NC Medicaid Outpatient Pharmacy Prior Approval Criteria Monoclonal Antibody	Medicaid and Health Choice Effective Date: November 1, 2011 Amended Date:

DRAFT

Therapeutic Class Code: Z2L, Z2O, V4D, V4G, V4F
Therapeutic Class Description: Monoclonal Antibody

Medication
Xolair
Fasenra
Nucala
Dupixent
Adbry
Tezspire

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

a. 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.
b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid and NC Health Choice Billing Guide,* sections 2 and 6, 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

Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

EPSDT does not apply to NCHC beneficiaries. If a NCHC beneficiary does not meet the clinical coverage criteria within **the Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the NC Medicaid clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

1. Xolair

A. Allergic Asthma:

Criteria for Initial Therapy of Xolair (Allergic Asthma):

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

1) be six (6 years) of age and older weighing between 20 kg (44 lbs) and 150kg (330 lbs);
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;
5) IgE level above 30 IU/mL.
6) 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 records documenting the beneficiary's current asthma status, response to Xolair treatment, and current smoking status.

Approval length up to 12 months.

B. <u>Chronic Idiopathic Urticaria for Xolair:</u>

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.

C. <u>Nasal Polyps for Xolair</u>

Criteria for Initial Therapy of Xolair (Nasal Polyps)

1. Beneficiary is 18 years of age or older; **AND**
2. Beneficiary weighs between 30 kg (66 lbs) and 150kg (330 lbs); AND
3. Beneficiary has an IgE level above 30 IU/mL
4. Beneficiary has a diagnosis of nasal polyps; **AND**
5. Beneficiary has tried and failed monotherapy with nasal steroids; **AND**
6. Beneficiary must continue to receive intranasal steroid concomitantly

Criteria for Continuation of Therapy of Xolair (Nasal Polyps):

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;
3) have a pre-treatment serum eosinophil count of 150 cells/mcL or greater at screening (within the past six (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 three (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 (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;
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

Approval length up to 12 months.

3. Nucala

A. Asthma

Criteria for Initial Therapy of Nucala (Asthma):

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

1) be 6 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 three (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;
7) 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 other monoclonal antibody treatments; **and** Initial approval up to six (6) months.

Criteria for Continued Therapy Nucala (Asthma):
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.

Approval length up to 12 months.

B. <u>Eosinophilic Granulomatosis with Polyangiitis</u>

Criteria for Initial Therapy of Nucala (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 six (6) months.

Criteria for Continued Therapy of Nucala (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.

Approval length up to 12 months.

C. <u>Hypereosinophilic Syndrome (HES)</u>

Criteria for Initial Therapy of Nucala (HES):

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

1) 12 years of age or older
2) Diagnosis of Hypereosinophilic Syndrome (HES) for at least 6 months
3) Beneficiary must NOT have an identifiable non-hematologic secondary cause of HES

Initial approval up to 6 months.

Criteria for Continued Therapy of Nucala (HES):
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.

Approval length up to 12 months.

D. Nasal Polyps

Criteria for Initial Therapy of Nucala (Nasal Polyps)
1. Beneficiary is 18 years of age or older; **AND**
2. Beneficiary has a diagnosis of chronic rhinosinusitis with nasal polyps; **AND**
3. Beneficiary has tried and failed monotherapy with nasal steroids; **AND**
4. Beneficiary must continue to receive intranasal steroid concomitantly

Criteria for Continuation Therapy of Nucala (Nasal Polyps)
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.

