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 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 + Rhode 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

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 has been evaluated by a rheumatologist
   AND
3. Member is over 18 years of age
   AND
4. The Member has previously tried and failed treatment with, or the patient has a contraindication 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 Humira and Enbrel
   OR
6. The Member is new to the plan and has been stable on Kineret prior to enrollment.

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. Initial authorization will be for 1 year. Subsequent authorization may be given in 12-month intervals based on submission of current progress notes from the physician documenting efficacy.
3. 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 this medication. This medication must be obtained via the Member's pharmacy benefit.

**REFERENCES**


**APPROVAL HISTORY**

October 18, 2013: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
- March 10, 2014: Reviewed by the Pharmacy and Therapeutics Committee.
- September 16, 2015: Removed coverage guidelines for Juvenile Idiopathic Arthritis.
- January 1, 2016: Administrative change to rebranded template.
- September 13, 2016: No changes
- 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 CareLink℠ 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.