Pharmacy Medical Necessity Guidelines: Stelara® (ustekinumab)

Effective: 10/1/15

Clinical documentation and prior authorization required ✓ Type of review – case management

Not covered Type of review – clinical review
Fax: 617-673-0988 ✓

Pharmacy (RX) or medical (MED) benefit RX Department to review RxUM

OVERVIEW

FDA-APPROVED INDICATIONS

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 (MTX).

Stelara (ustekinumab) 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) is a human IgG1κ monoclonal antibody that 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.

PHARMACY COVERAGE GUIDELINES

Tufts Health Plan – Network Health may authorize coverage of Stelara (ustekinumab) for members when all the following criteria for a particular regimen are met and limitations do not apply:

For Plaque Psoriasis
1. The Member has been evaluated by a dermatologist or rheumatologist AND
2. The Member must have a definitive diagnosis from a dermatologist of moderate-to-severe chronic plaque psoriasis AND
3. The Member is 18 years of age or older 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 Tufts Health Plan – Network Health and has been stable on Stelara prior to enrollment

For 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, methotrexate, 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 Tufts Health Plan – Network Health and has been stable on Stelara prior to enrollment

LIMITATIONS
1. For the diagnosis of Plaque Psoriasis, coverage of Stelara (ustekinumab) will be limited as follows:
   • 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.

• Patient weight of more than 100 kg:
  – Stelara 90mg prefilled syringe or vial – 2 syringes for the initial 28 days, then 1 syringe per 84 days thereafter.

2. For the diagnosis of Psoriatic Arthritis, coverage of Stelara (ustekinumab) will be limited as follows:

• Stelara 45mg prefilled syringe or vial – 2 syringes for the initial 28 days, then 1 syringe per 84 days thereafter.

3. For members with the diagnosis of Psoriatic Arthritis and co-existent moderate-to-severe plaque psoriasis weighing more than 100 kg:

• Stelara 90mg prefilled syringe or vial – 2 syringes for the initial 28 days, then 1 syringe per 84 days thereafter.

CODES

Medical billing codes may not be used for this medication. This medication must be obtained via the member’s pharmacy benefit.

REFERENCES


APPROVAL HISTORY
- April 15, 2010: Reviewed by the Pharmacy and Therapeutics Committee
- December 12, 2013: Reviewed by the Pharmacy and Therapeutics Committee
- October 7, 2014: Reviewed by the Pharmacy and Therapeutics Committee
- September 16, 2015: Clarified quantity limitations for Stelara.

BACKGROUND, PRODUCT, AND DISCLAIMER INFORMATION
Pharmacy Medication Request Guidelines have been developed for determining coverage for Tufts Health Plan – Network Health benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with the applicable Member Handbook and in coordination with the member’s physician(s). Pharmacy Medication Request 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 Tufts Health Plan – Network Health service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan – Network Health reviews Pharmacy Medication Request Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Pharmacy Medication Request Guidelines apply to all insured offerings unless otherwise noted in this policy or the applicable Member Handbook. Check the applicable Preferred Drug List (formulary) in the pharmacy section of our website to determine if the drug requires you to get prior authorization.

For Tufts Health Unify (Medicare-Medicaid One Care for people ages 21 – 64), please refer to the Tufts Health Unify Prior Authorization Medical Necessity Guidelines.

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.