CareSource

PHARMACY POLICY STATEMENT **Marketplace**	
DRUG NAME	Kineret (anakinra)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include Actemra, Enbrel, Cimzia, Kevzara, Olumiant and Xeljanz for RA QUANTITY LIMIT— 28 syringes per 28 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Kineret (anakinra) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

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 documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy.
6. **Dosage allowed:** 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 member meets all the requirements listed above, 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 member meets all the reauthorization requirements above, 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 documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy.
5. **Dosage allowed:** Starting dose: Inject 1-2 mg/kg subQ once daily. May adjust up to a max of 8 mg/kg per day.

If member meets all the requirements listed above, 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 member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

RHEUMATOID ARTHRITIS (RA)

For **initial** authorization:

1. Member must be 18 years of age or older with moderately to severely active RA; AND
2. Medication must be prescribed by or in consultation with a rheumatologist; AND
3. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; AND
4. Member must have a trial and failure of, or intolerance to methotrexate and **one** other non-biologic DMARD (i.e., hydroxychloroquine, sulfasalazine, and leflunomide) for 3 months per trial, either together or separately; AND
   Note: only one non-biologic DMARD is required if member has a poor prognostic factor such as high swollen joint count, presence of early joint erosions, presence of autoantibodies (RF and/or ACPA).
5. Member has tried and failed treatment with at least **two** of the following: Actemra, Enbrel, Cimzia and Kevzara, Olumiant and Xeljanz. Treatment failure requires at least 12 weeks of therapy with each drug.
6. **Dosage allowed:** Inject 100 mg subcutaneously once daily.

If member meets all the requirements listed above, 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 member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Kineret (anakinra) not medically necessary for the treatment of diseases not listed in this document.

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.

References:

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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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