Clover Health

EXCEPTIONS CRITERIA

DISEASE-MODIFYING ANTIRHEUMATIC DRUG PRODUCTS

PREFERRED PRODUCTS: ENTYVIO AND SIMPONI ARIA

POLICY

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

I. PLAN DESIGN SUMMARY

This program applies to the disease-modifying antirheumatic drug (DMARD) products specified in this policy. 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. This program applies to 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. Disease-modifying antirheumatic drugs for autoimmune conditions

	Products	
Preferred*	• **Entyvio** (vedolizumab)	• **Simponi Aria** (golimumab, intravenous)
Targeted (non-preferred)	• **Actemra** (tocilizumab) • **Cimzia** (certolizumab pegol) • **Ilumya** (tildrakizumab-asmn)	• **Orencia** (abatacept) • **Stelara** (ustekinumab)

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

II. EXCEPTION CRITERIA

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

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

A. For Cimzia, when any of the following criteria is met:
   1. Member has received treatment with the targeted product in the past 365 days.
   2. Member has a documented inadequate response or intolerable adverse event with each of the following where the product's indications overlap:
      a. Entyvio
      b. Simponi Aria
   3. Member is currently pregnant or breastfeeding

B. For all other targeted products, when any of the following criteria is met:
   1. Member has received treatment with the targeted product in the past 365 days.
   2. Member has a documented inadequate response or intolerable adverse event with both Entyvio and Simponi Aria where the product's indications overlap, unless there is a documented clinical reason to avoid TNF inhibitors (see Appendix).

III. 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.; February 2022.
2. Cimzia [package insert]. Smyrna, GA: UCB, Inc.; September 2019.
3. Entyvio [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A. Inc.; August 2021.
4. Ilumya [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; July 2020.
5. Orencia [package insert]. Princeton, NJ: Bristol-Meyers Squibb Company; December 2021.
6. Simponi Aria [package insert]. Horsham, PA: Janssen Biotech, Inc.; February 2021.
7. Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc.; December 2020.