Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: **Kineret® (anakinra)**

Effective: March 1, 2026

Guideline Type	☒ Prior Authorization ☒ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Kineret (anakinra) is an interleukin-1 receptor antagonist indicated for:

Disease State	
Deficiency of Interleukin-1 Receptor Antagonist	X
Neonatal-onset Multisystem Inflammatory Disease	X
Rheumatoid Arthritis	X

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Kineret for Members when **ALL** of the following criteria are met:

Deficiency of Interleukin-1 Receptor Antagonist

Initial Authorization Criteria

1. Documented diagnosis of deficiency of interleukin-1 receptor antagonist

AND

2. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the Member has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of deficiency of interleukin-1 receptor antagonist

AND

3. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

4. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Neonatal-onset Multisystem Inflammatory Disease

Initial Authorization Criteria

1. Documented diagnosis of neonatal-onset multisystem inflammatory disease

AND

2. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the Member has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of neonatal-onset multisystem inflammatory disease

AND

3. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

4. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Rheumatoid Arthritis

Initial Authorization Criteria

1. Documented diagnosis of moderately to severely active rheumatoid arthritis

AND

2. Patient is at least 18 years of age or older

AND

3. Prescribed by a rheumatologist

AND

4. Documentation of history of failure to **one (1)** traditional disease modifying antirheumatic drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine), unless contraindicated or clinically significant adverse effects are experienced *(Note: document drug, date, and duration of trial)*

AND

5. Documentation of history of failure to **two (2)** of the listed medications from each of the following therapeutic categories (only one medication is required if only one is available for a listed therapeutic category), unless contraindicated *(Note: document drugs, dates, and duration of trials)*:
    a. Interleukin Antagonists: Actemra
    b. Janus Kinase Inhibitors: Olumiant, Rinvoq, Xeljanz
    c. Selective T Cell Stimulators: Orencia
    d. Tumor Necrosis Factors: Cimzia, Enbrel, Simlandi, Simponi

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the Member has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of moderately to severely active rheumatoid arthritis

AND

3. Patient is at least 18 years of age or older

AND

4. Prescribed by a rheumatologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Limitations

1. Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response and will not be considered for prior authorization.
2. Authorizations will be provided in 12-month intervals.
3. A patient who has received less than 12 months of therapy or who is restarting therapy with the requested drug is reviewed under Initial Authorization Criteria.
4. Members new the plan stable on the requested medication should be reviewed against Initial Authorization Criteria.

Codes

None

References

1. Kineret (anakinra) [prescribing information]. Stockholm Sweden: Swedish Orphan Biovitrum; September 2024.
2. Cohen S, et al. Treatment of Rheumatoid Arthritis with anakinra, a recombinant human interleukin-1 receptor antagonist, in combination with methotrexate. Arthritis & Rheum 2002; 46(3):614-24.
3. Nuki, G et al. Long-term safety and maintenance of clinical improvement following treatment with anakinra (recombinant human interleukin-1 receptor antagonist) in patients with Rheumatoid Arthritis. Am College of Rheumatol. 2005; 46(11):2838-46.
4. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res. 2021;73(7):924-939.
5. Nigrovic, PA. Cryopyrin-associated periodic syndromes and related disorders. In: TePas (ed). UpToDate, 2021. http://www.uptodate.com. Accessed October 24, 2021.
6. Nigrovic, PA. The autoinflammatory diseases: An overview. In: TePas (ed). UpToDate, 2021. http://www.uptodate.com. Accessed October 20, 2021.

Approval And Revision History

July 8, 2025: Reviewed by the Pharmacy & Therapeutics Committee.

- October 14, 2025: Approvals limited to 12 months with annual reauthorization coverage criteria added. Provider requirements no longer allow with in consultation with the specialist. Added coverage criteria to prevent duplicative targeted immunomodulator therapy. For rheumatoid arthritis, added non-biologic prerequisites to Initial Authorization Criteria and updated biologic prerequisite language (no change in prerequisites) (eff 1/1/26).
- December 9, 2025: Replaced Humira with Simlandi as Simlandi is the preferred adalimumab product (eff 3/1/26).

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. 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.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

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.