

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 18 years of age or older and who have received Stelara, Otezla, or any other biologic DMARD indicated for the treatment of moderate to severe plaque psoriasis in a paid claim through a pharmacy or medical benefit in the previous 120 days of the initial request for Stelara.
2. Authorization of 24 months may be granted for treatment of moderate to severe plaque psoriasis in members 18 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)

1. Authorization of 24 months may be granted for members who are 18 years of age or older and who have received Stelara, Cosentyx or Otezla in a paid claim through a pharmacy or medical benefit in the previous 120 days of the initial request for Stelara.
2. Authorization of 24 months may be granted for treatment of active PsA in members 18 years of age or older when any of the following criteria is met:
 - a. Member has had an inadequate response to at least a 3-month trial of at least one TNF inhibitor indicated for PsA (see Appendix B).
 - b. Member has experienced an intolerance or adverse event to a trial of at least one TNF inhibitor indicated for PsA.
 - c. All TNF inhibitors indicated for PsA are not appropriate for the member (e.g., due to comorbidities or a history of infections).

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 and who have received Stelara or any other biologic indicated for the treatment of Crohn's disease in a paid claim through a pharmacy or medical benefit in the previous 120 days of the initial request for Stelara.
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 (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) in a paid claim through a pharmacy or medical benefit in the previous 120 days of the continuation request 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 (male or female)
6. Significant comorbidity prohibits use of systemic agents (examples include liver or kidney disease, blood dyscrasias, uncontrolled hypertension)

Appendix B: TNF Inhibitors Indicated for Psoriatic Arthritis

1. Cimzia® (certolizumab pegol)
2. Enbrel® (etanercept)
3. Humira® (adalimumab)
4. Remicade® (infliximab)
5. Simponi® (golimumab)

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

VI. REFERENCES

1. Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc.; September 2016.
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.