

5.25 INFLIXIMAB, Powder for I.V. infusion 100 mg, Ixifi[®], Pfizer Australia Pty Ltd.

1 Purpose of Submission

- 1.1 The Category 3 submission requested Section 100 (Highly Specialised Drugs Program) Authority Required listings of a new infliximab biosimilar (Ixifi[®]).
- 1.2 The submission requested listing on a cost-minimisation basis and under the same circumstances as the existing PBS-listed biosimilar brands of infliximab 100 mg powder for injection (Inflectra[®] and Renflexis[®]), for the same indications.

2 Background

- 2.1 Ixifi was TGA registered on 27 September 2024 as a biosimilar to the reference brand (Remicade[®]) and with the same indications:
 - rheumatoid arthritis;
 - psoriatic arthritis;
 - Crohn’s disease in adults, and children and adolescents (6 to 17 years)
 - refractory Crohn’s disease;
 - ankylosing spondylitis;
 - psoriasis; and
 - ulcerative colitis in adults, and children and adolescents (6 to 17 years).

3 Requested listing

- 3.1 The submission requested listing Ixifi under the same circumstances as the PBS-listed biosimilars brands of infliximab (Inflectra and Renflexis). The submission also requested that the listings for Ixifi be consistent with the biosimilar uptake driver policy.
- 3.2 The full restrictions have not been reproduced here.

Add brand to existing items:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
INFLIXIMAB					
infliximab 100 mg injection, 1 vial	Multiple	-	-	-	Remicade (originator) Inflectra (biosimilar brand)

					Renflexis (biosimilar brand) Ixifi (proposed biosimilar brand)
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- 3.3 Ixifi will have the same drug, form and manner of administration as the existing infliximab (100 mg powder for injection) brands and, as such, will be required to have the same approved ex-manufacturer price (AEMP) as the existing infliximab (100 mg powder for injection) brands as per Section 85C of the National Health Act 1953.

4 Consideration of the evidence

Sponsor hearing

- 4.1 There was no hearing for this item.

Consumer comments

- 4.2 The PBAC noted and welcomed the input from the Australasian Society of Clinical Immunology and Allergy (ASCIA) via the Consumer Comments facility on the PBS website. ASCIA supported the PBS listing of Ixifi to facilitate early treatment of severe active rheumatoid arthritis and other relevant autoimmune conditions and considered that having multiple brands available of infliximab mitigates the risk of supply issues.

Clinical evidence

- 4.3 As per the Product Information, the TGA has confirmed that “Ixifi is a biosimilar medicine to Remicade. The evidence for comparability supports the use of Ixifi for the listed indications.”
- 4.4 As a Category 3 submission, no evaluation of the clinical evidence was undertaken.

Estimated PBS usage and financial implications

- 4.5 Listing of biosimilar brands does not change overall utilisation of the drug.
- 4.6 The submission stated that Ixifi is expected to substitute for the other brands of infliximab 100 mg powder for injection and, as such, there is expected to be nil financial impact to the PBS/RPBS with the proposed listing.

5 PBAC Outcome

- 5.1 The PBAC recommended Section 100 (Highly Specialised Drugs Program) Authority Required listings of a new infliximab biosimilar (Ixifi®) on a cost-minimisation basis and under the same circumstances as the existing PBS-listed biosimilar brands of infliximab 100 mg powder for injection (Inflectra® and Renflexis®), for the same indications.
- 5.2 The PBAC noted that the TGA has confirmed biosimilarity between Ixifi and the reference product Remicade.
- 5.3 The PBAC noted that the submission requested for the Ixifi listings to be consistent with the biosimilar uptake driver policy, that is, to have an Authority Required

(STREAMLINED) requirement for the subsequent continuing treatment listings and the inclusion of an administrative note across all Ixifi listings encouraging use of the biosimilar brand for treatment naïve patients. The PBAC considered that the application of biosimilar uptake drivers to Ixifi would be clinically appropriate and would not impact cost-effectiveness.

- 5.4 The PBAC advised that, under Section 101(4AACD) of the National Health Act 1953, Ixifi, Inflectra, Renflexis and Remicade should be considered equivalent for substitution on the Schedule of Pharmaceutical Benefits.
- 5.5 The PBAC considered that the listing of Ixifi would not result in a net cost to the PBS as it would likely substitute for the other brands of infliximab 100 mg powder for injection and not increase the overall market utilisation.
- 5.6 The PBAC noted its recommendation was on a cost-minimisation basis and advised that, because Ixifi is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity over the other brands of infliximab 100 mg powder for injection, or not expected to address a high and urgent unmet clinical need given the presence of alternative therapies, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* for Pricing Pathway A were not met.
- 5.7 The PBAC noted this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

6 Recommended listing

- 6.1 The restrictions are complex due to the number of items and indications requested for listing. As the submission requested the same restrictions as the existing brands, the full restrictions have not been reproduced.
- 6.2 Add Ixifi biosimilar listings, with schedule equivalence ('a' flag) for the same indications as Inflectra and Renflexis.
- 6.3 Amend existing listings as follows:
 - Add the Ixifi brand – Authority Required listing of Ixifi, with the Authority type for each treatment phase and indication to be consistent with current infliximab 100 mg powder for injection listings. A separate Authority Required (STREAMLINED) listing of Ixifi for the subsequent continuing treatment restriction for relevant listings.
 - Apply the 'Biosimilar prescribing policy' administrative note encouraging the use of biosimilar brands for treatment naïve patients:

Prescribing of the biosimilar brand Ixifi 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 Medicines webpage (www.health.gov.au/health-topics/medicines)

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INFLIXIMAB					
infliximab 100 mg injection, 1 vial	Multiple	-	-	-	Remicade (originator) Ixifi (biosimilar brand) Inflectra (biosimilar brand) Renflexis (biosimilar brand)
Category / Program: Section 100 – Highly Specialised Drugs Program (Public/Private hospitals)					

These restrictions may be subject to further review. Should there be any changes made to the restriction the sponsor will be informed.

7 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

8 Sponsor's Comment

The sponsor had no comment.