

Exdensur (depemokimab-ulaa) Injection

When requesting Exdensur (depemokimab-ulaa), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indication

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.

Coverage Guidelines

Severe Asthma

The individual must meet all of the following criteria for initial authorization:

- Is 12 years of age or older;
- Has a blood eosinophil level of greater than or equal to 150 cells per microliter within the previous 6 weeks or prior to treatment with Exdensur or another monoclonal antibody therapy that may alter blood eosinophil levels (e.g., Cinqair, Dupixent, Adbry, Nucala, Ebglyss, Nemluvio, Fasenra, Tezspire, Xolair);
- Has received at least 3 consecutive months of combination therapy with an inhaled corticosteroid and one additional asthma controller/maintenance medication (e.g., monoclonal antibody therapies, inhaled long-acting beta₂-agonists, inhaled long-acting muscarinic antagonists, a combination inhaler containing both an inhaled corticosteroid and a long acting beta₂-agonist);
- Asthma is/was uncontrolled prior to starting Exdensur or another monoclonal antibody therapy (e.g., Cinqair, Dupixent, Fasenra, Nucala, Tezspire, Xolair) defined by ONE of the following:
 - o Has experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year; OR
 - o Has experienced one or more asthma exacerbation(s) requiring hospitalization, emergency room visits, or urgent care visits in the previous year; OR
 - o Has a forced expiratory volume in 1 second (FEV₁) less than 80% predicted; OR
 - o Has an FEV₁/forced vital capacity (FVC) less than 0.80; OR
 - o Asthma worsens upon tapering of oral corticosteroid therapy;
- Exdensur is prescribed by or in consultation with an allergist, immunologist, or pulmonologist.

The individual must meet all of the following criteria for re-authorization:

- Has already received at least 6 months of Exdensur therapy (*NOTE: Patients who have received less than 6 months of therapy or those who are restarting therapy with Exdensur should be considered under initial criteria*);
- Continues to receive therapy with one inhaled corticosteroid (ICS) or one ICS-containing combination inhaler (e.g., Flovent Diskus/HFA, ArmonAir RespiClick, Arnuity);
- Has responded to Exdensur therapy (e.g., decreased asthma exacerbations; decreased asthma symptoms; decreased hospitalizations, emergency room visits, urgent care visits, or medical clinic visits due to asthma; decreased requirement for oral corticosteroids therapy).

Approval Duration (initial): 6 months

Approval Duration (renewal): 12 months

Dosing Recommendation

The recommended dosage is 100 mg once every 6 months administered by subcutaneous injection.

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.