Pharmacy Medical Necessity Guidelines: Kineret® (anakinra)

Effective: July 11, 2017

Prior Authorization Required:  
Type of Review – Care Management

Not Covered:  
Type of Review – Clinical Review

Pharmacy (RX) or Medical (MED) Benefit:  
Department to Review

Fax Numbers:

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

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

FDA-APPROVED INDICATIONS

Rheumatoid Arthritis (RA)
Kineret (anakinra) is indicated for the reduction in signs and symptoms and slowing the progression of structural damage in moderately to severely active rheumatoid arthritis, in patients 18 years of age or older who have failed one or more disease modifying antirheumatic drugs (DMARDs). Kineret can be used alone or in combination with DMARDs other than Tumor Necrosis Factor (TNF) blocking agents.

Neonatal-Onset Multisystem Inflammatory Disease (NOMID)
Kineret (anakinra) is indicated for the treatment of Neonatal-Onset Multisystem Inflammatory Disease (NOMID).

Kineret (anakinra) is a recombinant, nonglycosylated form of the human interleukin-1 receptor antagonist (IL-1Ra). Kineret blocks the biologic activity of IL-1 by competitively inhibiting IL-1 binding to the interleukin-1 type 1 receptor (IL-1RI), which is expressed in a wide variety of tissues and organs.

COVERAGE GUIDELINES

The plan may authorize coverage for Kineret (anakinra) for members when requested by a rheumatologist and the following criteria are met:

For Rheumatoid Arthritis
1. The member has a documented diagnosis of rheumatoid arthritis

AND

2. The member must have an inadequate response after three months at optimal doses or an inability to take methotrexate

AND

3. Member is over 18 years of age

AND

4a. The Member has tried and failed treatment with, has a contraindication to or the provider has indicated clinical inappropriateness of treatment with at least two of the following agents:

- Enbrel® (etanercept)
- Humira® (adalimumab)
- Simponi® (golimumab)

OR

4b. The Member is new to the plan and has been stable on Kineret (anakinra) prior to enrollment
Note: Maximal doses of methotrexate are defined as 15mg to 25mg per week depending on the patient’s tolerance.

**For Neonatal-Onset Multisystem Inflammatory Disease (NOMID)**
1. The member has a documented diagnosis of Neonatal-Onset Multisystem Inflammatory Disease (NOMID).

**LIMITATIONS**
1. Samples, free goods or similar offerings of Kineret (anakinra) do not qualify for an established clinical response and will not be considered for prior authorization.
2. Coverage will be limited to a 28-day supply as follows:
   - Kineret 100 mg syringe – 28 syringes per 28 days

**CODES**
Medical billing codes may not be used for these medications. These medications must be obtained via the member’s pharmacy benefit.

**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 Guideline for Kineret (anakinra) in “Rheumatoid Arthritis – Injectable Drugs” originating in August 2002 (Document ID# 1035134).
- October 9, 2012: No changes.
- September 10, 2013: Added diagnosis of Neonatal-Onset Multisystem Inflammatory Disease to Pharmacy Coverage Guidelines.
- October 7, 2014: No changes.
- September 16, 2015: No changes.
January 1, 2016: Administrative change to rebranded template.

September 13, 2016: Effective 1/1/2017: Coverage requires trial and failure of treatment with, contraindication to or clinical inappropriateness of treatment with at least two of the following agents where indicated: Humira, Enbrel, Remicade, Simponi, and Simponi Aria. Added exception language for Members new to the plan and stable on Kineret prior to enrollment.

December 19, 2016: Updated coverage requirements effective 1/1/2017 to a required trial and failure with, contraindication to or clinical inappropriateness of treatment with at least two of the following where indicated: Humira, Enbrel, and Simponi.

April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template.

July 11, 2017: Administrative update to add the following Limitation: Samples, free goods or similar offerings of Kineret (anakinra) do not qualify for an established clinical response and will not be considered for prior authorization.

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.