Pharmacy Medical Necessity Guidelines: Stelara® (ustekinumab)

Effective: August 8, 2017

Prior Authorization Required √ Type of Review – Care Management
Not Covered Type of Review – Clinical Review √

Pharmacy (RX) or Medical (MED) Benefit

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<tr>
<th>Benefit Type</th>
<th>Department to Review</th>
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<tbody>
<tr>
<td>SQ: RX / IV: MED</td>
<td>RXUM / PRECERT / MM</td>
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This Pharmacy Medical Necessity Guideline applies to the following:

**Tufts Health Plan Commercial Plans**
- Tufts Health Plan Commercial Plans – large group plans
- Tufts Health Plan Commercial Plans – small group and individual plans

**Tufts Health Public Plans**
- Tufts Health Direct – Health Connector
- Tufts Health Together – A MassHealth Plan
- Tufts Health RItogether – A RIte Care + Rhody Health Partners Plan

**Tufts Health Freedom Plan products**
- Tufts Health Freedom Plan – large group plans
- Tufts Health Freedom Plan – small group plans

Fax Numbers:
- Subcutaneous Formulation: RXUM: 617.673.0988
- Intravenous Formulation: All plans except Tufts Health Direct – Health Connector PRECERT: 617.972.9409
- Tufts Health Direct – Health Connector Only MM: 888.415.9055

Note: For Tufts Health Plan Medicare Preferred Members, please refer to the Tufts Health Plan Medicare Preferred Prior Authorization Criteria. Background, applicable product and disclaimer information can be found on the last page.

**OVERVIEW**

**FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS**

Stelara (ustekinumab) is a human IgG1κ monoclonal antibody indicated for the following:

- **Plaque Psoriasis:**
  Stelara (ustekinumab) is indicated for the treatment of adult patients (18 years or older) with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

- **Psoriatic Arthritis:**
  Stelara (ustekinumab) is indicated for the treatment of adult patients (18 years or older) with active psoriatic arthritis. Stelara (ustekinumab) can be used alone or in combination with methotrexate.

- **Crohn’s Disease:**
  Stelara (ustekinumab) is indicated for the treatment of adult patients with moderately to severely active Crohn’s disease who have failed or were intolerant to treatment with immunomodulators or corticosteroids, but never failed a tumor necrosis factor (TNF) blocker or failed or were intolerant to treatment with one or more TNF blockers.

Stelara (ustekinumab) for the treatment of plaque psoriasis and psoriatic arthritis is for subcutaneous administration and is intended for use under the guidance and supervision of a physician. Stelara (ustekinumab) should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician.

Stelara (ustekinumab) for the maintenance treatment of Crohn’s disease is also for subcutaneous administration; however, patients should receive a onetime weight based loading dose via intravenous infusion.

Stelara (ustekinumab) binds with high affinity and specificity to the p40 protein subunit used by both the interleukin (IL)-12 and IL-23 cytokines. IL-12 and IL-23 are naturally occurring cytokines that are involved in inflammatory and immune responses, such as natural killer cell activation and CD4+ T-cell differentiation and activation.

**COVERAGE GUIDELINES**

The plan may authorize coverage of Stelara (ustekinumab) for adult Members 18 years of age or older when all of the following criteria are met:
**Crohn’s Disease**
1. The Member must have a definitive diagnosis from a gastroenterologist of Crohn’s disease
   **AND**
2. The Member has demonstrated an inadequate response to an appropriate trial with two or more of
   the following agents:
   a. Corticosteroids (e.g., prednisone, prednisolone, methylprednisolone)
   b. 5-Aminosalicylates (e.g., sulfasalazine, Azulfidine®, Asacol®, Pentasa®, Rowasa®,
      Dipentum®, Colazal®)
   c. 6-mercaptopurine (6-MP, Purinethol®) and/or azathioprine (Imuran®)
   d. Methotrexate (MTX)
   OR
3. The Member has tried and failed treatment with another biological agent indicated for the
   treatment of Crohn’s Disease
   OR
4. The Member is new to the plan and has been stable on Stelara (ustekinumab) prior to enrollment

**Plaque Psoriasis**
1. The Member must have a definitive diagnosis from a dermatologist of moderate-to-severe chronic
   plaque psoriasis
   **AND**
2. The Member has failed to respond to, or has been unable to tolerate phototherapy and ONE of
   the following therapeutically-similar medications:
   • Sotradecol (acitretin)
   • Methotrexate
   • Cyclosporine
   OR
3. The Member has tried and failed treatment with another biological agent indicated for the
   treatment of plaque psoriasis
   OR
4. The Member is new to the plan and has been stable on Stelara (ustekinumab) prior to enrollment

