POLICY Document for TEZSPIRE (benralizumab)

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, and overall, clinically appropriate use. This document provides specific information to both sections of the overall policy.

Section 1: Preferred Product
- Policy information specific to preferred medications

Section 2: Site of Care
- Policy information specific to site of care (outpatient, hospital outpatient, home infusion)

Section 3: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 1: Preferred Product

CAREFIRST: EXCEPTIONS CRITERIA
ASTHMA

PREFERRED PRODUCTS: FASENRA, NUCALA, XOLAIR, TEZSPIRE

Client Requested: The intent of the criteria is to ensure that patients follow selection elements as established by CareFirst.

POLICY
This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the asthma products specified in this policy. Coverage for targeted product is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment with a targeted product.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Asthma Products

	Product(s)
Preferred*	• **Fasenra** (benralizumab) • **Nucala** (mepolizumab) • **Xolair** (omalizumab) • **Tezspire** (benralizumab)
Targeted	• **Cinqair** (reslizumab)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review

II. EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred products.

Coverage for the targeted product is provided when the following criteria is met:

A. Member has a documented inadequate response, contraindication, or intolerable adverse event to all preferred products.

Section 2: Site of Care

Site of Care Criteria
Tezspire

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Tezspire (pre-filled pen) is not targeted in this policy.

Brand Name	Generic Name	Dosage Form
Tezspire	tezepelumab-ekko	subcutaneous

Criteria for Approval for Administration in Outpatient Hospital Setting

This policy provides coverage for provider administered Tezspire in an outpatient hospital setting for up to 45 days when a member is new to therapy or is reinitiating therapy after not being on therapy for at least 6 months.

This policy provides coverage for administration of Tezspire in an outpatient hospital setting for a longer course of treatment when ANY of the following criteria are met:

- The member has experienced an adverse reaction to the drug that did not respond to conventional interventions (eg, acetaminophen, steroids, diphenhydramine, fluids or other pre-medications) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after administration.
- The member is medically unstable (e.g., respiratory, cardiovascular, or renal conditions).

- The member has significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND the patient does not have access to a caregiver.
- Alternative infusion sites (pharmacy, physician office, ambulatory care, etc.) are greater than 30 miles from the member's home.
- The member is less than 14 years of age.

For situations where administration of Tezspire does not meet the criteria for outpatient hospital administration, coverage for Tezspire is provided when administered in alternative sites such as; physician office, home infusion or ambulatory care.

Required Documentation

The following information is necessary to initiate the site of care prior authorization review (where applicable):

- Medical records supporting the member has experienced an adverse reaction that did not respond to conventional interventions or a severe adverse event during or immediately after administration
- Medical records supporting the member is medically unstable
- Medical records supporting the member has behavioral issues and/or physical or cognitive impairment and no access to a caregiver
- Records supporting alternative infusion sites are greater than 30 miles from the member's home
- Medical records supporting the member is new to therapy

Section 3: Clinical Criteria

Specialty Guideline Management
Tezspire

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Tezspire	tezepelumab-ekko

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Tezspire is indicated for add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma.

Limitations of use

Not for relief of acute bronchospasm or status asthmaticus.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency, and duration.
- Continuation requests: Chart notes or medical record documentation supporting improvement in asthma control.

Prescriber Specialties

This medication must be prescribed by or in consultation with an allergist/immunologist or pulmonologist.

Coverage Criteria

Authorization of 6 months may be granted for members 12 years of age or older who have previously received a biologic drug (e.g., Dupixent, Nucala) indicated for asthma in the past year.

Authorization of 6 months may be granted for treatment of severe asthma when all of the following criteria are met:

- Member is 12 years of age or older.

- Member has uncontrolled asthma as demonstrated by experiencing at least one of the following within the past year:
    - Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment.
    - One or more asthma exacerbation(s) resulting in hospitalization or emergency medical care visit(s).
    - Poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma).
- Member has inadequate asthma control despite current treatment with both of the following medications at optimized doses:
    - High-dose inhaled corticosteroid.
    - Additional controller (i.e., long-acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline).
- Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with the requested medication.

Continuation of Therapy

Authorization of 12 months may be granted for members for continuation of treatment of severe asthma when all of the following criteria are met:

- Member is 12 years of age or older.
- Asthma control has improved on the requested medication as demonstrated by at least one of the following:
    - A reduction in the frequency and/or severity of symptoms and exacerbations.
    - A reduction in the daily maintenance oral corticosteroid dose.
- Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with the requested medication.

Other

Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Note: If the member is a current smoker or vaper, they should be counseled on the harmful effects of smoking and vaping on pulmonary conditions and available smoking and vaping cessation options.

REFERENCES:

SECTION 1

1. Cinqair [package insert]. West Chester, PA: Teva Respiratory, LLC; June 2020.
2. Fasenra [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2021.
3. Nucala [package insert]. Research Triangle Park, NC: GlaxoSmithKline; March 2023.
4. Xolair [package insert]. South San Francisco, CA: Genentech, Inc.; March 2023.

5. Tezspire [package insert]. Wilmington, DE; AstraZeneca; December 2021.

SECTION 2

1. Tezspire [package insert]. Thousand Oaks, CA: Amgen Inc.; May 2023.

SECTION 3

1. Tezspire [package insert]. Thousand Oaks, CA: Amgen Inc.; May 2023.
2. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2023 update. Available at: https://ginasthma.org/wp-content/uploads/2023/07/GINA-Full-Report-23_07_06-WMS.pdf. Accessed March 8, 2024.
3. Cloutier MM, Dixon AE, Krishnan JA, et al. Managing asthma in adolescents and adults: 2020 asthma guideline update from the National Asthma Education and Prevention Program. JAMA. 2020;324(22): 2301-2317.
4. Wechsler ME, Colice G, Griffiths JM, et al. SOURCE: a phase 3, multicentre, randomized, double-blind, placebo-controlled, parallel group trial to evaluate the efficacy and safety of tezepelumab in reducing oral corticosteroid used in adults with oral corticosteroid dependent asthma. Respir Res. 2020;21(1):264.