4. Dupixent

A. Atopic Dermatitis

Criteria for Initial Therapy of Dupixent (Atopic Dermatitis)

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

1. Be 6 years of age or older
2. have a diagnosis of moderate to severe Atopic Dermatitis
3. have failed at least 2 prescription topical steroids or have a documented adverse reaction or contraindication that precludes trial of at least 2 prescription topical steroids
4. Trial and failure or documented adverse reaction or contraindication that precludes use of one of the following:
─Topical calcineurin inhibitor (e.g., pimecrolimus or tacrolimus)
─ Topical phosphodiesterase-4 inhibitor (e.g., crisaborole)
─ Topical Janus kinase inhibitor (e.g., ruxolitinib)

Approval length up to six months

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

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

Asthma

Criteria for Initial Therapy of Dupixent (Asthma)

1. Beneficiary is ~~12~~ 6 years of age or older and has **ONE** of the following:
   a. A diagnosis of Asthma with eosinophilic phenotype with a pre-treatment serum eosinophil count of 150 cells/mcL or greater at screening (within the past six weeks prior to the request for Dupixent) or 300 cells/mcL or greater within 12 months prior to use, or sputum eosinophilic count greater than 3% **OR**
   b. Oral corticosteroid dependent asthma with at least 1 month of daily oral corticosteroid use within the last 3 months **AND**
2. Inadequate control of asthma symptoms after a minimum of 3 months of compliant use of **ONE** of the following within the past 6 months:
   a. Inhaled corticosteroids & long acting beta2 agonist **OR**
   b. Inhaled corticosteroids & long acting muscarinic antagonist **AND**
3. **NOT** being used for the relief of acute bronchospasm or status asthmaticus **AND**
4. **NOT** receiving dual therapy with another monoclonal antibody for the treatment of asthma

Approval length up to six months

Criteria for Continued Therapy of Dupixent (Asthma):
For beneficiaries already receiving Dupixent, 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 Dupixent treatment.

B. Nasal Polyps

Criteria for Initial Therapy of Dupixent (Nasal Polyps)

1. Beneficiary is 18 years of age or older; **AND**
2. Has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP); **AND**
3. Has failed monotherapy with nasal steroids; **AND**
   a. Has had previous sino-nasal surgery, **OR**
   b. Has had treatment for nasal polyps with systemic corticosteroids in the past 2 years, or has contraindication to systemic corticosteroids; **AND**
4. Must continue to receive intranasal steroid concomitantly)

5. Adbry

- **Atopic Dermatitis**

Criteria for Initial Therapy

Beneficiary must meet all of the following for approval:

1. 18 years of age or older; **AND**
2. Will not receive live vaccines during therapy; **AND**
3. Has a diagnosis of moderate to severe atopic dermatitis with at least 1 of the following:
   - Involvement of at least 10% of body surface area (BSA); **OR**
   - Eczema Area and Severity Index (EASI) score of 16 or greater; **OR**
   - Investigator's Global Assessment (IGA) score of 3 or more; **OR**
   - Scoring Atopic Dermatitis (SCORAD) score of 25 or more; **OR**
   - Incapacitation due to AD lesion location (i.e.,head and neck, palms, soles, or genitalia); **AND**
4. Trial and failure of at least 2 prescription topical steroids or have a documented adverse reaction or contraindication that precludes trial of at least 2 prescription topical steroids; **AND**
5. Trial and failure or documented adverse reaction or contraindication that precludes use of one of the following:
   - Topical calcineurin inhibitor (e.g., pimecrolimus or tacrolimus)
   - Topical phosphodiesterase-4 inhibitor (e.g., crisaborole)
   - Topical Janus kinase inhibitor (e.g., ruxolitinib); **AND**
6. Tralokinumab-ldrm will not be used in combination with other monoclonal antibody biologics (e.g., tezepelumab, omalizumab, mepolizumab, reslizumab, benralizumab, dupilumab).

Initial approval length: 16 weeks

Criteria for continuation of therapy

Patient must continue to meet the above criteria; **AND**
Patient must have disease improvement and/or stabilization from baseline; **AND**
Patient has NOT experienced serious treatment-related adverse events (e.g., serious infection, conjunctivitis, keratitis, eosinophilia).

