Exdensur (depemokimab-ulaa)
(Subcutaneous)

Effective date: 08/01/2026
Dates Reviewed: 05/12/2026
Pharmacy Scope: Medicaid
Medical Scope: Medicaid, Commercial, Medicare

I. Length of Authorization

- Initial: Coverage will be provided for 12 months
- Renewal: Coverage may be renewed every 12 months thereafter.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 100 mg every 6 months

III. Initial Approval Criteria

Coverage will be provided when ALL of the following are met:

1. The member is 12 years of age or older; **AND**
2. Exdensur is prescribed by, or in consultation with, a pulmonologist or allergist/immunologist; **AND**
3. The member has a diagnosis of severe* eosinophilic asthma; **AND**
4. The member has a baseline (prior to therapy with the requested agent) blood eosinophil count of 150 cells/microliter or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids within the last 6 weeks; **AND**
5. Member is adherent to current treatment with both of the following medications at optimized doses for at least 3 months with or without oral corticosteroids:
    - High-dose inhaled corticosteroid; **AND**
    - Additional controller medication (e.g., long acting beta$_2$-agonist, long-acting muscarinic antagonist, leukotriene modifier); **AND**
6. The member has a history of uncontrolled asthma while on asthma control therapy (e.g., high dose inhaled corticosteroid [ICS]/long-acting beta-2 agonist [LABA] combination therapy) as demonstrated by ONE of the following in the past 12 months:
    A. Two or more asthma exacerbations requiring systemic corticosteroids; **OR**
    B. At least one asthma exacerbation requiring hospitalization or emergency medical care visit; **AND**
7. The member will continue asthma control therapy (e.g., ICS, ICS/LABA, LTRA, LAMA, theophylline) in combination with the requested agent; **AND**
8. Documentation that member has had an inadequate treatment response or intolerance to treatment with Fasenra or Nucala, or contraindication to both Fasenra and Nucala; **AND**

9. If member has previous documented failure with anti–IL-5 or IL-5 receptor therapies (i.e., Fasenra, Nucala, Cinqair), documentation of clinical rationale why failure is not expected to occur with Exdensur; **AND**
10. Documentation of baseline measurements of at least one of the following for assessment of clinical status:
    a. Use of systemic corticosteroids
    b. Use of inhaled corticosteroids
    c. Number of hospitalizations, ER visits, or unscheduled visits to healthcare provider due to condition
    d. Forced expiratory volume in 1 second (FEV_1); **AND**
11. The member will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors)**; AND**
12. The member does NOT have any FDA labeled contraindications to the requested agent

***Components of severity for classifying asthma as <u>severe</u> may include any of the following (not all):**
• Symptoms throughout the day • Nighttime awakenings, often 7x/week • SABA use for symptom control occurs several times per day • Extremely limited normal activities • Lung function (percent predicted FEV_1) <60% • Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

IV. Renewal Criteria

Authorization of 12 months may be granted when ALL of the following are met:

1. The member has been previously approved for the requested agent through the plan's Prior Authorization process (Note: members not previously approved for the requested agent will require initial evaluation review); **AND**

2. The member has had clinical benefit with the requested agent as evidenced by:
    A. A decrease in one of the following:
        a) Use of systemic corticosteroids
        b) Hospitalizations
        c) ER visits
        d) Unscheduled visits to healthcare provider; OR
    B. Improvement from baseline in forced expiratory volume in 1 second (FEV1); **AND**
3. If the member has a diagnosis of severe eosinophilic asthma, then the member is currently treated within the past 90 days and is compliant with asthma control therapy (e.g., inhaled corticosteroids [ICS], ICS/long-acting beta-2 agonist [ICS/LABA], leukotriene receptor antagonist [LTRA], long-acting muscarinic antagonist [LAMA], theophylline); **AND**
4. The member will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors); **AND**

5. The member does NOT have any FDA labeled contraindications to the requested agent

V. Dosage/Administration

Indication	Dose
Severe Eosinophilic Asthma	The recommended dosage is 100 mg once every 6 months administered by subcutaneous (SC) injection into the upper arm, thigh, or abdomen avoiding 2 inches (5 cm) around the navel

VI. Billing Code/Availability Information

HCPCS code(s):

- J2361- Injection, depemokimab-ulaa, 1 mg

NDC:

- Exdensur 100 mg/mL single-dose, prefilled pen or syringe: 00173-0927-xx

VII. References

1. Exdensur prescribing information. GlaxoSmithKline LLC; December 2025.
2. Chung KF, Wenzel SE, Brozek J, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. *The European Respiratory Journal*. 2014;43(2):343-373. doi:10.1183/09031936.00202013
3. Louis R, Satia I, Ojanguren I, et al. European Respiratory Society guidelines for the diagnosis of asthma in adults. *European Respiratory Journal*. 2022;60(3):2101585. doi:10.1183/13993003.01585-2021
4. Global Initiative for Asthma (GINA). *Global Strategy for Asthma Management and Prevention (2025 Update)*. 2025. https://www.ginasthma.org
5. Bourdin A, Brusselle G, Couillard S, et al. Phenotyping of severe asthma in the era of broad-acting anti-asthma biologics. *The Journal of Allergy and Clinical Immunology in Practice*. 2024;12(4):809-823. doi:10.1016/j.jaip.2024.01.023.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority

Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
J45.50	Severe persistent asthma, uncomplicated
J82.81	Chronic eosinophilic pneumonia
J82.82	Acute eosinophilic pneumonia
J82.83	Eosinophilic asthma
J82.89	Other pulmonary eosinophilia, not elsewhere classified