

DRUG POLICY

Exdensur® (depemokimab-ulaa)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Exdensur (depemokimab-ulaa) drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines, and clinical studies. The indications below including FDA-approved indications are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy. For this program, Dupixent, Fasenra, Nucala, Tezspire, and Xolair are the preferred products and applies to members requesting treatment for an indication that is FDA-approved for the preferred products. Coverage for non-preferred products, Cinqair and Exdensur, 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.

FDA-Approved Indications

Exdensur is indicated for add-on maintenance treatment of severe asthma characterized by an eosinophilic phenotype in adult and pediatric patients 12 years of age and older.

Limitations of Use

Not for relief of acute bronchospasm or status asthmaticus.

POLICY

Required Documentation

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

A. For initial requests:

1. Chart notes or medical record documentation showing pre-treatment blood eosinophil count, dependence on corticosteroids, if applicable.

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

Must meet BOTH the Preferred Drug Plan Design and Criteria for Initial Approval/Continuation of Therapy when both are applicable.

Preferred Drug Plan Design

Coverage for a non-preferred product is provided when the following criteria is met:

- The member has had a documented inadequate response or intolerable adverse event with at least three of the preferred products.

Table. Asthma Products

	Product(s)
Preferred	• Dupixent (dupilumab) • Fasenra (benralizumab) • Nucala (mepolizumab) • Tezspire (Tezepelumab-ekko) • Xolair (omalizumab)
Targeted	• Cinqair (reslizumab) • Exdensusur (depemokimab-ulaa)

Prescriber Specialties

The requested medication must be prescribed by or in consultation with one of the following:

1. Pulmonologist
2. Allergist
3. Immunologist

Criteria for Initial Approval

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

1. Member is 12 years of age or older
2. Member has a documented blood eosinophil count of:
 - a. Baseline ≥ 150 cells/ μ L
 - b. Any history of ≥ 300 cells/ μ L in the previous 12 months
3. Member has uncontrolled asthma as demonstrated by experiencing at least one of the following within the past year:
 - a. Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment
 - b. One or more asthma exacerbation resulting in hospitalization or emergency medical care visit
 - c. Poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma)
4. Member has inadequate asthma control despite current treatment with both of the following medications at maximally tolerated doses:
 - a. Medium-to-high dose inhaled corticosteroid
 - b. Additional controller (i.e., long-acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)
5. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with Exdensusur

6. Member will not use Exdensur concomitantly with other biologics indicated for asthma (e.g., Dupixent, Fasenra, Nucala, Tezspire, Xolair, Cinqair)

Continuation of Therapy

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

1. Member is 12 years of age or older
2. Asthma control has improved on Exdensur treatment as demonstrated by at least one of the following:
 - a. A reduction in the frequency and/or severity of symptoms and exacerbations
 - b. A reduction in the daily maintenance oral corticosteroid dose
3. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with Exdensur
4. Member will not use Exdensur concomitantly with other biologics indicated for asthma (e.g., Dupixent, Fasenra, Nucala, Tezspire, Xolair, Cinqair)

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 on pulmonary conditions and available smoking and vaping cessation options.

Exdensur (depemokimab-ulaa) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.

Non-Formulary Exception Criteria

Non-Formulary Exception criteria applies to formularies which do not include the requested product(s) on the formulary drug list. Meeting the criteria above may satisfy some, or all, portions of the Non-Formulary Exception Criteria. A medication that is non-formulary may be covered when the Criteria for Approval AND the following criteria are met:

1. The requested drug must be used for an FDA-approved indication, or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines). Diagnostic testing/lab results required when applicable.
2. The prescribed dose/quantity must fall within the FDA-approved labeling or dosing guidelines found in the compendia of current literature.
3. All covered formulary alternative drugs on any tier will be ineffective, have been ineffective, would not be as effective as the non-formulary drug, or would have adverse effects. Documentation is required and must include chart note(s) or other documentation indicating prior treatment failure, severity of the adverse event (if any), and dosage and duration of the prior treatment, or contraindication to formulary alternatives.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits Apply

Medication	Standard Limit	FDA Recommended Dosing
Exdensur (depemokimab-ulaa) Strength dosage form	Two 100mg/ml prefilled syringes or pens per 12 months	100 mg subcutaneously every 6 months

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J2361 - Injection, depemokimab-ulaa, 1 mg (effective 7/1/26)
- J3490 Unclassified drugs
- J3590 Unclassified biologics
- C9399 Unclassified drugs or biologicals

REFERENCES

- Exdensur [package insert]. Philadelphia, PA: GlaxoSmithKline LLC; December 2025.
- Jackson DJ, Wechsler ME, et al. Twice-Yearly Depemokimab in Severe Asthma with an Eosinophilic Phenotype. N Engl J Med 2024;391:2337-2349
- Kraft, Monica, et al. Twice-yearly depemokimab reduces exacerbations in patients with asthma and only two prior exacerbations in the past year: analysis of Phase III SWIFT-1/2 studies. CHEST, 2025;168(4):A44–A46.
- Pavord, ID, et al. Twice-yearly depemokimab reduces exacerbations and improves quality of life in patients with uncontrolled asthma symptoms at baseline: subgroup analyses of the Phase III SWIFT-1/2 studies, Am J Resp Crit Care Med. 2025;211(Suppl_1):A5234

POLICY HISTORY

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