

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

**Effective Date: June 27, 2018  
Amended Date: January 2, 2025**

**Therapeutic Class Code:** S2V

**Therapeutic Class Description:** Immunomodulatory Agents

| Medication |
|------------|
| Ilaris     |

**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. Systemic Onset Juvenile Idiopathic Arthritis (SJIA):**

- Beneficiary has a diagnosis of Systemic Juvenile Idiopathic Arthritis.  
AND
- Beneficiary is not on another injectable biologic immunomodulator.  
AND
- Beneficiary has a diagnosis of Systemic Juvenile Idiopathic Arthritis.  
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.  
OR
- Beneficiary has systemic arthritis with active systemic features and features of poor prognosis, as determined by the prescribing physician (e.g. arthritis of the hip, radiographic damage).

#### **2. Cryopyrin-Associated Periodic Syndromes (CAPS) including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS):**

- Beneficiary has a diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS) including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS).  
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.

#### **3. Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS):**

- Beneficiary has a diagnosis of Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS).  
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.

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- 4. Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD):**
- Beneficiary has a diagnosis of Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD).  
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.
- 5. Familial Mediterranean Fever (FMF):**
- Beneficiary has a diagnosis of Familial Mediterranean Fever (FMF).  
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.
- 6. Adult Onset Still's Disease:**
- Beneficiary has a diagnosis of Adult Onset Still's 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.  
OR
  - Beneficiary has systemic arthritis with active systemic features and features of poor prognosis, as determined by the prescribing physician (e.g. arthritis of the hip, radiographic damage).

**Procedures**

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

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**References**

1. Novartis Pharmaceuticals Corporation. Ilaris prescribing information. East Hanover, NJ: September 2016. Updated June 2020

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**Criteria Change Log**

|            |  |
|------------|--|
| 06/27/2018 | Criteria effective date                                      |
| 02/01/2021 | Added adult-onset Still's disease (AOSD) criteria for Ilaris |
| 01/02/2025 | Separated out criteria by individual agents                  |