Reference number(s)
7329-A

Standard Medicare Part B 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

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[1]

Exdensur is 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 will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Documentation

The following documentation must be available, upon request, for all submissions:

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Initial requests

- Chart notes or medical record documentation showing baseline blood eosinophil count.
- 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 benefit from therapy.

Coverage Criteria

Eosinophilic Asthma

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

- Member is 12 years of age or older.
- Member has a baseline (pre-treatment with a biologic indicated for asthma) blood eosinophil count of at least 150 cells per microliter.
- Member has a history of severe asthma despite adherence to current treatment with both of the following medications at optimized doses, unless the member has a clinical reason to avoid these therapies:
    - Inhaled corticosteroid
    - Additional controller (i.e., long-acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)
- Member will not use the requested medication concomitantly with other biologics indicated for asthma (e.g., Dupixent, Fasenra, Nucala, Tezspire, Xolair).

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested medication.

Authorization for 12 months may be granted when all of the following criteria are met:

- Member is 12 years of age or older.
- The member is currently receiving therapy with Exdensur.
- Exdensur is being used to treat an indication in the coverage criteria section.
- The member is receiving benefit from therapy as defined by a reduction in the frequency and/or severity of symptoms and exacerbations.

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- Member will not use the requested medication concomitantly with other biologics indicated for asthma (e.g., Dupixent, Fasenra, Nucala, Tezspire, Xolair).

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Exdensur.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention 2025 update
- Managing asthma in adolescents and adults: 2020 asthma guideline update from the National Asthma Education and Prevention Program

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Exdensur are covered.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Exdensur to treat severe asthma can be found in the Global Initiative for Asthma (GINA) guidelines. For adults and adolescents, consider add-on anti-interleukin-5 (IL-5) or anti-IL-5 antagonists for patients with exacerbations and/or poor symptom control despite taking at least high-dose inhaled corticosteroids with long-acting beta2-agonist, and who have allergic or eosinophilic biomarkers or need maintenance oral corticosteroids.

References

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.

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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.

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