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of the Blue Cross and Blue Shield Association

Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

P&T Date: 02/12/2026

Exdensur™ (depemokimab-ulaa)

HCPCS: J3590

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

- A. Coverage of the requested drug is provided when all the following are met:
 - a. FDA approved indication
 - b. FDA approved age
 - c. Blood eosinophils greater than or equal to 150 cells/microliter at initiation of treatment or greater than or equal to 300 cells/microliter within the past 12 months
 - d. Chronic administration of systemic corticosteroids or high dose inhaled corticosteroids (listed in table 1) in combination with
 - i. Long-acting inhaled β_2 agonist (LABA) for at least 3 months fails to maintain adequate control
OR
 - ii. Leukotriene modifier for at least 3 months fails to maintain adequate control
OR
 - iii. Long-acting muscarinic antagonists (LAMA) in adults and children ≥ 12 years old for at least 3 months fails to maintain adequate control
 - e. Must be used as add-on maintenance treatment with severe uncontrolled eosinophilic asthma
 - f. Patient is currently receiving, and will continue to receive, standard of care regimen
 - g. Not to be used in combination with other biologics or targeted DMARDs for the same indication.
 - h. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in BCBSM/BCN's utilization management medical drug list.
- B. Quantity Limitations, Authorization Period and Renewal Criteria
 - a. Quantity Limits: Align with FDA recommended dosing
 - b. Authorization Period: One year at a time
 - c. Renewal Criteria: Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

This policy and any information contained herein is the property of Blue Cross Blue Shield of Michigan and its subsidiaries, is strictly confidential, and its use is intended for the P&T committee, its members and BCBSM employees for the purpose of coverage determinations.

Background Information:

- Exdensusur is indicated for 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 for relief of acute bronchospasm or status asthmaticus.
- Severe asthma is defined as asthma that requires treatment with medium- to high-dose inhaled corticosteroids plus a second therapy (i.e., systemic corticosteroid or biologic) to prevent it from becoming uncontrolled, or which remains uncontrolled despite therapy. Type 2 inflammation is the underlying cause of pathology in more than 80% of patients with severe asthma, in which patients exhibit elevated levels of eosinophils. Around 4-10% of the 25+ million Americans with asthma have severe asthma with a suggestion that around 700,000 U.S. individuals would be eligible for a biologic, though actual use is lower.
- The 2025 Global Strategy for Asthma Management and Prevention (GINA guidelines 2025), which has not been updated to include Exdensusur at this time, recommends add-on biologic therapy for patients with uncontrolled severe asthma despite optimized maximal therapy and includes:
 - Add-on anti-immunoglobulin E (anti-IgE) (subcutaneous (SC) omalizumab) treatment: for patients aged ≥ 6 years with severe allergic asthma (Evidence A).
 - Add-on anti-IL-5/5R treatment (SC mepolizumab for patients aged ≥ 6 years; intravenous (IV) reslizumab for ages ≥ 18 years; or SC benralizumab for ages ≥ 12 years), with severe eosinophilic asthma (Evidence A).
 - Add-on anti-IL-4R α treatment (SC dupilumab) for patients aged ≥ 6 years with severe eosinophilic/Type 2 asthma, or those requiring treatment with maintenance OCS (Evidence A).
 - Add-on anti-thymic stromal lymphopoietin (anti-TSLP) (SC tezepelumab): for patients aged ≥ 12 years with severe asthma (Evidence A).
- The efficacy of Exdensusur for the add-on maintenance treatment of severe asthma characterized by an eosinophilic phenotype was evaluated in 2 replicate, randomized (2:1 to Exdensusur or placebo), double-blind, parallel-group, placebo-controlled, multicenter clinical trials (SWIFT-1 and SWIFT-2) of 52 weeks duration. The trials enrolled adult and pediatric patients aged 12 years and older with asthma characterized by an eosinophilic phenotype, defined as a blood eosinophil count ≥ 150 cells/mcL at screening or ≥ 300 cells/mcL documented in the year prior to study entry. Patients were required to have 2 or more asthma exacerbations requiring treatment with systemic corticosteroids (SCS) in the prior year while on background asthma therapy consisting of a medium- to high-dose inhaled corticosteroids (ICS) plus at least one additional asthma controller with or without maintenance oral corticosteroids (OCS).
 - In these studies, Exdensusur demonstrated sustained exacerbation reduction with two doses per year versus placebo, both plus standard of care. Treatment with Exdensusur resulted in a significant 58% and 48% reduction in the rate of annualized asthma exacerbations (AER; asthma attacks) over 52 weeks from SWIFT-1 and SWIFT-2, respectively (p-value: SWIFT-1 $p < 0.001$ and SWIFT-2 $p < 0.001$).
 - In a secondary endpoint from SWIFT-1 and SWIFT-2, patients treated with Exdensusur experienced numerically fewer exacerbations requiring hospitalization and/or emergency department (ED) visits (1% and 4%) compared with placebo (8% and 10%), respectively.

