Pharmacy Medical Necessity Guidelines
Kineret (anakinra)

Effective: April 1, 2015

| Clinical Documentation and Prior Authorization Required | ✓ | Type of Review – Case Management |
| Not Covered | ✓ | Type of Review – Clinical Review |
| Pharmacy (RX) or Medical (MED) Benefit | RX | Department to Review |

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 I receptor (IL-1RI), which is expressed in a wide variety of tissues and organs.

PHARMACY COVERAGE GUIDELINES
Tufts Health Plan – Network Health 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 Tufts Health Plan – Network Health and has been stable on Kineret prior to enrollment.

Juvenile Idiopathic Arthritis (JIA)
1. The member has a documented diagnosis of juvenile idiopathic arthritis AND
2. The member has been evaluated by a rheumatologist AND
3. Member is over 2 years of age AND
4. The member has tried and failed treatment with, or the patient has a contraindication to methotrexate AND corticosteroids (i.e. prednisone, hydrocortisone or methylprednisolone) AND
5. The member tried and failed treatment with or the provider indicated clinical inappropriateness of Humira and Enbrel if the member is over 4 years of age or has tried and failed treatment with or the provider indicated clinical inappropriateness of Enbrel OR
6. The member is new to Tufts Health Plan – Network Health 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. 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.
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 this medication. This medication must be obtained via the member’s pharmacy benefit.

**REFERENCES**


**APPROVAL HISTORY**

- October 18, 2013: Reviewed by the Pharmacy and Therapeutics Committee.
- March 10, 2014: Reviewed by the Pharmacy and Therapeutics Committee.

**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 fully insured Tufts Health Plan – Network Health offerings unless otherwise noted in this policy or the applicable Member Handbook. Check the applicable product 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 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.