Pharmacy Medical Necessity Guidelines: Stelara® (ustekinumab)

Effective: November 20, 2017

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	SQ: RX/ IV: MED	Department to Review	RXUM/ MM

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:
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 has a documented diagnosis of Crohn's disease by a gastroenterologist

AND

2. The Member is at least 18 years of age

AND

3. The Member has demonstrated an inadequate response to, or the Member has a contraindication 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 (e.g., 6-MP, Purinethol®), azathioprine (Imuran®), and/or cyclosporine (Gengraf®, Neoral®, Sandimmune®)
d. Methotrexate (MTX)

AND

4. The Member had tried and failed treatment with, or the provider has indicated clinical inappropriateness of Humira

OR

5. The Member is new to the plan and has been stable on Stelara (ustekinumab) prior to enrollment

Plaque Psoriasis

1. The Member has been evaluated by a dermatologist or rheumatologist

AND

2. The Member must have a definitive diagnosis of moderate-to-severe chronic plaque psoriasis

AND

3. The Member is at least 12 year of age

AND

4. The Member has tried and failed treatment with, or the provider provides clinical justification of inappropriateness of treatment with Enbrel and Humira

OR

5. The Member is new to the plan and has been stable on Stelara prior to enrollment

Psoriatic Arthritis

1. The Member has been evaluated by a dermatologist or rheumatologist

AND

2. The Member has a documented diagnosis of psoriatic arthritis

AND

3. The Member is 18 years of age or older

AND

4. The Member has tried and failed, or the provider indicated clinical inappropriateness, to at least one DMARD (Disease Modifying Anti-rheumatic Drugs), such as azathioprine, gold therapy, hydroxychloroquine, MTX, penicillamine, sulfasalazine, cyclosporine or leflunomide

AND

5. The Member has tried and failed treatment with, or the provider provides clinical justification of inappropriateness of treatment with Enbrel and Humira

OR

6. The Member is new to the plan and has been stable on Stelara prior to enrollment

LIMITATIONS

1. 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
2. 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

3. 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.
4. 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 for the initial 28 days, then 1 syringe per 84 days thereafter.
5. 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:

Code	Description
J3358	Ustekinumab, for intravenous injection, 1 mg

REFERENCES

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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: Clarified quantity limitations for Stelara
- January 1, 2016: Administrative change to rebranded template.
- September 13, 2016: No changes
- October 18, 2016: Added coverage criteria for Stelara for the diagnosis of Crohn's disease
- April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.

- 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. For the diagnosis of plaque psoriasis, removed that the diagnosis is required by a dermatologist as the member is required to have been evaluated by a dermatologist or rheumatologist.
- January 1, 2018: Administrative update: Added new J code J3358, removed expired C and Q codes (C9487, Q9989), and removed J code J3357 because that formulation is covered on the pharmacy benefit only.

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.