

This policy applies to the following:

	Standard Opt-in		PDPD		Marketplace		Medical Benefit	✓	Medicare Part B	Reference # 3452-D
	Standard Opt-out		ACSF		MMT		Medical Benefit: Biosimilars First		Medicare Part B: Biosimilars First	
	VF		Balanced		Medical Benefit: Managed Medicaid		Medical Benefit: Add-on		Medicare Part B: Add-on	

## 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, lower cost site of care and overall clinically appropriate use. This document provides specific information to each section 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 DRUG PRODUCTS

#### PREFERRED PRODUCTS: ENTYVIO, ILUMYA, REMICADE, SIMPONI ARIA, STELARA IV

### 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	
<b>Preferred</b>	<ul style="list-style-type: none"> <li>• <b>Entyvio</b> (vedolizumab)</li> <li>• <b>Ilumya</b> (tildrakizumab-asmn)</li> <li>• <b>Remicade</b> (infliximab)</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Simponi Aria</b> (golimumab, intravenous)</li> <li>• <b>Stelara IV</b> (ustekinumab)*</li> </ul>
<b>Targeted</b>	<ul style="list-style-type: none"> <li>• <b>Actemra</b> (tocilizumab)</li> <li>• <b>Avsola</b> (infliximab-axxq)</li> <li>• <b>Cimzia</b> (certolizumab pegol)</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Inflectra</b> (infliximab-dyyb)</li> <li>• <b>Orencia</b> (abatacept)</li> <li>• <b>Renflexis</b> (infliximab-abda)</li> </ul>

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\*Stelara IV is indicated for a one time induction dose for Crohn’s disease and ulcerative colitis.

**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 Avsola, Inflectra and Renflexis, 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 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.
    - b. Member has a documented inadequate response or intolerable adverse event with Entyvio, Ilumya, 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 Entyvio, Ilumya, Remicade, and Simponi Aria where the product’s indications overlap
  - 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 Entyvio, Ilumya, Remicade, and Simponi Aria where the product’s indications overlap, unless there is a documented clinical reason to avoid TNF inhibitors (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
- Risk of lymphoma

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## **Section 2: Clinical Criteria**

# STANDARD MEDICARE PART B MANAGEMENT

### 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

- A. For the treatment of patients 12 years or older with moderate to severe plaque psoriasis (Ps) who are candidates for phototherapy or systemic therapy
- B. For the treatment of adult patients with active psoriatic arthritis (PsA), alone or in combination with methotrexate
- C. For the treatment of adult patients with moderately to severely active Crohn’s disease (CD).
- D. For the treatment of adult patients 18 years or older with moderately to severely active ulcerative colitis.

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

#### II. CRITERIA FOR INITIAL APPROVAL

This policy applies to the following:

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**A. Plaque Psoriasis**

Authorization of 24 months may be granted for treatment of moderate to severe plaque psoriasis (Ps)

**B. Psoriatic Arthritis**

Authorization of 24 months may be granted for treatment of active psoriatic arthritis (PsA).

**C. Crohn's Disease**

Authorization of 24 months may be granted for treatment of moderately to severely active CD.

**D. Ulcerative colitis**

Authorization of 24 months may be granted for treatment of ulcerative colitis.

**III. CONTINUATION OF THERAPY**

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 24 months may be granted when all of the following criteria are met:

- A. The member is currently receiving therapy with Stelara
- B. Stelara is being used to treat an indication enumerated in Section II
- C. The member is receiving benefit from therapy.

**REFERENCES:**

**SECTION 1**

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.

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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.

**SECTION 2**

1. Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc.; October 2019.