

## PHARMACY POLICY STATEMENT

### Georgia Medicaid

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 <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

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.**

<b>05/10/2017</b>	New policy for Kineret created. Policy SRx-0042 archived. List of diagnoses considered not medically necessary was added.
<b>02/26/2019</b>	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.
<b>11/23/2020</b>	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.
<b>06/04/2021</b>	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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