MEDICAL NECESSITY CRITERIA

DRUG CLASS	MEDICAL NECESSITY CRITERIA (NON COVERED DRUGS)

Status: CVS Caremark Criteria
Type: Medical Necessity Criteria

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient cannot be switched to a preferred drug/product

AND

- The requested drug is being used for an FDA-Approved indication OR an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines)

AND

- The prescribed dose and quantity fall within the FDA approved labeling or within dosing guidelines found in the compendia of current literature

AND

- The patient has tried and had an inadequate treatment response or intolerance to the required number of formulary alternatives

  OR

- The patient has a contraindication to all the alternatives

REFERENCES

N/A

EXCEPTIONS CRITERIA

DISEASE-MODIFYING ANTIRHEUMATIC DRUGS FOR AUTOIMMUNE CONDITIONS

PREFERRED PRODUCTS: ORENCIA, REMICADE, SIMPONI ARIA

POLICY

This prior authorization program informs prescribers of preferred autoimmune products for treatment of plaque psoriasis, inflammatory joint related conditions (RA), or inflammatory bowel disease. This program limits coverage to certain autoimmune drugs for treatment of specific conditions, and therefore not all FDA labeled uses of a drug are covered.

The prior authorization process evaluates if a clinical exception exists for use of a non-preferred autoimmune drug for these specific conditions. Coverage for a non-preferred autoimmune drug is provided when all preferred drugs have been tried, and either are not tolerated, ineffective, or contraindicated for the patient.

I. PLAN DESIGN SUMMARY

This program applies to non-preferred autoimmune products used in the treatment of plaque psoriasis, inflammatory joint related conditions (RA), or inflammatory bowel disease. Coverage for targeted products (those which are non-preferred and not covered for the prescribed indication) is provided based on clinical circumstances that would exclude the use of the preferred product(s) for the indication. For plaque psoriasis indication, this program does not apply to members currently receiving therapy with a non-preferred product for which there is no preferred product in the same subclass (e.g., interleukin antagonist). For inflammatory joint or bowel disease indications, coverage for the non-preferred product will continue in situations where the patient is currently receiving treatment.

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	• **Orencia** (abatacept) • **Remicade** (infliximab) • **Simponi Aria** (golimumab, intravenous)
Non-Preferred	• **Actemra** (tocilizumab) • **Entyvio** (vedolizumab) • **Inflectra** (infliximab-dyyb) • **Stelara** (ustekinumab)

*If applicable for approved indication

II. EXCEPTION CRITERIA

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

1. Member has had an inadequate response to treatment with a preferred product
2. Member has experienced an intolerable adverse event to all applicable preferred products
3. For indications where Remicade is the only preferred product option (i.e., Crohn's disease, ulcerative colitis, etc.), member has a contraindication to therapy with Remicade (i.e., moderate to severe heart failure defined as NYHA Functional Class III to IV or risk of lymphoma or serious injection) *(Note: does not apply to Inflectra)*

4. Member is currently receiving therapy with the requested product through insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) and has received at least a 28-day supply within the past 90 days

REFERENCES

1. Actemra [package insert]. South San Francisco, CA: Genentech, Inc.; November 2014.
2. Cimzia [package insert]. Smyrna, GA: UCB, Inc.; April 2016.
3. Entyvio [package insert]. Deerfield, IL: Takeda Pharmaceutical America, Inc.; May 2014.
4. Inflectra [package insert]. Lake Forest, IL: Hospira, a Pfizer Company; April 2016.
5. Orencia [package insert]. Princeton, NJ: Bristol-Meyers Squibb Company; June 2016.
6. Remicade [package insert]. Horsham, PA: Janssen Biotech, Inc.; October 2015.
7. Simponi Aria [package insert]. Horsham, PA: Janssen Biotech, Inc.; August 2016.
8. Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc.; September 2016.