Pharmacy Medical Necessity Guidelines: Cosentyx® (secukinumab)

Effective: July 10, 2018

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

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:

RXUM: 617.673.0988

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Cosentyx (secukinumab) is a human interleukin-17A antagonist indicated for:

- **Ankylosing Spondylitis:**
  Treatment of adult patients with active ankylosing spondylitis.
- **Plaque psoriasis:**
  Treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.
- **Psoriatic Arthritis:**
  Treatment of adult patients with active psoriatic arthritis.

COVERAGE GUIDELINES

The plan may authorize coverage of Cosentyx (secukinumab) for Members when all of the following criteria for a particular regimen are met and limitations do not apply:

Ankylosing Spondylitis

1. The Member has a documented definitive diagnosis of active ankylosing spondylitis from a rheumatologist

AND

2. The Member is 18 years of age or older

AND

3. The Member has tried and failed treatment with, or the Member has a contraindication to at least two NSAID

AND

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

OR

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

Plaque Psoriasis

1. The Member has a documented definitive diagnosis from a dermatologist of moderate to severe chronic plaque psoriasis

AND

2. The Member is 18 years of age or older

AND

3. The Member has tried and failed treatment with, or the Member has a contraindication to, at least 2 of the preferred therapies, such as PUVA or UVB phototherapy, acitretin, cyclosporine or methotrexate

AND

4. The Member has tried and failed treatment with, or the provider has indicated clinical inappropriateness of treatment with Humira (adalimumab) and Enbrel (etanercept)

OR

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

Psoriatic Arthritis

1. The Member has a documented definitive diagnosis of active psoriatic arthritis from a rheumatologist

AND

2. The Member is 18 years of age or older

AND

3. The Member has a documented inadequate response or inability to take methotrexate OR sulfasalazine at maximal doses for three months.

AND

4. The Member has tried and failed treatment with, or the provider has indicated clinical inappropriateness of treatment with Humira (adalimumab) and Enbrel (etanercept)

OR

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

Note: Maximal doses of methotrexate are defined as 15mg to 25mg per week depending on the patient's tolerance.

LIMITATIONS

1. Samples, free goods or similar offerings of Cosentyx (secukinumab) do not qualify for an established clinical response and will not be considered for prior authorization.
2. For the diagnosis of plaque psoriasis, inconvenience does not qualify as a contraindication to phototherapy.
3. Documentation of a Member being a social drinker does not qualify as a medically acceptable contraindication or clinically inappropriateness to methotrexate therapy.
4. Coverage for Cosentyx (secukinumab) for the diagnosis of ankylosing spondylitis will be limited to 28-day supplies as follows:
   Initial prescription:
   - 150 mg dose
     - Four cartons (4 doses) of one 150 mg/mL Sensoready pen **OR**
     - Four cartons (4 doses) of one 150 mg/mL single-use prefilled syringe

   Followed by:
   - 150 mg dose
     - One carton of one 150 mg/mL Sensoready pen per 28 days **OR**
     - One carton of one 150 mg/mL single-use prefilled syringe per 28 days
5. For the diagnosis of active psoriatic arthritis, the Plan requires documentation of a therapeutic failure (i.e., the member continues to have active psoriatic arthritis) on Cosentyx 150 mg every 4 weeks before the 300 mg dose may be approved.
6. Coverage for Cosentyx (secukinumab) for the diagnoses of plaque psoriasis and psoriatic arthritis will be limited to 28-day supplies as follows:
   Initial prescription:
   - 150 mg dose
     - Four cartons (4 doses) of one 150 mg/mL Sensoready pen **OR**
     - Four cartons (4 doses) of one 150 mg/mL single-use prefilled syringe
   - 300 mg dose
     - Four cartons of two 150 mg/mL (300 mg dose) Sensoready pens **OR**
     - Four cartons of two 150 mg/mL (300 mg dose) single-use prefilled syringes

   Followed by:
   - 150 mg dose
     - One carton of one 150 mg/mL Sensoready pen per 28 days **OR**
     - One carton of one 150 mg/mL single-use prefilled syringe per 28 days
   - 300 mg dose
     - One carton of two 150 mg/mL (300 mg dose) Sensoready pens per 28 days **OR**
     - One carton of two 150 mg/mL (300 mg dose) single-use prefilled syringes

CODES

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

REFERENCES

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APPROVAL HISTORY

July 14, 2015: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- January 1, 2016: Administrative change to rebranded template.
- February 9, 2016: Effective April 1, 2016, added pharmacy coverage guidelines for indications ankylosing spondylitis and psoriatic arthritis.
- September 13, 2016: No changes
- April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
- July 11, 2017: Administrative update to add the following Limitation: Samples, free goods or similar offerings of Cosentyx (secukinumab) do not qualify for an established clinical response and will not be considered for prior authorization.
- May 8, 2018: Administrative update to add the following Limitations: For the diagnosis of plaque psoriasis, inconvenience does not qualify as a contraindication to phototherapy and documentation of a Member being a social drinker does not qualify as a medically acceptable contraindication or clinically inappropriateness to methotrexate therapy.

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^{SM} 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.