# Pharmacy Medical Necessity Guidelines: Kineret® (anakinra)

*Effective: January 1, 2018*

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| 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 |

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| This Pharmacy Medical Necessity Guideline applies to the following:<br>**Tufts Health Plan Commercial Plans**<br>☐ Tufts Health Plan Commercial Plans – large group plans<br>☐ Tufts Health Plan Commercial Plans – small group and individual plans<br>**Tufts Health Public Plans**<br>☐ Tufts Health Direct – Health Connector<br>☒ Tufts Health Together – A MassHealth Plan<br>☐ Tufts Health RITogether – A RIte Care + Rhody Health Partners Plan<br>**Tufts Health Freedom Plan products**<br>☐ Tufts Health Freedom Plan - large group plans<br>☐ Tufts Health Freedom Plan - small group plans | **Fax Numbers:**<br><br>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 I 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:

**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

**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. Members new to the plan and stable on Kineret (anakinra) are not required to provide documentation of prerequisite trials with conventional (i.e., non-biologic) therapies (e.g., hydroxychloroquine, methotrexate, sulfasalazine).
3. 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.
4. 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


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2. Enbrel prescribing information. Thousand Oaks, CA: Amgen Inc. and Pfizer Inc.; 2015 March.
3. Humira prescribing information. North Chicago, IL: AbbVie Inc.; 2016 June.
4. Kineret (anakinra) [package insert]. Thousand Oaks, CA: Amgen Inc.; October 2013.
5. McEvoy GK, ed. AHFS 2012 Drug Information. Bethesda, MD: American Society of Health-Systems Pharmacists, Inc. 2012.
6. Nuki G, Bresnihan B, Bear MB, McCabe D. Long-term safety and maintenance of clinical improvement following treatment with anakinra (recombinant human interleukin-1 receptor antagonist) in patients with rheumatoid arthritis: extension phase of a randomized, double-blind, placebo-controlled trial. *Arthritis Rheum* 2002; 46:2838-46.
7. Saag KG, Teng GG, Patkar NM, Anuntiyo J, Finney C, Curtis JR. American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. *Arthritis Rheum*. Jun 15 2008; 59(6):762-84.
8. Sibley CH, Plass N, Snow J, et al. Sustained response and prevention of damage progression in patients with neonatal-onset multisystem inflammatory disease treated with anakinra: a cohort study to determine three- and five-year outcomes. *Arthritis Rheum*. 2012 Jul;64(7):2375-86.
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10. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. Arthritis Rheumatol. 2016 Jan;68(1):1-26.
11. Smolen JS, Landewé R, Breedveld FC, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs. *Ann Rheum Dis* 2010; 69: 964 – 75.
12. Tosh JC, Wailoo AJ, Scott DL, Deighton CM. Cost-effectiveness of combination nonbiologic disease-modifying antirheumatic drug strategies in patients with early rheumatoid arthritis. *J Rheumatol*. Aug 2011; 38(8):1593-600.


## 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.
- December 12, 2017: Effective January 1, 2018, removed criteria allowing members new to the plan stable on Kineret (anakinra) to be authorized due to new state requirements. Added the following limitation: Members new to the plan and stable on Kineret (anakinra) are not required to provide documentation of prerequisite trials with conventional (i.e., non-biologic) therapies (e.g., hydroxychloroquine, methotrexate, sulfasalazine).

## 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.