Pharmacy Medical Necessity Guidelines: Stelara® (ustekinumab)

Effective: November 14, 2017

Prior Authorization Required: √  Type of Review – Care Management

<table>
<thead>
<tr>
<th>Not Covered</th>
<th>Type of Review – Clinical Review</th>
<th>Type of Review – Care Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy (RX) or Medical (MED) Benefit</td>
<td>Department to Review</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

**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 patients 12 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 Members 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 is at least 18 years of age AND
3. 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
4. The Member has tried and failed treatment with another biological agent indicated for the treatment of Crohn’s Disease OR
5. 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 is at least 12 years of age AND
3. The Member has failed to respond to, or has been unable to tolerate phototherapy and ONE of the following therapeutically-similar medications:
   • Soriatane (acitretin)
   • MTX
   • Cyclosporine OR
4. The Member has tried and failed treatment with another biological agent indicated for the treatment of plaque psoriasis OR
5. 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 Member is at least 18 years of age AND
3. The prescription is written by a rheumatologist AND
4. The Member has a documented inadequate response or inability to take MTX or sulfasalazine at maximal doses for three months OR
5. The Member has tried and failed treatment with another biological agent indicated for the treatment of psoriatic arthritis OR
6. The Member is new to the plan and has been stable on Stelara (ustekinumab) prior to enrollment

LIMITATIONS
1. For the diagnosis of plaque psoriasis, inconvenience does not qualify as a contraindication to phototherapy.
2. For the diagnosis of Crohn’s disease, coverage of Stelara (ustekinumab) will be limited as follows:
   a. Intravenous (IV) formulation: single IV infusion loading dose
      i. Patient weight ≤55 kg
         1. Stelara 130 mg/26 mL (5 mg/mL) vial – 2 vials (one time loading dose)
      ii. Patient weight >55 kg to ≤85 kg
1. Stelara 130 mg/26 mL (5 mg/mL) vial – 3 vials (one time loading dose)
   iii. Patient weight >85 kg
   1. Stelara 130 mg/26 mL (5 mg/mL) vial – 4 vials (one time loading)
   b. Subcutaneous (SC) formulation:
      i. Stelara 90 mg prefilled syringe – following a single IV infusion loading dose, 1 syringe per 56 days

3. For the diagnosis of adolescent plaque psoriasis, coverage of Stelara (ustekinumab) will be limited as follows:
   a. Patient weight <60 kg:
      i. Stelara 45 mg single-dose vial – 2 vials for the initial 28 days, then 1 vial per 84 days thereafter.
   b. Patient weight ≥60 kg to ≤100 kg:
      i. Stelara 45 mg prefilled syringe or single-dose vial – 2 vials for the initial 28 days, then 1 syringe or vial per 84 days thereafter.
   c. Patient weight >100 kg:
      i. Stelara 90 mg prefilled syringe – 2 syringes for the initial 28 days, then 1 syringe per 84 days thereafter.

4. For the diagnosis of adult plaque psoriasis, coverage of Stelara (ustekinumab) will be limited as follows:
   a. Patient weight ≤100 kg:
      i. Stelara 45 mg prefilled syringe or single-dose vial – 2 syringes or vials for the initial 28 days, then 1 syringe per 84 days thereafter.
   b. Patient weight >100 kg:
      i. Stelara 90 mg prefilled syringe – 2 syringes for the initial 28 days, then 1 syringe per 84 days thereafter.

5. For the diagnosis of psoriatic arthritis, coverage of Stelara (ustekinumab) will be limited as follows:
   a. Stelara 45 mg prefilled syringe or single-dose vial – 2 syringes or vials for the initial 28 days, then 1 syringe per 84 days thereafter.

6. For Members with the diagnosis of psoriatic arthritis and co-existent moderate-to-severe plaque psoriasis weighing >100 kg:
   a. Stelara 90 mg prefilled syringe – 2 syringes for the initial 28 days, then 1 syringe per 84 days thereafter.

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

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<th>Code</th>
<th>Description</th>
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<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**


27. Ungprasert P, Thongprayoon C, Davis JM 3rd. Indirect comparisons of the efficacy of biological agents in patients with psoriatic arthritis with an inadequate response to traditional disease-

**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 J 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
- November 14, 2017: Updated coverage criteria for plaque psoriasis to allow coverage for Members at least 12 years of age based on updated package labeling. Administrative update adding a limitation to clarify that for plaque psoriasis, inconvenience does not qualify as a contraindication to phototherapy.

**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 CareLinkSM 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.