



## Australian Government

### Department of Health

#### **Information for Consumers and Carers Pharmaceutical Benefits Scheme Listing Changes – Biosimilar INFLIXIMAB**

Inflextra<sup>®</sup> and Renflexis<sup>®</sup> are biosimilar brands of infliximab and are listed on the Pharmaceutical Benefits Scheme (PBS) together with the reference biological medicine Remicade<sup>®</sup>.

From 1 October 2019 changes were made to the PBS listings to allow for a consistent approach to prescribing infliximab in public and private hospitals. This means that your doctor can apply for approval to prescribe these medicines using the same processes in both hospital settings. Further changes from 1 November 2019 have resulted in a more consistent approach to enabling substitution between brands.

Medicines on the PBS are subsidised by the Australian Government.

#### **What is infliximab?**

Infliximab is a biological medicine that is used to treat a range of serious and chronic diseases, including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, plaque psoriasis, ulcerative colitis, and Crohn's disease. Your doctor can discuss with you the detailed requirements around prescribing PBS subsidised infliximab.

Infliximab is prescribed by specialists. It is administered in specialist infusion clinics and given through an infusion into a vein.

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

#### **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 chemical based medicines.

A biosimilar medicine is a highly similar version of a reference biological medicine, which is 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.

#### **Infliximab and PBS brand substitution**

The independent expert Pharmaceutical Benefits Advisory Committee (PBAC) recommended that Inflextra<sup>®</sup> and Renflexis<sup>®</sup> be listed on the PBS as substitutable biosimilars of the Remicade<sup>®</sup> reference brand of infliximab. All three brands are substitutable with each other.

When PBS brands are listed as substitutable the pharmacist can dispense any brand, with permission from the patient, unless directed otherwise by the prescriber.

**Who chooses the brand?**

The choice of which brand of infliximab to use is made by the doctor in consultation with the patient. Specific patient requirements will remain for discussion between a patient and their doctor.

**Will I have the same health outcome no matter which brand of infliximab I use?**

Yes. The Therapeutic Goods Administration approved Inflectra<sup>®</sup> and Renflexis<sup>®</sup> as biosimilars of Remicade<sup>®</sup> because they were determined to be as safe and effective as Remicade<sup>®</sup> and they provide the same health outcomes.

**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. Seven of the ten most expensive medicines subsidised by the PBS in 2017-18 were biological medicines with a combined cost of \$1.53 billion. The introduction of biosimilar medicines encourages brand competition in the Australian market. This will lead to a reduction in the cost of biological medicines, ensuring the government can continue to subsidise access to new and innovative treatments for seriously ill patients.

**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](#)