NC Medicaid
Outpatient Pharmacy
Prior Approval Criteria
Arcalyst **Effective Date: June 27, 2018**
Systemic Immunomodulators **Amended Date: January 2, 2025**

Therapeutic Class Code: S2M
Therapeutic Class Description: Anti-inflam Interleukin-1 Receptor Antagonist

Medication
Arcalyst

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 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

1. **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.

2. **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
   - 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
     - Agent is being used for maintenance of remission.
       AND
     - Beneficiary weighs at least 10kg.

3. **Recurrent pericarditis (RP) and reduction in risk of recurrence**
   - Beneficiary has diagnosis of recurrent pericarditis;
     AND
   - Beneficiary is at least 12 years of age;
     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.

Procedures

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

References

1. Regeneron Pharmaceuticals, INC. Arcalyst prescribing information. Tarrytown, NY; September 2016. Updated Dec 2020. Updated March 2021.

Criteria Change Log

06/27/2018	Criteria effective date
10/1/2021	Added Deficiency of Interleukin-1 Receptor Antagonist (DIRA) for Arcalyst
01/02/2025	Criteria separated out by drug Recurrent Pericarditis added for Arcalyst