POLICY Document for EXDENSUR

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: 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) • **Dupixent** (dupilumab) • **Exdensur (**depemokimab)

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

I. 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. For Cinqair and Exdensur, when any of the following criteria is met:
   1. Member has a documented inadequate response, contraindication, or intolerable adverse event to all preferred products.

B. For Dupixent, when any of the following criteria is met:
   1. Request is for Atopic Dermatitis, Eosinophilic Esophagitis (EoE), or Prurigo Nodularis (PN).
   2. Member has a documented inadequate response, contraindication, or intolerable adverse event to Xolair for moderate asthma.
   3. Member is less than 12 years of age and has a documented inadequate response, contraindication, or intolerable adverse event to Fasenra, Nucala, and Xolair for severe asthma.
   4. Member is 12 years or older and has a documented inadequate response, contraindication, or intolerable adverse event to all preferred products for severe asthma.
   5. Member is less than 18 years of age and has a documented inadequate response, contraindication, or intolerable adverse event to Tezspire for chronic rhinosinusitis with nasal polyps (CRSwNP).
   6. Member is an adult and has a documented inadequate response, contraindication, or intolerable adverse event to Nucala and Tezspire for chronic rhinosinusitis with nasal polyps (CRSwNP).
   7. Member has a documented inadequate response, contraindication, or intolerable adverse event to Nucala for Chronic Obstructive Pulmonary Disease (COPD).
   8. Member has a documented inadequate response, contraindication, or intolerable adverse event to Xolair for Chronic Spontaneous Urticaria (CSU).

Section 2: Clinical Criteria

Specialty Guideline Management
Exdensur

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
Exdensur	depemokimab-ulaa

Indications

FDA-Approved Indications

Indicated for the add-on maintenance treatment of severe asthma characterized by an eosinophilic phenotype in adult and pediatric patients aged 12 years and older.

Limitations of Use

Not indicated for the 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 or medical record documentation showing pre-treatment blood eosinophil count, or dependance on systemic corticosteroids, if applicable.
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

Asthma[1-4]

Authorization of 12 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 12 months.

Authorization of 12 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 meets either of the following criteria:

  - Member has a baseline blood eosinophil count of at least 150 cells per microliter.
  - Member is dependent on oral systemic corticosteroids.
- Member has uncontrolled asthma as demonstrated by experiencing at least one of the following within the past 12 months:
  - 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 adherence to current treatment with both of the following medications at maximal optimized doses:
  - High-dose inhaled corticosteroid (See Appendix).
  - 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 and additional controller) in combination with the requested medication.

Continuation of Therapy

Asthma[1-4]

Authorization of 12 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.
- 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 or discontinuation in the daily maintenance oral corticosteroid dose
- Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid and 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.

Appendix

Table. Examples of High-dose Inhaled Corticosteroids (Alone or in Combination with LABA) for Adults and Adolescents (12 years and older)[3]

Drug	Dosage Form	Total Daily Dose
Beclomethasone dipropionate	Pressurized metered-dose inhaler (pMDI), standard particle size hydrofluoroalkane propellant (HFA)	>1000 mcg
Beclomethasone dipropionate	Dry-powder inhaler (DPI) or pMDI, extra-fine particle size HFA	>400 mcg
Budesonide	DPI or pMDI, standard particle size HFA	>800 mcg
Ciclesonide	pMDI, extra-fine particle size HFA	>320 mcg
Fluticasone furoate	DPI	200 mcg
Fluticasone propionate	DPI or pMDI, standard particle size HFA	>500 mcg
Mometasone furoate	DPI or pMDI, standard particle size HFA	>400 mcg

REFERENCES:

SECTION 1

1. Cinqair [package insert]. West Chester, PA: Teva Respiratory, LLC; June 2020.
2. Dupixent [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc; June 2025.
3. Exdensur [package insert]. Philadelphia, PA: GlaxoSmithKline LLC; December 2025.
4. Fasenra [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; September 2024.
5. Nucala [package insert]. Research Triangle Park, NC: GlaxoSmithKline; May 2025.
6. Xolair [package insert]. South San Francisco, CA: Genentech, Inc.; February 2024.
7. Tezspire [package insert]. Wilmington, DE; AstraZeneca; October 2025.

SECTION 2

1. Exdensur [package insert]. Philadelphia, PA: GlaxoSmithKline LLC; December 2025.
2. Jackson DJ, Wechsler ME, Jackson DJ, et al. Twice-Yearly Depemokimab in Severe Asthma with an Eosinophilic Phenotype. N Engl J Med. 2024;391:2337-2349.
3. Global Strategy for Asthma Management and Prevention. 2025. Available at: https://ginasthma.org/2025-gina-strategy-report/. Accessed December 18, 2025.
4. 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.