

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

**Medicaid and Health Choice  
 Effective Date: 11/01/2011  
 Revised Date: 06/15/2012**

**Therapeutic Class Code:** Z2L  
**Therapeutic Class Description:** Monoclonal Antibody

Medication	Generic Code Number(s)	NDC Number(s)
Xolair	19966	

**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://www.ncdhhs.gov/dma/epsdt/>.

**Criteria for Initial Therapy:**

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;
  - 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.

**Criteria for Continuation of Therapy:**

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 records documenting the beneficiary's:

- 1) current asthma status  
and
- 2 response to Xolair treatment  
and
- 3) current smoking status.

**Procedures:**

1. Approval length up to 12 months.

**References**

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1) Genentech, Inc. Xolair Package Insert. San Francisco, CA. July 2010.