I. Medication Description

Ustekinumab (Stelara®) is a human IgG1-kappa monoclonal antibody that acts as an interleukin (IL)-12 and IL-23 antagonist. These cytokines are involved in inflammatory and immune responses. In in-vitro models, ustekinumab was shown to disrupt IL-12 and IL-23 mediated signaling and cytokine cascades by disrupting the interactions of these cytokines with a shared cell-surface receptor chain, IL-12 beta 1.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request. When administered by a healthcare professional, Stelara is considered a medical benefit. In all other situations, Stelara is considered a pharmacy benefit.

III. Policy

Coverage for Stelara is provided for the following conditions when the listed criteria are met:

- **Plaque psoriasis (moderate to severe disease):**
  - Member is at least 12 years of age **AND**
  - The medication is prescribed by a rheumatologist or dermatologist **AND**
  - At least 10% of BSA affected or less than 10% BSA is affected but with palmar, plantar, head/neck, or genitalia involvement **AND**
  - Member has had an inadequate response to PUVA or UVB therapy unless contraindicated **AND**
  - For members 18 years of age or older:
    - Member has had an inadequate response to non-biologic systemic therapy (i.e. methotrexate, cyclosporine, acitretin) unless contraindicated

- **Psoriatic arthritis (active disease):**
  - Member is at least 18 years of age **AND**
  - The medication is prescribed by a rheumatologist or dermatologist **AND**
  - One of the following is true:
    - Member has tried therapy with at least one non-biologic DMARD with either treatment failure after 12 weeks or intolerable side effects (unless DMARDs are contraindicated) **OR**
    - If predominantly axial disease is documented, the member has experienced treatment failure with at least two oral NSAIDs (unless NSAIDs are contraindicated)

- **Crohn’s disease (moderate to severe):**
  - Member is at least 18 years of age **AND**
The medication is prescribed by a gastroenterologist AND

One of the following is true:

- Member has had an inadequate response to or not tolerated immune modulators (ex. azathioprine, 6-MP, methotrexate) OR
- Member has not responded to steroids or is steroid refractory OR
- The member has fistulizing disease

IV. Quantity Limits

- For the treatment of adolescents (12 – 17 years old) with plaque psoriasis:
  - Weight-based maintenance dose (after initial doses at weeks 0 and 4):
    - For 60 kg or less: 0.75 mg/kg every 12 weeks
    - For 60 mg to 100 kg: 45 mg every 12 weeks
    - For more than 100 kg: 90 mg every 12 weeks
- For the treatment of adults with plaque psoriasis and/or psoriatic arthritis:
  - Weight –based maintenance dose (after initial doses at weeks 0 and 4):
    - For 100 kg or less: 45 units every 12 weeks
    - For more than 100 kg: 90 units every 12 weeks
- For the treatment of adults with Crohn’s disease:
  - Weight-based  induction intravenous infusion dose:
    - For 55 kg or less: 260 mg IV infusion as a single dose
    - For 56 kg to 85 kg: 390 mg IV infusion as a single dose
    - For 85 kg or more: 520 mg IV infusion as a single dose
  - Maintenance dose (starting 8 weeks after the initial intravenous induction dose):
    - 90 mg every 8 weeks
- Annual Maximum units for the treatment of adolescents with plaque psoriasis:
  - Adolescents < 60 kg: 270 units in first treatment year, 225 units in second treatment year (if only 5 doses are received in first treatment year), 180 units in years 3-4.
  - Adolescents 60 kg – 100 kg: 270 units in first treatment year, 225 units in second treatment year (if only 5 doses are received in first treatment year), 180 units in years 3-4.
  - Adolescents > 100 kg: 540 units in first treatment year, 450 units in second treatment year (if only 5 doses are received in first treatment year), 360 units in years 3-4.
- Annual Maximum units for the treatment of adults with plaque psoriasis and/or psoriatic arthritis:
  - Adults > 100kg: 540 units in first treatment year; 450 units in second treatment year (if only 5 doses are received in first treatment year), 360 units in years 3-4.
  - Adults < 100kg: 270 units in first treatment year; 225 units in second treatment year (if only 5 doses are received in first treatment year), 180 units in years 3-4.
- Annual Maximum units for the treatment of adults with Crohn’s disease:
  - Up to 520 mg intravenous induction dose in addition to 540 units for maintenance dosing in the first treatment year; 630 units for maintenance dosing in the second treatment year and thereafter.
V. **Coverage Duration**

Coverage will be authorized for 12 months and may be renewed up to a total duration of years medication has been studied to provide safety and efficacy. Additional coverage can be reviewed on a case by case basis.

VI. **Coverage Renewal Criteria**

Coverage can be renewed based upon the following criteria:

- Clinical response or remission of disease is maintained with continued use **AND**
- Absence of unacceptable toxicity from the drug

VII. **Billing/Coding Information**

- Pertinent diagnoses:
  - Plaque Psoriasis: L40.0 – L40.4, L40.8
  - Psoriatic Arthritis: L40.54, L40.59
  - Crohn’s disease: K50.00 – K 50.91
- For the treatment of plaque psoriasis and/or psoriatic arthritis:
  - Available as 45mg/0.5ml or 90mg/ml solution for injection
  - J3357, 1 billable unit = 1 mg
- For the treatment of Crohn’s disease (induction intravenous infusion dose):
  - Available as 130mg/26mL solution for Injection
  - J3358: 1 billable unit = 1 mg
- For the treatment of Crohn’s disease (maintenance dose):
  - Available as 90mg/ml solution for injection
  - J3357, 1 billable unit = 1 mg

VIII. **Summary of Policy Changes**

- 9/1/11: Disease severity details outlined; Total treatment duration of 2 years added; Dosing and quantity limitations expanded; Policy reformatted.
- 6/15/12: Increased coverage duration to 12 month increments
- 6/15/13: increased total lifetime coverage to 4 years
- 9/2013: Stelara availability on the pharmacy benefit added to policy
- 12/15/13: Step therapy added under the pharmacy benefit
- 6/15/14: Added diagnosis of psoriatic arthritis, removed total lifetime coverage limitation of 4 years, updated coding to include ICD 10, reformatted policy for medical and pharmacy benefits sections
- 2/23/15: Medicaid/FHP coverage criteria added to policy
- 7/1/15: formulary distinctions made, removal of need for Tb testing on patients not at high risk
- 12/15/15: no policy changes
- 9/15/16: no policy changes
- 1/1/17: addition of criteria for CD coverage; Stelara becomes preferred agent in PsA and PP treatment
- 10/16/17: no policy changes
IX. References


The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

*These guidelines are not applicable to benefits covered under Medicare Advantage. Medicare Advantage benefit coverage requests are reviewed in accordance with the guidance set forth in Chapter 15 Section 50 of the Centers for Medicare & Medicaid Services Medicare Benefit Policy Manual.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.