**Psoriatic Arthritis**
1. The Member has a documented diagnosis of psoriatic arthritis
   **AND**
2. The prescription is written by a rheumatologist
   **AND**
3. The Member has a documented inadequate response or inability to take methotrexate OR
   sulfasalazine at maximal doses for three months
   OR
4. The Member has tried and failed treatment with another biological agent indicated for the
   treatment of psoriatic arthritis
   OR
5. The Member is new to the plan and has been stable on Stelara (ustekinumab) prior to enrollment

**LIMITATIONS**
1. For the diagnosis of Crohn’s disease, coverage of Stelara (ustekinumab) will be limited as follows:
   a) Intravenous formulation: single intravenous infusion loading dose
      • Patient weight 55 kg or less
        o Stelara 130mg/26 mL (5mg/mL) vial – 2 vials (one time loading dose)
      • Patient weight greater than 55 kg to 85 kg
        o Stelara 130mg/26 mL (5mg/mL) vial – 3 vials (one time loading dose)
      • Patient weight more than 85 kg
        o Stelara 130mg/26 mL (5mg/mL) vial – 4 vials (one time loading dose)
   b) Subcutaneous formulation:
      • Stelara 90mg prefilled syringe – following a single intravenous infusion loading dose, 1
        syringe every 56 days
2. For the diagnosis of Plaque Psoriasis, coverage of Stelara (ustekinumab) will be limited as follows:
   a) Patient weight of 100 kg or less:
      • Stelara 45mg prefilled syringe or vial – 2 syringes for the initial 28 days, then 1 syringe
        per 84 days thereafter.
b) Patient weight of more than 100 kg:
   - Stelara 90mg prefilled syringe – 2 syringes for the initial 28 days, then 1 syringe per 84 days thereafter.

3. For the diagnosis of Psoriatic Arthritis, coverage of Stelara (ustekinumab) will be limited as follows:
   a) Stelara 45mg prefilled syringe or vial – 2 syringes for the initial 28 days, then 1 syringe per 84 days thereafter.

4. For Members with the diagnosis of Psoriatic Arthritis and co-existent moderate-to-severe plaque psoriasis weighing more than 100 kg:
   a) Stelara 90mg prefilled syringe – 2 syringes for the initial 28 days, then 1 syringe per 84 days thereafter.

**CODES**
The following HCPCS/CPT code(s) are:

<table>
<thead>
<tr>
<th>Code</th>
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<tr>
<td>J3357</td>
<td>Ustekinumab, for subcutaneous injection, 1 mg</td>
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<tr>
<td>C9487</td>
<td>Ustekinumab, for intravenous injection, 1 mg</td>
</tr>
<tr>
<td>Q9989</td>
<td>Ustekinumab, for intravenous injection, 1 mg</td>
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**REFERENCES**


APPROVAL HISTORY
November 15, 2011: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
- November 15, 2011: This policy replaces the Medical Necessity Guidelines for Stelara (ustekinumab) in “Injectable Drugs for the Treatment of Psoriasis” originating in November 2003 (Document ID# 2099988).
- November 6, 2012: No changes
- July 9, 2013: Updated benefit, overview and quantity limitations sections to reflect addition of pharmacy benefit coverage for self-administration of Stelara (ustekinumab).
- October 15, 2013: Added coverage criteria for the diagnosis of psoriatic arthritis.
- October 7, 2014: Effective 1/1/2015, Stelara (ustekinumab) will only be covered on the pharmacy benefit.
- September 16, 2015: No changes
- January 1, 2016: Administrative change to rebranded template.
- September 13, 2016: Effective 1/1/17 for the diagnosis of Plaque Psoriasis and Psoriatic Arthritis, added exception language for Members new to the plan and stable on Stelara prior to enrollment. Added trial and failure with another biological agent indicated for the same condition.
- October 18, 2016: Effective 10/31/17, added approval criteria for Crohn’s disease.
- April 1, 2017: Administrative update: added new C code (C9487) to Medical Necessity Guideline and updated the description of C code J3357.
- April 11, 2017: Administrative update, adding Tufts Health RITogether to the template.
- July 1, 2017: Administrative update: added new C code (C9487) and Q code (Q9989) to Medical Necessity Guideline.
- August 8, 2017: No changes
BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with a Member’s benefit document and in coordination with the Member’s physician(s). The plan makes coverage decisions on a case-by-case basis considering the individual Member’s health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member’s benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLink℠ Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to Member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.