NC Medicaid
Outpatient Pharmacy Prior Approval Criteria
Nemluvio

Effective Date: xx/xx/xxxx

DRAFT

Therapeutic Class Code: V4J
Therapeutic Class Description: Interleukin-31 (IL-31) Receptor Alpha Antagonist, MAB

Medication
Nemluvio (nemolizumab-ilto)

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

1. 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.

2. **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

Clinical Coverage

- **A. Atopic Dermatitis**
  - The beneficiary must meet all of the following:
    1. Be 12 years of age or older
    2. Have a diagnosis of moderate to severe Atopic Dermatitis
    3. Have failed at least 1 prescription topical steroid or have a documented adverse reaction or contraindication that precludes trial of at least 1 prescription topical steroid
    4. Trial and failure or documented adverse reaction or contraindication that precludes use of (unless trial precluded by age): ─Topical calcineurin inhibitor (e.g., pimecrolimus (ages 2 and older) or tacrolimus 0.03% (ages 2 and older) and 0.1% (ages 18and older))

    Criteria for Continuation of Therapy of Nemluvio (Atopic Dermatitis):

    For beneficiaries already receiving Nemluvio, coverage is provided when criteria for initial therapy are met and there is continued clinical benefit from baseline supported by medical records.

- **B. Prurigo Nodularis (PN)**
  1. Beneficiary is 18 years of age or older; **AND**
  2. Beneficiary has a diagnosis of Prurigo Nodularis; **AND**
  3. Beneficiary has tried and failed, or has contraindication, or intolerance to at least one preferred medium to very high potency topical steroid; **AND**
  4. Prescribed by or in consultation with a dermatologist, allergist, or immunologist

Criteria for Continuation of Therapy of Nemluvio (Prurigo Nodularis):

For beneficiaries already receiving Nemluvio, coverage is provided when criteria for initial therapy are met and there is continued clinical benefit from baseline supported by medical records.

Duration of Approval

- 6 months

References

1 Nemluvio [package insert]. Dallas, TX; Galderma Laboratories; August 2024

Criteria Change Log

xx/xx/xxxx	Criteria effective date