Approval length: 6 months

6. Tezspire

Criteria for Initial Therapy

Beneficiary must meet all of the following for approval:

1. Beneficiary must be ≥ 12 years of age; **AND**

2. Beneficiary must have a diagnosis of severe asthma with evidence of severe disease indicated by ≥ 1 of the following:
    a. Symptoms throughout the day; **OR**
    b. Nighttime awakenings, often 7x/week; **OR**
    c. SABA use for symptom control occurs several times per day; **OR**
    d. Extremely limited normal activities; **OR**
    e. Lung function (percent predicted FEV1) < 60%; **OR**
    f. Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma; **AND**
3. Must be used for add-on maintenance treatment in beneficiary regularly receiving BOTH of the following:
    a. Medium- to high-dose inhaled corticosteroids; **AND**
    b. An additional controller medication (e.g., long-acting beta agonist, leukotriene modifiers); **AND**
4. Beneficiary must have had, in the previous year, ≥ 2 exacerbations requiring oral or injectable corticosteroid treatment (in addition to the regular maintenance therapy defined above) OR one exacerbation resulting in a hospitalization; **AND**
5. Baseline measurement of ≥ 1 of the following for assessment of clinical status:
    a. Use of systemic corticosteroids; **OR**
    b. Use of inhaled corticosteroids; **OR**
    c. Number of hospitalizations, ER visits, or unscheduled visits to healthcare provider due to condition; **OR**
    d. FEV1; **AND**
6. Will NOT be used for the relief of acute bronchospasm or status asthmaticus; **AND**
7. Must not be used in combination with anti-IgE, anti-IL4, or anti-IL5 monoclonal antibody agents (e.g., benralizumab, omalizumab, mepolizumab, reslizumab, dupilumab); **AND**
8. Beneficiary must not have hypersensitivity to tezepelumab-ekko or any of its excipients; **AND**
9. Beneficiary does not have an active or untreated helminth infection; **AND**
10. Must not be administered concurrently with live vaccines.

Approval length: 6 months

Criteria for Continuation of Therapy

1. Beneficiary must continue to meet the above criteria; **AND**
2. Improvement in asthma symptoms, asthma exacerbations, or airway function as evidenced by decrease in ≥ 1 of the following:
    a. Use of systemic corticosteroids; **OR**
    b. Hospitalizations; **OR**
    c. ER visits; **OR**
    d. Unscheduled visits to healthcare provider; **OR**
    e. Improvement from baseline in FEV1; **AND**
3. Beneficiary has not experienced any treatment-restricting adverse effects (e.g., parasitic [helminth] infection, severe hypersensitivity reactions).

Approval length: 6 months

References

1. Genentech, Inc. Xolair Package Insert. San Francisco, CA. September 2014. updated November 2020.

2. Astra Zeneca, Inc. Fasenra Package Insert. Wilmington, DE. November 2017.

3. GlaxoSmithKline, LLC. Nucala Package Insert. Philadelphia, PA. November 2015, updated 12/2017. updated September 2020.updated August 2021.

4. Regeneron Pharmaceuticals, INC. Dupixent package insert. Tarrytown, NJ: March 2017, updated June 2019.updated October 2021.

5. Adbry [package insert]. Madison, NJ; Leo Pharma; December 2021.

6. Tezspire [package insert]. Thousand Oaks, CA; Amgen; December 2021.

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 criterion
11/20/2018	Add continuation criteria for Xolair for Idiopathic Urticaria and Nucala for Granulomatosis Polyangiitis, change eosinophilic count to 150 cells/mcl for Fasenra and Nucala.
06/10/2019	Added Dupixent to monoclonal antibody criteria and added additional criteria for Dupixent for Asthma diagnosis. Added 2 new GCN's for Xolair.
01/29/2020	Removed GSNs. Added nasal polyp criteria to Dupixent. Add weight to Xolair for Allergic Asthma
10/01/2021	Change age requirement for Nucala for asthma from 12 years to 6 years
10/01/2021	Change age for Dupixent used for Atopic Dermatitis from 12 years to 6 years
10/01/2021	Add hypereosinophilic syndrome criteria to Nucala and add nasal polyps to Xolair
xx/xx/xxxx	Add coverage criteria for Nucala for Nasal Polyps and change age for Dupixent for Asthma from 12 years to 6 years
xx/xx/xxxx	Add Adbry Add topical janus kinase inhibitor to bullet as option for step for Dupixent for

	atopic dermatitis
Xx/xx/xxxx	Add Tezspire