Neighborhood Health Plan OF RHODE ISLAND™
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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. Summary of Evidence

Exdensur is an interleukin-5 (IL-5) antagonist, a monoclonal antibody (humanized immunoglobulin G [IgG]1 kappa) indicated for add-on maintenance treatment of severe asthma characterized by an eosinophilic phenotype in adult and pediatric patients aged 12 years and older. Exdensur is not for relief of acute bronchospasm or status asthmaticus. Exdensur was evaluated in two Phase 3, randomized, double-blind, parallel-group, placebo-controlled clinical trials, SWIFT-1 and SWIFT-2. In total, 762 patients 12 years of age and older were enrolled in the studies. Patients all had blood eosinophils ≥150 cells/mcL at screening or ≥300 cells/mcL in the prior year, and 2 or more asthma exacerbations requiring systemic corticosteroids (SCS) in the prior year despite medium- to high-dose inhaled corticosteroids (ICS) plus one or more controller with or without maintenance oral corticosteroids (OCS). Patients were excluded from studies if they received monoclonal antibodies (mAbs) targeting IL-5/5Rs (e.g. Nucala, Cinqair, or Fasenra) within the 12 months prior to Visit 1 or had a previous documented failure with anti-IL-5/R therapy. Patients were randomized 2:1 to receive Exdensur 100 mg SC every 6 months or placebo. The primary endpoint was the annualized rate of clinically significant exacerbations over 52 weeks. In SWIFT-1 and SWIFT-2, patients treated with Exdensur experienced a 58% and 48% reduction in exacerbations over 52 weeks (annualized exacerbation rate 0.46 vs. 1.11, $p<0.001$ and 0.56 vs. 1.08, $p<0.001$, respectively). The most common adverse reactions are upper respiratory tract infection, allergic rhinitis, influenza, arthralgia, and pharyngitis.

IV. 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; **AND**

Medicare members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

***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

V. 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

VI. 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

VII. 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

VIII. 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

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA

documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

Policy Rationale: Exdensur was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Exdensur according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For Medicare members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.