

Criteria Date: 2/13/19

## **SPECIALTY GUIDELINE 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

1. Moderate to severe plaque psoriasis
2. Active psoriatic arthritis
3. Moderately to severely active Crohn's disease

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

##### **II. CRITERIA FOR INITIAL APPROVAL**

###### **A. Moderate to severe plaque psoriasis**

1. 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.
2. Authorization of 24 months may be granted for treatment of moderate to severe plaque psoriasis in members 12 years of age and older when all of the following criteria is met:
  - a. 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.
  - b. 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 members who are 18 years of age or older and 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:



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- 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. 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. 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
- b. Member has a documented inadequate response or intolerable adverse event with all of the preferred products indicated for the condition being treated, unless there is a documented clinical reason to avoid TNF inhibitors
- c. Requested product is Otezla and member has one of the following documented exclusions to therapy with the preferred products:
  1. Prior or active malignancy
  2. Routine travel to tuberculosis (TB)-endemic areas
- d. Requested product is Cimzia and member is currently pregnant or breastfeeding

### VI. 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 (male or female)
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, oral mesalamine
  - b. Alternatives: metronidazole, ciprofloxacin, rifaximin
2. Mild to moderate disease – maintenance of remission:
  - a. Azathioprine, mercaptopurine
  - b. Alternatives: oral budesonide, methotrexate intramuscularly (IM)



3. Moderate to severe disease – induction of remission:
  - a. Prednisone, methylprednisolone intravenously (IV)
  - b. Alternatives: methotrexate IM
4. Moderate to severe disease – maintenance of remission:
  - a. Azathioprine, mercaptopurine
  - b. Alternative: methotrexate IM
5. Perianal and fistulizing disease – induction of remission:
  - a. Metronidazole ± ciprofloxacin
6. Perianal and fistulizing disease – maintenance of remission:
  - a. Azathioprine, mercaptopurine
  - b. Alternative: methotrexate IM

## VII. REFERENCES

1. Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc.; October 2017.
2. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. *J Am Acad Dermatol*. 2011;65(1):137-174.
3. Gossec L, Smolen JS, Ramiro S, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update. *Ann Rheum Dis*. 2016;75(3):499-510.
4. Gladman DD, Antoni C, P Mease, et al. Psoriatic arthritis: epidemiology, clinical features, course, and outcome. *Ann Rheum Dis* 2005;64(Suppl II):ii14–ii17.
5. Talley NJ, Abreu MT, Achkar J, et al. An evidence-based systematic review on medical therapies for inflammatory bowel disease. *Am J Gastroenterol*. 2011;106(Suppl 1):S2-S25.