

**NC Medicaid  
Outpatient Pharmacy  
Prior Approval Criteria  
Systemic Immunomodulators**

**Effective Date: August 15, 2014  
Amended Date: January 2, 2025**

**Therapeutic Class Code:** S2M  
**Therapeutic Class Description:** Immunomodulatory Agents

Medication
Kineret

**Eligible Beneficiaries**

NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

**EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age**

**42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]**

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

- a. that is unsafe, ineffective, or experimental/investigational.
- b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

**EPSDT and Prior Approval Requirements**

If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.

**IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the NCTracks Provider Claims and Billing Assistance Guide, and on the EPSDT provider page. The Web

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addresses are specified below.

*NCTracks Provider Claims and Billing Assistance Guide:*

<https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html>

*EPSDT provider page:* <https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid-benefit-children-and-adolescents>

### **Criteria for approval**

#### **1. Neonatal Onset Multisystem Inflammatory Disease (NOMID):**

- Beneficiary has a diagnosis of neonatal-onset multisystem inflammatory disease.  
AND
- Beneficiary is not on another injectable biologic immunomodulator.  
AND
- Beneficiary has been considered and screened for the presence of latent tuberculosis infection.  
AND
- Beneficiary has been tested with Hep B SAG and Core Ab.

#### **2. Rheumatoid arthritis:**

- Beneficiary has a diagnosis of Rheumatoid Arthritis.  
AND
- Beneficiary is not on another injectable biologic immunomodulator.  
AND
- Beneficiary has been considered and screened for the presence of latent tuberculosis infection.  
AND
- Beneficiary has been tested with Hep B SAG and Core Ab.  
AND
- Beneficiary has experienced a therapeutic failure/inadequate response with methotrexate or at least one disease modifying antirheumatic drug (e.g. leflunomide, hydroxychloroquine, minocycline, sulfasalazine).  
OR
- Beneficiary is unable to receive methotrexate or disease modifying antirheumatic drug due to contraindications or intolerabilities.  
OR
- Beneficiary has clinical evidence of severe or rapidly progressing disease.  
AND
- Coverage of non-preferred medications require a trial and failure of Enbrel or Humira or a clinical reason beneficiary cannot try either Enbrel or Humira.

#### **3. Deficiency of Interleukin-1 Receptor Antagonist (DIRA):**

- Beneficiary has diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA).  
AND
- Beneficiary is not on another injectable biologic immunomodulator.  
AND

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- Beneficiary has been considered and screened for the presence of latent tuberculosis infection.  
AND
- Beneficiary has been tested with Hep B SAG and Core Ab.

**Procedures**

- Approve for up to 12 months.
- Coverage of one injectable immunomodulator at a time.

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**References**

1. Swedish Orphan Biovitrum AB. Kineret package insert. Stockholm, Sweden:2001.Updated Dec 2020

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**Criteria Change Log**

08/15/2014	Criteria effective date
10/1/2021	Added Deficiency of Interleukin-1 Receptor Antagonist (DIRA) for Kineret
01/02/2025	Separated out criteria by individual agents