NC Medicaid
Prior Approval Criteria
Actemra **Date: June 27, 2018**
Systemic Immunomodulators **Amended Date: January 2, 2025**

Therapeutic Class Code: Z2V
Therapeutic Class Description: INTERLEUKIN-6 RECEPTOR INHIBITORS

Medication
Actemra SQ
Actemra Infusion

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 for approval:

1. **Polyarticular Juvenile Idiopathic Arthritis (PJIA)**:
- Beneficiary has a diagnosis of Polyarticular Juvenile Idiopathic 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 tried one systemic corticosteroid (e.g. prednisone, methylprednisolone) or methotrexate, leflunomide or sulfasalazine with inadequate response or is unable to take these therapies due to contraindications.
  OR
- Beneficiary has PJIA subtype enthesitis related arthritis.
  AND
- Coverage of non-preferred medications require a trial and failure of Enbrel or Humira or a clinical reason beneficiary cannot try Enbrel or Humira.

2. **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).

3. **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.

4. Giant Cell Arteritis:

- Beneficiary has a diagnosis of Giant Cell Arteritis.
  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. Cytokine Release Syndrome:

- Beneficiary has a diagnosis of Cytokine Release Syndrome.
  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. Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)

- Beneficiary has a diagnosis of Systemic Sclerosis-Associated Interstitial Lung 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.

Procedures

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

References

1. Genentech Inc. Actemra Prescribing Information. San Fransisco CA: revised May 2018. Updated March 2021.

Criteria Change Log

06/27/2018	Criteria effective date
02/26/2019	Add Actemra and Actemra SQ to Giant Cell Arteritis and Cytokine Release Syndrome
01/02/2025	Separated document out by individual agents Added criteria for Systemic Sclerosis-Associated Interstitial Lung Disease for Actemra SQ & Actemra Infusion