Reference number(s)
4957-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☐
Standard Control – Choice (SCCF)	☐
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☐
Advanced Control Specialty – Choice (ACSCF)	☐
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☐

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☐
Medical Benefit	☑
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Autoimmune Conditions

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

These criteria were developed to align with the following: Medical Benefit.

Plan Design Summary

This program applies to the autoimmune drug products specified in this document. Coverage for targeted 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. For plaque psoriasis, this program applies to all members requesting treatment with a targeted product. For all other indications, this program applies to all members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Drugs for Autoimmune Conditions

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

Skyrizi intravenous (IV) and Stelara IV are indicated for induction treatment for Crohn's disease (CD) and ulcerative colitis (UC).

	Product(s)
Preferred	• Entyvio IV (vedolizumab) • Ilumya (tildrakizumab-asmn) • Simponi Aria (golimumab) • Skyrizi IV (risankizumab-rzaa) • Stelara IV (ustekinumab)
Target	• Actemra IV (tocilizumab) • Cimzia lyophilized powder (certolizumab pegol) • Orencia IV (abatacept)

Exception Criteria

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

Plaque Psoriasis

Coverage for a targeted product is provided when either of the following criteria is met:

- Member has a documented inadequate response or intolerable adverse event with the preferred product (Ilumya).
- The requested product is Cimzia lyophilized powder, and the member is currently breastfeeding, pregnant, or planning pregnancy.

Crohn's Disease

Coverage for a targeted product is provided when any of the following criteria is met:

- Member has a documented inadequate response or intolerable adverse event with all of the preferred products (Entyvio IV, Skyrizi IV, and Stelara IV), unless the member is a documented primary non-responder to an IL-23 inhibitor.
- The requested product is Cimzia lyophilized powder, and the member is currently breastfeeding, pregnant, or planning pregnancy.
- Member is currently receiving treatment with the requested targeted product, excluding when it is obtained as samples or via manufacturer's patient assistance programs.

All Other Indications

Coverage for a targeted product is provided when any of the following criteria is met:

- Member has a documented inadequate response or intolerable adverse event with the preferred product (Simponi Aria) where the products' indications overlap, unless there is a documented clinical reason to avoid TNF inhibitors (see Appendix).
- The requested product is Cimzia lyophilized powder, and the member is currently breastfeeding, pregnant, or planning pregnancy.
- Member is currently receiving treatment with the requested targeted product, excluding when it is obtained as samples or via manufacturer's patient assistance programs.

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]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; April 2024.
4. Ilumya [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; April 2024.
5. Orencia [package insert]. Princeton, NJ: Bristol-Meyers Squibb Company; May 2024.
6. Simponi Aria [package insert]. Horsham, PA: Janssen Biotech, Inc.; February 2021.
7. Skyrizi [package insert]. North Chicago, IL: AbbVie Inc.; June 2024.
8. Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc.; March 2024.