Drug Coverage Policy

Effective Date.....6/1/2026
Coverage Policy Number.....IP0787
Policy Title.....Exdensur

Immunologicals – Exdensur

- Exdensur (depemokimab-ulaa subcutaneous injection – GlaxoSmithKline)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

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.[1]

Limitations of Use: Exdensur is not indicated for the relief of acute bronchospasm or status asthmaticus.

Clinical Efficacy
In the pivotal asthma studies of Exdensur, patients were generally required to have elevated eosinophils at baseline (e.g., peripheral blood eosinophil count ≥ 150 cells/microliter at screening or ≥ 300 cells/microliter at some time during the previous year). Across the studies, efficacy was assessed at Week 52.[1-2]

Dosing Information
The recommended dosage of Exdensur for severe asthma is 100 mg once every 6 months administered by subcutaneous injection.[1] Exdensur should be administered by a healthcare provider.

Guidelines
The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention (2025) proposes a stepwise approach to asthma treatment.[3] Exdensur is not addressed. Other IL-5 antagonists are listed as an option for add-on therapy in patients with severe eosinophilic asthma. Severe asthma is defined as asthma that is uncontrolled despite adherence to optimized high-dose inhaled corticosteroid (ICS)/long-acting beta$_2$-agonist (LABA) therapy or that worsens when high-dose treatment is decreased. Higher blood eosinophil levels, higher number of severe exacerbations in the previous year, adult-onset asthma, nasal polyps, maintenance oral corticosteroid requirements, and low lung function may predict a good asthma response to IL-5 antagonist therapy.

According to the European Respiratory Society/American Thoracic Society guidelines (2014; updated in 2020), severe asthma is defined as asthma which requires treatment with a high-dose ICS in addition to a second controller medication (and/or systemic corticosteroids) to prevent it from becoming uncontrolled, or asthma which remains uncontrolled despite this therapy.[4,5] Uncontrolled asthma is defined as asthma that worsens upon tapering of high-dose ICS or systemic corticosteroids or asthma that meets one of the following four criteria:

1) Poor symptom control: Asthma Control Questionnaire consistently ≥ 1.5 or Asthma Control Test < 20;
2) Frequent severe exacerbations: two or more bursts of systemic corticosteroids in the previous year;
3) Serious exacerbations: at least one hospitalization, intensive care unit stay, or mechanical ventilation in the previous year;
4) Airflow limitation: forced expiratory volume in 1 second (FEV_1) < 80% predicted after appropriate bronchodilator withholding.

Coverage Policy

POLICY STATEMENT
Prior Authorization is required for benefit coverage of Exdensur. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication(s). Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. 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 to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Exdensur is considered medically necessary when the following are met:

FDA-Approved Indication

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, v, vi and vii):
     - **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).
     - **iii.** Patient has received at least 3 consecutive months of combination therapy with BOTH of the following (a and b):
       - **a)** An inhaled medium- or high- dose 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 a history of ONE of the following (a or b):
       - **a)** Patient meets BOTH of the following (1 and 2):
         - **(1)** Patient has a forced expiratory volume in 1 second (FEV_1) <80% predicted; AND
           Note: The reduced FEV_1 should not be due to smoking-related chronic obstructive pulmonary disease.
         - **(2)** Patient has an FEV1/forced vital capacity (FVC) < 0.80; OR
       - **b)** Patient meets ONE of the following (1, 2, 3, 4, or 5):
         - **(1)** Increase of ≥ 12% and ≥ 200ml in FEV_1 following administration of a standard dose of a short-acting bronchodilator; OR
         - **(2)** Increase of ≥ 12% and ≥ 200ml in FEV_1 between prescriber visits; OR
         - **(3)** Increase of ≥ 12% and ≥ 200ml in FEV_1 from baseline to after at least 4 weeks of asthma treatment; OR
         - **(4)** Positive exercise challenge testing; OR
         - **(5)** Positive bronchial challenge testing; AND
     - **v.** 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 asthma that worsens upon tapering of oral (systemic) corticosteroid therapy; AND

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

vii. Preferred product criteria are met for the product(s) as listed in the below table(s).

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

i. 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).

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

iii. 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.

Dosing. Approve up to 100 mg given subcutaneously once every 6 months.

Employer:

Product	Criteria
Exdensur (depemokimab-ulaa subcutaneous injection)	Patient meets ONE of the following (A or B): A. Initial therapy in a patient ≥ 12 years of age: Patient has tried BOTH of the following: Nucala and Fasenra **[may require prior authorization]**; OR B. Patient has already been started on therapy with Exdensur.

Individual and Family Plans:

Product	Criteria
Exdensur (depemokimab-ulaa subcutaneous injection)	Patient meets ONE of the following (A or B): A. Initial therapy in a patient ≥ 12 years of age: Patient has tried BOTH of the following: Nucala **Vial** and Fasenra **Syringes [may require prior authorization]**; OR Note: The use of other Nucala dosage forms would count towards this requirement. Note: The use of other Fasenra dosage forms would count towards this requirement. B. Patient has already been started on therapy with Exdensur.

Conditions Not Covered

Exdensur for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

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).

Coding Information

1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
C9399	Unclassified drugs or biologicals
J3490	Unclassified drugs
J3590	Unclassified biologics

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.

Revision Details

Summary of Changes	Review Date	Effective Date
New policy. **Coding Information:** **Added** C9399 J3490 J3590	4/16/2026	6/1/2026

The policy effective date is in force until updated or retired.