MEDICAL MUTUAL®

Drug Policy

Policy:	Exdensur (depemokimab-ulaa subcutaneous injection – GlaxoSmithKline)	**Annual Review Date:** **08/20/2026** **Last Revised Date:** **08/20/2026**

OVERVIEW

Exdensur, an interleukin (IL)-5 antagonist monoclonal antibody, is indicated for the add-on maintenance treatment of severe asthma characterized by an eosinophilic phenotype in adults and pediatric patients ≥ 12 years of age.

POLICY STATEMENT

This policy involves the use of Exdensur. Prior authorization is recommended for pharmacy benefit coverage of Exdensur. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Exdensur as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Exdensur be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Exdensur is recommended in those who meet the following criteria:

1. Asthma. Approve Exdensur for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, iv, and v):

i. Patient is ≥ 12 years of age; AND

ii. Patient meets ONE of the following* (a or b):

a) Patient has a blood eosinophil level ≥ 150 cells per microliter within the previous 6 weeks; OR

b) Patient had a blood eosinophil level ≥ 150 cells per microliter prior to treatment with Exdensur or another monoclonal antibody therapy that may alter blood eosinophil levels; AND

Note: Examples of monoclonal antibody therapies that may alter blood eosinophil levels include Exdensur, Adbry (tralokinumab-ldrm subcutaneous injection), Cinqair (reslizumab intravenous infusion), Dupixent (dupilumab subcutaneous injection), Ebglyss (lebrikizumab-lbkz subcutaneous injection), Fasenra (benralizumab subcutaneous injection), Nemluvio (nemolizumab-ilto subcutaneous injection), Nucala (mepolizumab subcutaneous injection), Tezspire (tezepelumab-ekko subcutaneous injection), Xolair (omalizumab subcutaneous injection).

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iii. Patient has received at least 3 consecutive months of combination therapy with BOTH of the following (a and b):
- **a)** An inhaled corticosteroid; AND
- **b)** At least one additional asthma controller or asthma maintenance medication; AND
  Note: Examples of additional asthma controller or asthma maintenance medications are inhaled long-acting beta$_2$-agonists, inhaled long-acting muscarinic antagonists, and monoclonal antibody therapies for asthma (e.g., Cinqair, Dupixent, Exdensur, Fasenra, Nucala, Tezspire, and Xolair). Use of a combination inhaler containing both an inhaled corticosteroid and additional asthma controller/maintenance medication(s) would fulfill the requirement for both criteria a and b.

iv. Patient has asthma that is uncontrolled or was uncontrolled at baseline as defined by ONE of the following (a, b, c, d, or e):
Note: "Baseline" is defined as prior to receiving Exdensur or another monoclonal antibody therapy for asthma. Examples of monoclonal antibody therapies for asthma include Cinqair, Dupixent, Exdensur, Fasenra, Nucala, Tezspire, and Xolair.
- **a)** Patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year; OR
- **b)** Patient experienced one or more asthma exacerbation(s) requiring a hospitalization, an emergency department visit, or an urgent care visit in the previous year; OR
- **c)** Patient has a forced expiratory volume in 1 second (FEV_1) < 80% predicted; OR
- **d)** Patient has an FEV_1/forced vital capacity (FVC) < 0.80; OR
- **e)** Patient has asthma that worsens upon tapering of oral (systemic) corticosteroid therapy; AND

v. The medication is prescribed by or in consultation with an allergist, immunologist, or pulmonologist; OR

B) Patient is Currently Receiving Exdensur. Approve for 1 year if the patient meets ALL of the following (i, ii, iii, and iv):

i. Patient is ≥ 12 years of age; AND

ii. Patient has already received at least 6 months of therapy with Exdensur; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy with Exdensur should be considered under criterion 1A (Asthma, Initial Therapy).

iii. Patient continues to receive therapy with one inhaled corticosteroid or one inhaled corticosteroid-containing combination inhaler; AND

iv. According to the prescriber, the patient has responded to therapy*.
Note: Examples of a response to Exdensur therapy are decreased asthma exacerbations; decreased asthma symptoms; decreased hospitalizations, emergency department, urgent care, or medical clinic visits due to asthma; and decreased requirement for oral corticosteroid therapy.

Initial Approval/ Extended Approval.
A) *Initial Approval: 6 months*
B) *Extended Approval: 1 year*

CONDITIONS NOT RECOMMENDED FOR APPROVAL

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Exdensur has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Concurrent use of Exdensur with another Monoclonal Antibody Therapy.** The efficacy and safety of Exdensur used in combination with other monoclonal antibody therapies have not been established.
   Note: Monoclonal antibody therapies are Adbry® (tralokinumab-ldrm subcutaneous injection), Cinqair® (reslizumab intravenous injection), Dupixent® (dupilumab subcutaneous injection), Ebglyss® (lebrikizumab-lbkz subcutaneous injection), Fasenra® (benralizumab subcutaneous injection), Nemluvio® (nemolizumab-ilto subcutaneous injection), Nucala® (mepolizumab subcutaneous injection), Tezspire® (tezepelumab-ekko subcutaneous injection), or Xolair® (omalizumab subcutaneous injection).

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

***Documentation Requirements:**
The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational, or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Exdensur subcutaneous injection [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; 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 Initiative for Asthma. Global strategy for asthma management and prevention. Updated November 15, 2025. Available at: http://www.ginasthma.org. Accessed on December 22, 2025.
4. Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. *Eur Respir J*. 2014;43:343-373.
5. Holguin F, Cardet JC, Chung KF, *et al*. Management of severe asthma: a European Respiratory Society/American Thoracic Society Guideline. *Eur Respir J*. 2020;55:1900588.

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