NC Division of Medical Assistance **Medicaid and Health Choice**
Outpatient Pharmacy **Effective Date: April 26, 2016**
Prior Approval Criteria **Amended Date:**
Nucala

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Therapeutic Class Code: Z2O
Therapeutic Class Description: Monoclonal Antibody

Medication	Generic Code Number(s)	NDC Number(s)
Nucala **(mepolizumab)**	40084	

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.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified. **EPSDT does not apply to NCHC beneficiaries**.

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

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. Additional information on EPSDT guidelines may be accessed at http://dma.ncdhhs.gov/.

Nucala (mepolizumab)

1. Asthma

Criteria for Initial Therapy:

The beneficiary must have the following:

Severe asthma with an eosinophilic phenotype

AND ALL of the following:

a) be 12 years of age or older
b) Nucala is being used in combination with a corticosteroid inhaler and long acting beta-agonist
c) Have inadequate control of asthmatic symptoms after a minimum of 3 months of high dose corticosteroid inhaler in combination with a long acting beta-agonist
d) Nucala is not being used for the treatment of other eosinophilic conditions
e) Nucala is not being used for the relief of acute bronchospasm or status asthmaticus
f) Nucala is not being used as dual therapy with omalizumab (Xolair)

Procedures:

- Approval length up to 6 months.

Criteria for Continued Therapy (Asthma):

The beneficiary must have the following:

Severe asthma with an eosinophilic phenotype

AND ALL of the following:

a) be 12 years of age or older

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b) Nucala is being used in combination with a corticosteroid inhaler and long acting beta-agonist
c) The beneficiary has a documented response of decreased exacerabations and improvement in symptoms

d) The beneficiary has had a decreased utilization of rescue medications
e) Nucala is not being used for the treatment of other eosinophilic conditions
f) Nucala is not being used for the relief of acute bronchospasm or status asthmaticus
g) Nucala is not being used as dual therapy with omalizumab (Xolair)

Procedures:

- Approval length up to 12 months.

2. Eosinophilic Granulomatosis with Polyangiitis

Criteria for Initial Therapy:

The beneficiary must have the following:

a. Confirmed diagnosis of Eosinophilic Granulomatosis with Polyangiitis
b. Be 18 years old or older

Procedures:

Approval length up to 12 months

References

1. GlaxoSmithKline, LLC. Nucala Package Insert. Philadelphia, PA. November 2015, updated 12/2017

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Criteria Change Log

4/26/2016	Criteria effective date
	Dx of Eosinophilic Granulomatosis with Polyangiitis