CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Georgia Medicaid

DRUG NAME	Kineret (anakinra)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
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 (anakinra) will be considered for coverage when the following criteria are met:

Rheumatoid Arthritis (RA)

For **initial** authorization:

1. Member must be 18 years of age or older; 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 has had a negative tuberculosis test within the past 12 months; AND
5. 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
6. 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.
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. Member has elevated inflammatory markers (e.g. serum levels of amyloid A, C-reactive protein, erythrocyte sedimentation rate); AND
4. Member displays symptoms of NOMID (e.g. skin rash, musculoskeletal pain, central nervous system manifestations, hearing loss, conjunctivitis); AND
5. Must have a negative tuberculosis (TB) test within the last 12 months.
6. **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 genetic testing with IL1RN mutations; AND
3. Member has symptoms of skin and/or bone inflammation; AND
4. Must have a negative tuberculosis (TB) test within the last 12 months.
5. **Dosage allowed/Quantity limit:** Starting dose: Inject 1-2 mg/kg subQ once 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.

References:

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7. Galloway JB, et al. The risk of serious infections in patients receiving anakinra for rheumatoid arthritis: results from the British Society for Rheumatology Biologics Register. Rheumatology (Oxford). 2011 Jul;50(7):1341-2.
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12. Welzel T, Kuemmerle-Deschner JB. Diagnosis and Management of the Cryopyrin-Associated Periodic Syndromes (CAPS): What Do We Know Today?. *J Clin Med*. 2021;10(1):128. Published 2021 Jan 1. doi:10.3390/jcm10010128
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