



Factsheet for Healthcare Professionals

Infliximab Biosimilars on the Pharmaceutical Benefits Scheme

Renflexis[®] is a new brand of infliximab listed on the Pharmaceutical Benefits Scheme (PBS) on 1 August 2017. Like Inflectra[®], which was PBS listed on 1 December 2015, it is a biosimilar to the reference biological medicine Remicade[®].

All three brands contain infliximab.

The biosimilar brands have been assessed by the Therapeutic Goods Administration on the basis of comparability and clinical studies to be highly similar to the reference brand. This means Inflectra[®], Remicade[®] and Renflexis[®] provide the same health outcomes and are as safe and effective as each other.

What is infliximab?

Infliximab is a biological medicine used to treat a range of inflammatory and autoimmune diseases, including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, plaque psoriasis, ulcerative colitis, and Crohn's disease. Infliximab is supplied on the PBS under a *National Health Act* s100 arrangement and can only be prescribed by specialists.

The three infliximab brands are dosed the same and are available as 100mg vials for infusion.

Details of the PBS prescribing restrictions are available in the [online Schedule of Pharmaceutical Benefits](#), or in your prescribing software.

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 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 to be approved for marketing, its structural variability must not be greater than the acceptable limits of batch variation for the reference biological medicine, and all critical quality attributes (i.e. those important for the function of the molecule) must be highly similar.

Infliximab and PBS brand substitution

The independent expert Pharmaceutical Benefits Advisory Committee (PBAC) recommended Inflectra[®] and Renflexis[®] be listed on the PBS as substitutable biosimilars of the Remicade[®] reference brand of infliximab. All three brands are substitutable with each other. The PBAC stated it had no reason to consider that substitution between more than two brands of infliximab would affect patient outcomes.

When PBS brands are listed as substitutable with each other, the pharmacist may dispense any of these brands from the script, 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, infliximab infusions are administered in specialist infusion clinics within hospitals. The choice of brand generally used in a hospital 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.

If you or your patient are unsure about the brand previously dispensed on the PBS, this can be checked easily for patients with a My Health Record, including through My Health Record information in many prescribing software products, or by the patient checking their Record.

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 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. Six of the ten most expensive medicines subsidised by the PBS in 2015-16 were biological medicines, with a combined cost of \$1.28 billion.

Increasing use of biosimilar medicines is expected to deliver significant savings, due to price competition in the market. These savings can be reinvested into other areas of the Australian health system, expand access to biologic medicines as they become more affordable, and reduce the risk of medicine shortages.

Where can I find more information?

Australian Government Department of Health: <http://www.health.gov.au/biosimilars>

Therapeutic Goods Administration: www.tga.gov.au/publication/evaluation-biosimilars

The PBAC Public Summary Document for Renflexis®: <http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2016-11/infliximab-biosimilar-psd-november-2016>

The PBAC Public Summary Document for Inflectra®: <http://www.pbs.gov.au/industry/listing/elements/pbac-meetings/psd/2015-07/files/infliximab-psd-july-2015.pdf>

