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. EXCLUSIONS

Coverage will not be provided for members with any of the following exclusions:
A. Untreated latent TB infection (treatment must be initiated prior to starting Stelara)
B. Active tuberculosis infection (treatment must be completed prior to starting Stelara)

III. 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 at least a 28-day supply of Stelara 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 insufficient response to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine or acitretin despite adequate dosing and duration (see Appendix A).
      ii. Member has had an intolerance or adverse event to a trial of phototherapy or pharmacologic treatment with methotrexate, cyclosporine or acitretin.
      iii. Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine or acitretin (see Appendix B).
      iv. 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 at least a 28-day supply of 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 C).
   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 at least a 28-day supply Stelara or any other biologic DMARD 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 at least one conventional therapy option (see Appendix D).

IV. 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.

V. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The following dosing limits apply:

A. For moderate to severe plaque psoriasis
   1. The dosing limit is determined based on the member’s weight.
      a. 100 kg or less: 45 mg per dose
      b. Greater than 100 kg: 90 mg per dose
   2. Initial loading dose for the initial 28 days: 2 doses total
   3. Maintenance dose: one dose per 12 weeks

B. For active psoriatic arthritis
   1. Initial loading dose for the initial 28 days: 90 mg total
   2. Maintenance dose: 45 mg per 12 weeks

C. For active psoriatic arthritis with co-existent moderate to severe plaque psoriasis
   1. See section V.A. Moderate to severe plaque psoriasis above.

VI. 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 at least a 28-day supply of Stelara, 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 exempted from requirements related to TB screening and treatment in this Policy.
VII. APPENDICES

Appendix A: Time to Clinical Efficacy and Dose for Treatment of Plaque Psoriasis with Phototherapy, Methotrexate, Cyclosporine and Acitretin.
1. Phototherapy: at least 4 weeks or 10 sessions
2. Methotrexate: at least 1 month following a titration to the maximum tolerated dose. The maximum titrated dose must be 10 mg/week or higher.
3. Cyclosporine: 2.5 mg/kg/day or higher for at least 2 months
4. Acitretin: 25 mg/day or higher for at least 3 months

Appendix B: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine or Acitretin.
1. Alcohol intake / alcoholic 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: TNF Inhibitors Indicated for Psoriatic Arthritis
A. Cimzia® (certolizumab pegol)
B. Enbrel® (etanercept)
C. Humira® (adalimumab)
D. Remicade® (infliximab)
E. Simponi® (golimumab)

Appendix D: 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

VIII. REFERENCES
