Stelara (ustekinumab)

**BENEFIT APPLICATION**

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

**DESCRIPTION**

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.

**POLICY**

Must meet BOTH the Preferred Drug Plan Design and Criteria for Initial Approval/Continuation of Therapy when both are applicable.

**Preferred Drug Plan Design**

A) Crohn’s disease

1. Criteria for initial approval on Crohn’s disease will only apply when at least ONE of the following criteria are met:
   a) Member has had an inadequate response to treatment or intolerable adverse event with the preferred product Humira
   b) Member has a clinical reason to avoid Humira (See Appendix A)
   c) Member is currently receiving treatment with the requested product through insurance (excludes obtainment as samples or via manufacturer’s patient assistance programs) and experiencing a positive therapeutic outcome

Note: Submission of chart notes detailing the outcomes of treatment, intolerable adverse event(s) experienced, contraindication(s), or exclusion(s) to treatment with preferred product(s) is required (where applicable).

**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 members who are 12 years of age or older and who meet all of the following criteria:
   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 B).
      iii). Member has severe psoriasis that warrants a biologic DMARD as first-line therapy.

B) Active psoriatic arthritis (PsA)

1. Authorization of 24 months may be granted for members who are 18 years of age or older who have previously received Stelara, Cosentyx, Otezla, or Taltz.

2. Authorization of 24 months may be granted for treatment of active PsA in members 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 C)
   b.) At least ONE TNF-alpha inhibitor indicated for CD:
      i). Cimzia (certolizumab)
      ii). Humira (adalimumab)
      iii). Remicade, Inflectra, or Renflexis (infliximab)

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.

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.

APPENDIX

APPENDIX A: Clinical reasons to avoid TNF-inhibitors

1. History of demyelinating disorder
2. History of congestive heart failure

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3. History of hepatitis B infection
4. Autoantibody formation/lupus-like syndrome
5. Risk of lymphoma

Appendix B: 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 C: 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

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.
- J3357 Injection, ustekinumab, 1 mg for subcutaneous use
- Q9989 Injection, ustekinumab, 1mg for Intravenous use

REFERENCES

*Some content reprinted from CVSHealth

**POLICY HISTORY**

- **Policy #:** 05.01.28
- **Reviewed:** July 2018
- **Revised:** July 2018
- **Current Effective Date:** September 3, 2018