy Supplement*, which is available on the PBS Publications page of the PBS website.

Rituximab – Highly Specialised Drug Program (HSD) (Public) PBS Listings

Authority Required (STREAMLINED):

Form / Strength	Brand / a flag	PBS Indication	Treatment phase	Authority Code	PBS Item Code for Claiming
100 mg/10 mL injection, 2 x 10 mL vials	Riximyo **a** Truxima **a**	Severe active granulomatosis with polyangiitis (Wegeners granulomatosis) Severe active microscopic polyangiitis	Re-induction of remission	9336 9539	11813R
500 mg/50 mL injection, 50 mL vial	Riximyo **a** Truxima **a**	Severe active granulomatosis with polyangiitis (Wegeners granulomatosis) Severe active microscopic polyangiitis	Re-induction of remission	9336 9539	11800C
500 mg/50 mL injection, 50 mL vial	Riximyo **a** Truxima **a**	Adult patients with severe active Rheumatoid Arthritis	Subsequent continuing	9446	11805H

***Authority Required (Written)**:*

Form / Strength	Brand / a flag	PBS Indication	Treatment phase	PBS Item Code for Claiming
100 mg/10 mL injection, 2 x 10 mL vials	MabThera a Riximyo a Truxima a	Severe active granulomatosis with polyangiitis (Wegeners granulomatosis)	Induction of remission	10591K
		Severe active microscopic polyangiitis		
		Severe active granulomatosis with polyangiitis (Wegeners granulomatosis)	Re-induction of remission	
		Severe active microscopic polyangiitis		
500 mg/50 mL injection, 50 mL vial	MabThera a Riximyo a Truxima a	Severe active granulomatosis with polyangiitis (Wegeners granulomatosis)	Induction of remission	10593M
		Severe active microscopic polyangiitis		
		Severe active granulomatosis with polyangiitis (Wegeners granulomatosis)	Re-induction of remission	
		Severe active microscopic polyangiitis		

Form / Strength	Brand / a flag	PBS Indication	Treatment phase	PBS Item Code for Claiming
500 mg/50 mL injection, 50 mL vial	MabThera **a** Riximyo **a** Truxima **a**	Adult patients with severe active Rheumatoid Arthritis	Initial 1 (new patient) Initial 2 – (change or recommencement less than 24 months) Initial 3 – (change or recommencement more than 24 months) First continuing Subsequent continuing	9544H

A Note in the Schedule of Pharmaceutical Benefits states that prescribing of the biosimilar brands, Riximyo and Truxima, is encouraged for treatment naïve patients (ie for induction of remission).

Rituximab – Highly Specialised Drug Program (HSD) (Private) PBS Listings

Authority Required (STREAMLINED):

Form / Strength	Brand / a flag	PBS Indication	Treatment phase	Authority Code	PBS Item Code for Claiming
100 mg/10 mL injection, 2 x 10 mL vials	Riximyo **a** Truxima **a**	Severe active granulomatosis with polyangiitis (Wegeners granulomatosis) Severe active microscopic polyangiitis	Re-induction of remission	9640 9641	11810N
500 mg/50 mL injection, 50 mL vial	Riximyo **a** Truxima **a**	Severe active granulomatosis with polyangiitis (Wegeners granulomatosis) Severe active microscopic polyangiitis	Re-induction of remission	9640 9641	11804G
500 mg/50 mL injection, 50 mL vial	Riximyo **a** Truxima **a**	Adult patients with severe active Rheumatoid Arthritis	Subsequent continuing	9611	11790M

***Authority Required (Written)**:*

Form / Strength	Brand / a flag	PBS Indication	Treatment phase	PBS Item Code for Claiming
100 mg/10 mL injection, 2 x 10 mL vials	MabThera a Riximyo a Truxima a	Severe active granulomatosis with polyangiitis (Wegeners granulomatosis)	Induction of remission	10583B
		Severe active microscopic polyangiitis	Induction of remission	
		Severe active granulomatosis with polyangiitis (Wegeners granulomatosis)	Re-induction of remission	
		Severe active microscopic polyangiitis	Re-induction of remission	
500 mg/50 mL injection, 50 mL vial	MabThera a Riximyo a Truxima a	Severe active granulomatosis with polyangiitis (Wegeners granulomatosis) Severe active microscopic polyangiitis	Induction of remission	10576P
		Severe active granulomatosis with polyangiitis (Wegeners granulomatosis)	Re-induction of remission	
		Severe active microscopic polyangiitis	Re-induction of remission	

Form / Strength	Brand / a flag	PBS Indication	Treatment phase	PBS Item Code for Claiming
500 mg/50 mL injection, 50 mL vial	MabThera **a** Riximyo **a** Truxima **a**	Adult patients with severe active Rheumatoid Arthritis	Initial 1 (new patient) Initial 2 – (change or recommencement less than 24 months) Initial 3 – (change or recommencement more than 24 months) First continuing Subsequent continuing	9611W

A Note in the Schedule of Pharmaceutical Benefits states that prescribing of the biosimilar brands, Riximyo and Truxima, is encouraged for treatment naïve patients.