# POLICY Document for Stelara

The overall objective of this policy is to support the appropriate and cost effective use of the medication, specific to use of preferred medication options, and overall clinically appropriate use. This document provides specific information to both sections of the overall policy.

**Section 1: Preferred Product**
- Policy information specific to preferred medications

**Section 2: Clinical Criteria**
- Policy information specific to the clinical appropriateness for the medication

## Section 1: Preferred Product

### EXCEPTIONS CRITERIA

#### DISEASE-MODIFYING ANTIRHEUMATIC DRUGS PRODUCTS

#### PREFERRED PRODUCTS: REMICADE 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 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** | • **Remicade** (infliximab)<br>• **Simponi Aria** (golimumab, intravenous) | |
| **Targeted** | • **Actemra** (tocilizumab)<br>• **Cimzia** (certolizumab pegol)<br>• **Entyvio** (vedolizumab)<br>• **Ilumya** (tildrakizumab-asmn) | • **Inflectra** (infliximab-dyyb)<br>• **Orencia** (abatacept)<br>• **Renflexis** (infliximab-abda)<br>• **Stelara** (ustekinumab) |

**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. Actemra, Cimzia, Entyvio, Ilumya, Orencia and Stelara
   1. Member is currently receiving treatment with the requested targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs
   2. Member has a documented inadequate response or intolerable adverse event with all of the preferred product(s) indicated for the condition being treated, unless there is a documented clinical reason to avoid TNF inhibitors (Appendix)
   3. Requested product is Cimzia and member is currently pregnant or breastfeeding

B. Inflectra and Renflexis
   Member has a documented intolerable adverse event with the preferred product, Remicade, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information

**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

# Section 2: Clinical Criteria

**STELARA (ustekinumab)**

**POLICY**

**I. INDICATIONS**

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Moderate to severe plaque psoriasis (PsO)
2. Active psoriatic arthritis (PsA)
3. Moderately to severely active Crohn's disease (CD)

All other indications are considered experimental/investigational and are not a covered benefit.

## II. CRITERIA FOR INITIAL APPROVAL

### A. Moderate to severe plaque psoriasis (PsO)

A. Authorization of 24 months may be granted for members who are 12 years of age or older who have previously received Stelara, Otezla, or any other biologic DMARD indicated for the treatment of moderate to severe plaque psoriasis.

B. Authorization of 24 months may be granted for treatment of moderate to severe plaque psoriasis in members who are 12 years of age or older when all of the following criteria are met:
   1. At least 5% of body surface area (BSA) is affected OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
   2. Member meets any of the following criteria:
      i. Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine or acitretin.
      ii. Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine or acitretin (see Appendix A).
      iii. Member has severe psoriasis that warrants a biologic DMARD as first-line therapy.

### B. Active psoriatic arthritis (PsA)

Authorization of 24 months may be granted for treatment of active psoriatic arthritis in members who are 18 years of age or older.

### C. Moderately to severely active Crohn's disease (CD)

1. Authorization of 24 months may be granted for members who are 18 years of age or older who have previously received Stelara or any other biologic indicated for the treatment of Crohn's disease.

2. Authorization of 24 months may be granted for treatment of moderately to severely active CD in members who are 18 years of age or older who have had an inadequate response, intolerance or contraindication to EITHER of the following:
   a. At least ONE conventional therapy option (see Appendix B)
   b. At least ONE TNF-alpha inhibitor indicated for CD:
      i. Cimzia (certolizumab)
      ii. Humira (adalimumab)
      iii. Remicade (infliximab)

## III. CONTINUATION OF THERAPY

Authorization of 24 months may be granted for all members (including new members) who meet all initial authorization criteria and achieve or maintain positive clinical response after at least 4 months of therapy with Stelara as evidenced by low disease activity or improvement in signs and symptoms of the condition.

## IV. OTHER

For all indications: Member has a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB).

Note: Members who have received Stelara or any other biologic DMARD or targeted synthetic DMARD (e.g. Xeljanz) are exempt from requirements related to TB screening in this Policy.

Stelara for intravenous administration is FDA-approved for the treatment of Crohn's disease and will only be authorized for this condition.

## V. APPENDICES

**Appendix A: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine or Acitretin.**

1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Drug interaction
4. Cannot be used due to risk of treatment-related toxicity
5. Pregnancy or planning pregnancy
6. Significant comorbidity prohibits use of systemic agents (examples include liver or kidney disease, blood dyscrasias, uncontrolled hypertension)

**Appendix B: Examples of Conventional Therapy Options for CD**

1. Mild to moderate disease – induction of remission:
   a. Oral budesonide
   b. Alternatives: metronidazole, ciprofloxacin, rifaximin
2. Mild to moderate disease – maintenance of remission:
   a. Azathioprine, mercaptopurine
   b. Alternatives: oral budesonide, methotrexate intramuscular (IM) or subcutaneous (SC), sulfasalazine
3. Moderate to severe disease – induction of remission:
   a. Prednisone, methylprednisolone intravenously (IV)
   b. Alternatives: methotrexate IM or SC
4. Moderate to severe disease – maintenance of remission:
   a. Azathioprine, mercaptopurine
   b. Alternative: methotrexate IM or SC
5. Perianal and fistulizing disease – induction of remission:
   a. Metronidazole ± ciprofloxacin, tacrolimus
6. Perianal and fistulizing disease – maintenance of remission:
   a. Azathioprine, mercaptopurine

Alternative: methotrexate IM or SC

## REFERENCES

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## SECTION 1


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