Reference number(s)
5290-D

This document applies to the following:

Product	Applies
Medicare Part B	☑
Medicare Part B: Advanced Biosimilars First	☑

Medicare Part B Step Therapy Infliximab

This document informs prescribers of preferred products and provides an exception process for non-preferred products through prior authorization.

These criteria were developed to align with the following: Medicare Part B and Medicare Part B Advanced Biosimilars First.

Plan Design Summary

This program applies to the infliximab products specified in this document. Coverage for non-preferred products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment with a non-preferred product.

Step therapy is applied in addition to any applicable National Coverage Determination (NCD), Local Coverage Determination (LCD), and Medicare Part B utilization management (UM) programs implemented for the client.

Table. Infliximab Products

Medications considered preferred on your plan may still require a clinical prior authorization review.

	Products
Preferred	• Inflectra (infliximab-dyyb) • Renflexis (infliximab-abda)
Non-preferred	• Avsola (infliximab-axxq) • infliximab • Remicade (infliximab)

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Step Therapy Criteria

Coverage for a non-preferred product is provided when either of the following criteria is met:

- Member has received treatment with the non-preferred product in the past 365 days.
- Member has had a documented intolerable adverse event to both of the preferred infliximab products, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).

References

1. Avsola [package insert]. Thousand Oaks, CA: Amgen, Inc.; September 2021.
2. Inflectra [package insert]. New York, NY: Pfizer Inc.; April 2023.
3. infliximab [package insert]. Horsham, PA: Janssen Biotech, Inc.; March 2025.
4. Remicade [package insert]. Horsham, PA: Janssen Biotech, Inc.; February 2025.
5. Renflexis [package insert]. Jersey City, NJ: Organon & Co.; December 2023.