Reference number(s)
6931-D

This document applies to the following:

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

Medicare Part B Step Therapy Autoimmune Conditions

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 Advanced Biosimilars First.

Plan Design Summary

This program applies to the autoimmune drug products specified in this document. Coverage for non-preferred products is provided based on clinical circumstances that would exclude the use of the preferred products 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. Drugs for Autoimmune Conditions

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

Abbreviation: IV = intravenous

	Product(s)
Preferred	• Entyvio (IV) (vedolizumab) • Simponi Aria (golimumab) • Tremfya (IV) (guselkumab)

	Product(s)
Non-preferred	• Actemra (IV) (tocilizumab) • Cimzia lyophilized powder (certolizumab pegol) • Ilumya (tildrakizumab-asmn) • Orencia (IV) (abatacept) • Stelara (IV) (ustekinumab)

Step Therapy Criteria

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred products.

Cimzia lyophilized powder

Coverage for Cimzia lyophilized powder is provided when any of the following criteria is met:

- Member has received treatment with Cimzia lyophilized powder in the past 365 days.
- Member has a documented inadequate response or intolerable adverse event with all of the preferred products (Entyvio IV, Simponi Aria, and Tremfya IV), where the products' indications overlap. If the member is a documented primary non-responder to an interleukin-23 (IL-23) inhibitor, then the member would not need to use the corresponding preferred product(s) from the respective class.
- Member is currently breastfeeding, pregnant, or planning pregnancy.

All Other Non-Preferred Products

Coverage for all other non-preferred products 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 a documented inadequate response or intolerable adverse event with all of the preferred products (Entyvio IV, Simponi Aria, and Tremfya IV) where the products' indications overlap, unless there is a documented clinical reason to avoid tumor necrosis factor (TNF) inhibitors (see Appendix).

Appendix

Clinical Reasons to Avoid TNF Inhibitors

- History of demyelinating disorder
- History of congestive heart failure

- History of hepatitis B virus infection
- Autoantibody formation/lupus-like syndrome
- History or risk of lymphoma or other malignancy
- History of being a primary non-responder to a TNF inhibitor

References

1. Actemra [package insert]. South San Francisco, CA: Genentech, Inc.; September 2024.
2. Cimzia [package insert]. Smyrna, GA: UCB, Inc.; September 2024.
3. Entyvio [package insert]. Cambridge, MA: Takeda Pharmaceuticals U.S.A., Inc.; May 2024.
4. Ilumya [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; April 2024.
5. Orencia [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; May 2024.
6. Simponi Aria [package insert]. Horsham, PA: Janssen Biotech, Inc.; April 2025.
7. Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc.; November 2024.
8. Tremfya [package insert]. Horsham, PA: Janssen Biotech, Inc.; March 2025.