5.23 INFLIXIMAB, Powder for I.V. infusion 100 mg, Remsima®, Celltrion Healthcare 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 (Remsima®).

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 Remsima was TGA registered on 27 November 2015 as a biosimilar to the reference brand (Remicade®) and with the same indications:

- rheumatoid arthritis;
- psoriatic arthritis;
- Crohn's disease in adults and children (6 to 17 years)
- refractory Crohn's disease;
- ankylosing spondylitis;
- psoriasis; and
- ulcerative colitis in adults and children (6 to 17 years).

3 Requested listing

3.1 The submission requested listing Remsima under the same circumstances as the PBS-listed biosimilars brands of infliximab (Inflectra and Renflexis). The submission also requested that the listings for Remsima 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	№.of Rpts	Available brands
INFLIXIMAB					
infliximab 100 mg injection, 1 vial	Multiple	-	-	-	Remicade (originator) Inflectra (biosimilar brand) Renflexis (biosimilar brand) *Remsima (proposed biosimilar brand)*

3.3 Remsima 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 Crohn's and Colitis Australia (CCA) via the Consumer Comments facility on the PBS website. CCA supported the PBS listing of Remsima, stating that infliximab provides an important treatment option for people with Crohn's disease who have not responded to other treatments. CCA welcomed the addition of biosimilar versions where they are clinically equivalent and provide an economic or access benefit to people living with inflammatory bowel disease.

Clinical evidence

4.3 As per the Product Information, the TGA has confirmed that "Remsima is an approved biosimilar to the reference product Remicade. Comparability in safety, efficacy and quality between Remsima and Remicade has been established."

4.4 The submission stated that the equi-effective doses of Remsima and Remicade are: 1 mg of Remsima = 1 mg of Remicade (and/or other brands of PBS-listed infliximab).

4.5 As a Category 3 submission, no evaluation of the clinical evidence was undertaken.

Estimated PBS usage and financial implications

4.6 Listing of biosimilar brands does not change overall utilisation of the drug.

4.7 The submission stated that Remsima 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 (Remsima®) 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 advised the equi-effective doses to be 1 mg of Remsima = 1 mg of Remicade (and/or other brands of PBS-listed infliximab).

5.3 The PBAC noted that the TGA has confirmed that Remsima is a biosimilar medicine to Remicade.

5.4 The PBAC noted that the submission requested for the Remsima 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 Remsima listings encouraging use of the biosimilar brand for treatment naïve patients. The PBAC considered that the application of biosimilar uptake drivers to Remsima would be clinically appropriate and would not impact cost-effectiveness.

5.5 The PBAC advised that, under Section 101(4AACD) of the *National Health Act 1953*, Remsima, Inflectra, Renflexis and Remicade should be considered equivalent for the purpose of substitution at the pharmacy level (i.e., 'a' flagged in the Schedule of Pharmaceutical Benefits).

5.6 The PBAC considered that the listing of Remsima 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.

5.7 The PBAC noted its recommendation was on a cost-minimisation basis and advised that, because Remsima 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, and is 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.

5.8 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 Remsima biosimilar listings, with schedule equivalence ('a' flag) for the same indications as Inflectra and Renflexis and apply the biosimilar uptake policy to Remsima.

Add brand to existing items:

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