BlueCross BlueShield of Tennessee

Policy

Medical Policy Manual **Approved Rev: Do Not Implement until 12/1/26**

Depemokimab-ulaa (Exdensur)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
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.

Limitations of Use
Not indicated for the relief of acute bronchospasm or status asthmaticus.

All other indications are considered experimental/investigational and not medically necessary.

DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
Initial requests

- Chart notes or medical record documentation showing pretreatment blood eosinophil count, or dependance on systemic corticosteroids, if applicable.
- Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency, and duration.

Continuation requests
Chart notes or medical record documentation supporting improvement in asthma control.

PRESCRIBER SPECIALITIES

This medication must be prescribed by or in consultation with an allergist/immunologist or pulmonologist.

COVERAGE CRITERIA

Asthma

Authorization of 12 months may be granted for members 12 years of age or older who have previously received a biologic drug (e.g., Dupixent, Nucala) indicated for asthma in the past 12 months. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid [ICS] and additional controller) in combination with the requested medication.

Authorization of 12 months may be granted for treatment of severe asthma when all of the following criteria are met:

- Member is 12 years of age or older.
- Member meets either of the following criteria:
  - Member has a baseline blood eosinophil count of at least 150 cells per microliter.
  - Member is dependent on oral systemic corticosteroids.
- Member has uncontrolled asthma as demonstrated by experiencing at least one of the following within the past 12 months:
  - Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment.
  - One or more asthma exacerbation(s) resulting in hospitalization or emergency medical care visit(s).
  - Poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma).
- Member has inadequate asthma control despite adherence to current treatment with both of the following medications at optimized doses:
  - High-dose ICS (see Appendix).
  - Additional controller (i.e., long-acting beta2-agonist [LABA], long-acting muscarinic antagonist [LAMA], leukotriene modifier, or sustained-release theophylline).
- Member will continue to use maintenance asthma treatments (e.g., ICS and additional controller) in combination with the requested medication.

CONTINUATION OF THERAPY

Asthma

Authorization of 12 months may be granted for treatment of severe asthma when all of the following criteria are met:

- Member is 12 years of age or older.
- Asthma control has improved on the requested medication as demonstrated by at least one of the following:
  - A reduction in the frequency and/or severity of symptoms and exacerbations
  - A reduction or discontinuation in the daily maintenance oral corticosteroid dose
- Member will continue to use maintenance asthma treatments (e.g., ICS and additional controller) in combination with the requested medication.

OTHER

Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.
Note: If the member is a current smoker or vaper, they should be counseled on the harmful effects of smoking and vaping on pulmonary conditions and available smoking and vaping cessation options.

APPENDIX
Table. Examples of High-Dose ICS (Alone or in Combination with LABA) for Adults and Adolescents (12 Years and Older)

Drug	Dosage Form	Total Daily Dose
Beclomethasone dipropionate	Pressurized metered-dose inhaler (pMDI), standard particle size hydrofluoroalkane propellant (HFA)	>1000 mcg

Beclomethasone dipropionate	Dry-powder inhaler (DPI) or pMDI, extra-fine particle size HFA	>400 mcg
Budesonide	DPI or pMDI, standard particle size HFA	>800 mcg
Ciclesonide	pMDI, extra-fine particle size HFA	>320 mcg
Fluticasone furoate	DPI	200 mcg
Fluticasone propionate	DPI or pMDI, standard particle size HFA	>500 mcg
Mometasone furoate	DPI or pMDI, standard particle size HFA	>400 mcg

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Exdensur [package insert]. Philadelphia, PA: GlaxoSmithKline LLC; 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(24):2337-2349.
3. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2025 update. Available at: https://ginasthma.org/reports/. Accessed March 6, 2026.
4. Cloutier MM, Dixon AE, Krishnan JA, Lemanske Jr RF, Pace W, Schatz M. Managing asthma in adolescents and adults: 2020 asthma guideline update from the National Asthma Education and Prevention Program. JAMA. 2020;324(22): 2301-2317.

EFFECTIVE DATE 12/1/2026

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