

**NC Division of Medical Assistance
Outpatient Pharmacy
Prior Approval Criteria
Monoclonal Antibody**

**Medicaid and Health Choice
Effective Date: November 1, 2011
Amended Date:**

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Therapeutic Class Code: Z2L, Z2O

Therapeutic Class Description: Monoclonal Antibody

Medication	Generic Code Number(s)	NDC Number(s)
Xolair	19966	
Fasenra	44088	
Nucala	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

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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/>.

1. Xolair

~~Criteria for Initial Therapy of Xolair:~~

A. Allergic Asthma:

Criteria for Initial Therapy of Xolair (Allergic Asthma):

The beneficiary must meet **all** of the following criteria:

- 1) be 6 years of age and older;
- 2) have a diagnosis of asthma;
- 3) have inadequately controlled asthma meeting one of the following definitions:
 - a. Use of inhaled corticosteroids in the past 45 days and excessive use of short-acting beta agonists in the past 60 days; **OR**
 - b. Use of inhaled corticosteroids in the past 45 days and short-term oral steroid use in the past 45 days; **OR**
 - c. Use of inhaled corticosteroids in the past 45 days and an emergency room visit in the past 45 days;
- 4) A percutaneous skin test or RAST allergy test in the past twelve months indicating reactivity to at least one perennial aeroallergen; **and**
- 5) IgE level above 30 IU/mL.

Approval length up to 12 months.

Criteria for Continuation of Therapy of Xolair (Allergic Asthma):

For beneficiaries already receiving Xolair, coverage is provided when there is continued clinical benefit as evidenced by reductions in asthma exacerbations from baseline supported by medical

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records documenting the beneficiary's current asthma status, response to Xolair treatment, and current smoking status.

Procedures: Approval length up to 12 months.

B: Chronic Idiopathic Urticaria for Xolair:

Criteria for Initial Therapy of Xolair (Chronic Idiopathic Urticaria):

- 1) Covered for beneficiaries 12 years of age and above with moderate to severe chronic idiopathic urticaria who remain symptomatic despite treatment with at least two H1 antihistamines and one leukotriene modifier.
- 2) Omalizumab should also be prescribed in consultation with an allergy specialist.

Criteria for Continuation of Therapy of Xolair (Chronic Idiopathic Urticaria):

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

2. Fasenra

A. Severe Asthma:

Criteria for Initial Therapy of Fasenra (Asthma):

The beneficiary must meet **all** of the following criteria:

- 1) be 12 years of age and older;
- 2) have a diagnosis of severe eosinophilic asthma; ~~with an eosinophilic phenotype with blood eosinophil counts \geq 300 cells/microliter~~
- 3) have a pre-treatment serum eosinophil count of 150 cells/mcL or greater at screening (within the past 6 weeks prior to the request for Fasenra) or 300 cells/mcL or greater within 12 months prior to use, or sputum eosinophilic count greater than 3%;
- 4) 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;
- 5) have inadequately controlled severe asthma meeting one of the following definitions:
 - a. 2 or more asthma exacerbations requiring oral/systemic corticosteroid treatment; or
 - b. hospitalization in the past 12 months;
- 6) have prebronchodilator FEV1 below 80% in adults and 90% in adolescents;
- 7) Fasenra is being used as add on maintenance treatment;

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- 8) Fasenra is not being used for the treatment of other eosinophilic conditions;
 - 9) Fasenra is not being used for the relief of acute bronchospasm or status asthmaticus;
 - 10) Fasenra is not being used as dual therapy with other monoclonal antibody treatments;
- and

Initial approval up to 6 months.

Criteria for Continuation of Therapy of Fasenra (Asthma):

For beneficiaries already receiving Fasenra, coverage is provided when criteria for initial therapy are met and there is continued clinical benefit as evidenced by reductions in asthma exacerbations from baseline supported by medical records documenting the beneficiary's current asthma status and response to Fasenra treatment

Procedures:

Approval length up to 12 months.

3. Nucala

A. Asthma

Criteria for Initial Therapy (Asthma):

The beneficiary must meet **all** of the following criteria:

~~The beneficiary must have the following:~~

- ~~1) Severe asthma with an eosinophilic phenotype~~

~~AND ALL of the following:~~

- 1) be 12 years of age or older
- 2) have a diagnosis of severe eosinophilic asthma;
- 3) have a pre-treatment serum eosinophil count of 150 cells/mcL or greater at screening (within the past six weeks prior to the request for Fasenra) or 300 cells/mcL or greater within 12 months prior to use, or sputum eosinophilic count greater than 3%;
- 4) 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
- 5) have inadequately controlled severe asthma meeting one of the following definitions:
 - a. two or more asthma exacerbations requiring oral/systemic corticosteroid treatment; or
 - b. hospitalization in the past 12 months;
- 6) have prebronchodilator FEV1 below 80% in adults and 90% in adolescents;

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- 7) Nucala is being used in combination with a corticosteroid inhaler and long acting beta-agonist. **Nucala is being used as add on maintenance treatment;**
- 8) Nucala is not being used for the treatment of other eosinophilic conditions
- 9) Nucala is not being used for the relief of acute bronchospasm or status asthmaticus
- 10) Nucala is not being used as dual therapy with omalizumab (Xolair) **other monoclonal antibody treatments; and**

Procedures:

Initial approval length up to 6 months.

Criteria for Continued Therapy (Asthma):

The beneficiary must have the following:
Severe asthma with an eosinophilic phenotype

For beneficiaries already receiving Nucala, coverage is provided when **criteria for initial therapy are met and** there is continued clinical benefit as evidenced by reductions in asthma exacerbations from baseline supported by medical records documenting the beneficiary's current asthma status and response to Nucala treatment.

Procedures:

Approval length up to 12 months.

~~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~~
- e) ~~The beneficiary has a documented response of decreased exacerbations 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.

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B. Eosinophilic Granulomatosis with Polyangiitis

Criteria for Initial Therapy (Polyangiitis):

The beneficiary must have the following:

- 1) Confirmed diagnosis of Eosinophilic Granulomatosis with Polyangiitis
- 2) Be 18 years old or older

Approval length up to 6 months.

Criteria for Continued Therapy (Polyangiitis):

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

Procedures:

Approval length up to 12 months.

References

1. Genentech, Inc. Xolair Package Insert. San Francisco, CA. September 2014.
2. Astra Zeneca, Inc. Fasenra Package Insert. Wilmington, DE. November 2017.
3. GlaxoSmithKline, LLC. Nucala Package Insert. Philadelphia, PA. November 2015, updated 12/2017

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Criteria Change Log

11/01/2011	Criteria effective date (Xolair only)
05/20/2015	Criteria amended to include Chronic Idiopathic Urticaria for Xolair
04/26/2016	Nucala criteria effective
04/05/2018	Added criteria for Fasenra
05/04/2018	Added coverage for Eosinophilic Granulomatosis with Polyangiitis for Nucala
06/01/2018	Combined Nucala with Xolair and Fasenra into 1 criteria