CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Kineret (anakinra)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Kineret is an interleukin-1 (IL-1) receptor antagonist that was approved by the FDA in 2001. IL-1 production is induced in response to inflammatory stimuli and mediates various physiologic responses including inflammatory and immunological responses. Kineret has indications for rheumatoid arthritis, cryopyrin-associated periodic syndromes (CAPS), and deficiency of interleukin-1 receptor antagonist (DIRA).
CAPS and DIRA are rare interleukin-1 mediated systemic autoinflammatory diseases. Neonatal onset multisystem inflammatory disease (NOMID) is a severe phenotype of CAPS also known as chronic infantile neurological cutaneous and articular (CINCA).

Kineret (anakinra) will be considered for coverage when the following criteria are met:

Rheumatoid Arthritis (RA)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication is prescribed by or in consultation with a rheumatologist; AND
3. Member has a documented diagnosis of moderately to severely active RA; AND
4. Member must have a trial and failure of, or intolerance to methotrexate for at least 3 months;
   Note: If methotrexate is contraindicated, one of the following conventional DMARDs must be trialed instead: leflunomide, sulfasalazine, or hydroxychloroquine; AND
5. Member has tried and failed treatment with at least two preferred biologic DMARDs; treatment failure requires at least 12 weeks of therapy with each drug; AND
6. Member has had a negative tuberculosis test within the past 12 months.
7. **Dosage allowed/Quantity limit:** 100 mg subQ once daily. (28 syringes per 28 days)

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes demonstrate improvement of RA signs and symptoms (e.g. fewer number of painful and swollen joints, achievement of remission, slowed progression of joint damage, etc.).

If all the above requirements are met, the medication will be approved for an additional 12 months.

Cryopyrin-Associated Periodic Syndrome (CAPS)

For **initial** authorization:

1. Medication must be prescribed by or in consultation with a rheumatologist or other specialist familiar with CAPS; AND
2. Member must be diagnosed with Neonatal-Onset Multisystem Inflammatory Disease (NOMID); AND
3. Genetic testing results show gain-of-function mutation in the *NLRP3* gene; AND
4. Member has elevated inflammatory markers (e.g., serum levels of amyloid A, C-reactive protein, erythrocyte sedimentation rate [SAA, CRP, ESR]); AND
5. Member has symptoms of NOMID (e.g. rash, neurologic findings, skeletal abnormalities, hearing loss); AND
6. Member has had a negative tuberculosis test within the past 12 months.
7. **Dosage allowed/Quantity limit:** Starting dose: Inject 1-2 mg/kg subQ. Once daily administration is generally recommended, but the dose may be split into twice daily. May adjust up to a max of 8 mg/kg per day.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes demonstrate positive clinical response including decreased inflammatory marker values and symptom improvement.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

For **initial** authorization:

1. Medication must be prescribed by or in consultation with a rheumatologist, dermatologist, or geneticist; AND
2. Member has a diagnosis of DIRA confirmed by loss of function mutations of the *IL1RN* gene; AND
3. Member has elevated inflammatory markers (e.g., serum levels of amyloid A, C-reactive protein, erythrocyte sedimentation rate [SAA, CRP, ESR]); AND
4. Member has symptoms of skin and/or bone inflammation; AND
5. Member has had a negative tuberculosis test within the past 12 months.
6. **Dosage allowed/Quantity limit:** Starting dose: Inject 1-2 mg/kg subQ daily. May adjust up to a max of 8 mg/kg per day.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Must demonstrate positive clinical response to therapy such as improved skin and/or bone inflammation.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Kineret (anakinra) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
05/10/2017	New policy for Kineret created. Policy SRx-0042 archived. List of diagnoses considered not medically necessary was added.
02/26/2019	Humira was removed from criteria; Actemra, Cimzia, Kevzara, Olumiant and Xeljanz for RA added to trial agents list. TB test allowed to be done within 12 months prior to initiation of therapy; chest x-ray option removed. Referenced added.
11/23/2020	Updates for RA section: Removed repeat TB test. Updated references. Changed the trials to require methotrexate as one of the non-biologic DMARD trials; only one trial is needed if member has poor prognostic factors.
06/04/2021	Added criteria for new approved diagnosis of DIRA. CAPS: Updated references. Removed genetic test requirement (mutation only found in 60%). Added symptoms. Revised dosing. Specified renewal criteria and removed TB test from renewal criteria.
02/17/2022	Transferred to new template. RA: Added new reference. Edited the terminology “non-biologic” DMARD to “conventional” DMARD. Changed from requiring 2 csDMARD to just 1. Updated wording for preferred biologic trials.
08/08/2024	CAPS: Updated refs. Added genetic testing (EULAR 2021). DIRA: Updated refs. Added inflammatory marker elevation (EULAR 2021).

References:

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3. Smolen JS, Landewé RBM, Bijlsma JWJ, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2019 update. *Ann Rheum Dis*. 2020;79(6):685-699.
4. Scott IC, et al. A randomised trial evaluating anakinra in early active rheumatoid arthritis. Clin Exp Rheumatol. 2016 Jan-Feb;34(1):88-93.
5. Fleischmann RM, et al. Safety of extended treatment with anakinra in patients with rheumatoid arthritis. Ann Rheum Dis. 2006;65(8):1006-12.
6. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol*. 2021;73(7):1108-1123. doi:10.1002/art.41752
7. Aksentijevich I, Masters SL, Ferguson PJ, et al. An autoinflammatory disease with deficiency of the interleukin-1-receptor antagonist. *N Engl J Med*. 2009;360(23):2426-2437. doi:10.1056/NEJMoa0807865
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9. Romano M, Arici ZS, Piskin D, et al. The 2021 EULAR/American College of Rheumatology points to consider for diagnosis, management and monitoring of the interleukin-1 mediated autoinflammatory diseases: cryopyrin-associated periodic syndromes, tumour necrosis factor receptor-associated periodic syndrome, mevalonate kinase deficiency, and deficiency of the interleukin-1 receptor antagonist. *Ann Rheum Dis*. 2022;81(7):907-921. doi:10.1136/annrheumdis-2021-221801

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