Clover Health

# EXCEPTIONS CRITERIA

## DISEASE-MODIFYING ANTIRHEUMATIC DRUG PRODUCTS

## PREFERRED PRODUCTS: AVSOLA, ENTYVIO, INFLECTRA, RENFLEXIS, 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 adult 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*** | • **Avsola** (infliximab-axxq)<br>• **Entyvio** (vedolizumab)<br>• **Inflectra** (infliximab-dyyb) | • **Renflexis** (infliximab-abda)<br>• **Simponi Aria** (golimumab, intravenous) |
| **Targeted** | • **Actemra** (tocilizumab)<br>• **Cimzia** (certolizumab pegol)<br>• **Ilumya** (tildrakizumab-asmn) | • **Orencia** (abatacept)<br>• **Remicade** (infliximab)<br>• **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 Remicade when either of the following criteria are met:
   1. Member has received treatment with the targeted product in the past 365 days.
   2. When both of the following criteria are met:
      a. Member has a documented intolerable adverse event with all of the preferred products: Avsola, Inflectra, and Renflexis, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
      b. Member has a documented inadequate response or intolerable adverse event with Entyvio and Simponi Aria where the product's indications overlap.

B. For Cimzia, when any of the following criteria are 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. Avsola, Inflectra, or Renflexis
   b. Entyvio
   c. Simponi Aria
3. Member is currently pregnant or breastfeeding

C. For all other targeted products, when any of the following criteria are 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, unless there is a documented clinical reason to avoid TNF inhibitors (Appendix):
   a. Avsola, Inflectra, or Renflexis
   b. Entyvio
   c. Simponi Aria

**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
- Risk of lymphoma

**REFERENCES**

1. Actemra [package insert]. South San Francisco, CA: Genentech, Inc.; June 2019.
2. Avsola [package insert]. Thousand Oaks, CA: Amgen; December 2019.
3. Cimzia [package insert]. Smyrna, GA: UCB, Inc.; September 2019.
4. Entyvio [package insert]. Deerfield, IL: Takeda Pharmaceutical America, Inc.; May 2019.
5. Ilumya [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; August 2018.
6. Inflectra [package insert]. Lake Forest, IL: Hospira, a Pfizer Company; June 2019.
7. Orencia [package insert]. Princeton, NJ: Bristol-Meyers Squibb Company; March 2019.
8. Remicade [package insert]. Horsham, PA: Janssen Biotech, Inc.; June 2018.
9. Renflexis [package insert]. Kenilworth, NJ. Merck &Co., Inc; October 2019.
10. Simponi Aria [package insert]. Horsham, PA: Janssen Biotech, Inc.; September 2019.
11. Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc.; November 2019.