- A pre-specified pooled analysis of the two trials showed there was a 72% reduction in the annualized rate of clinically significant exacerbations requiring hospitalization and/or ED visits over 52 weeks for Exdensur compared with placebo (p=0.002).
- Across these trials, Exdensur was well-tolerated, with patients experiencing a similar rate and severity of side effects as those receiving placebo.

References:

1. Exdensur [prescribing information]. Philadelphia, PA: GlaxoSmithKline; December 2025.
2. Global Initiative for Asthma. (2025). Global Strategy for Asthma Management and Prevention, 2025. Updated May 2025. Available from <https://www.ginasthma.org/>
3. GSK Press Release: [Exdensur \(depemokimab\) approved by US FDA for the treatment of severe asthma | GSK](#) Issued: London, UK. December 16, 2025.
4. Jackson DJ, Wechsler ME, Jackson DJ, et. al. Twice-Yearly Depemokimab in Severe Asthma with an Eosinophilic Phenotype. Published September 9, 2024. N Engl J Med 2024;391:2337-2349. DOI: 10.1056/NEJMoa2406673

Policy History												
#	Date	Change Description										
1.2	Effective Date: 02/12/2026	New policy.										
1.1	Effective Date: 02/02/2026	UM medical management system update for MAPPO and BCNA <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	Yes	BCNA	Yes
Line of Business	PA Required in Medical Management System (Yes/No)											
BCBS	Yes											
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MAPPO	Yes											
BCNA	Yes											
1.0	Effective Date: 01/07/2026	UM medical management system update for BCBS and BCN <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	No	BCNA	No
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BCBS	Yes											
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* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://dailymed.nlm.nih.gov/dailymed/index.cfm>.

Blue Cross Blue Shield/Blue Care Network of Michigan

Medication Authorization Request Form



This form is to be used by participating physicians to obtain coverage for **drugs covered under the medical benefit**. For commercial members only, please complete this form and submit via fax to 1-877-325-5979. If you have any questions regarding this process, please contact BCBSM Provider Relations and Servicing or the Medical Drug Helpdesk at 1-800-437-3803 for assistance.

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PATIENT INFORMATION	PHYSICIAN INFORMATION
Name	Name
ID Number	Specialty
D.O.B. ☐ Male ☐ Female	Address
Diagnosis	City /State/Zip
Drug Name	Phone/Fax: P: () - F: () -
Dose and Quantity	NPI
Directions	Contact Person
Date of Service(s)	Contact Person Phone / Ext.

STEP 1: DISEASE STATE INFORMATION

- Is this request for: ☐ Initiation ☐ Continuation Date patient started therapy: _____
- Administered by patient or a medical professional? ☐ patient (self) ☐ health care professional (physician, nurse, etc.)
- Site of administration? ☐ Provider office/Home infusion ☐ Other: _____
☐ Hospital outpatient facility (go to #4) Reason for Hospital Outpatient administration: _____
☐ Hospital inpatient facility for Car-T therapy only (for example: Kymriah, Yescarta, or Tecartus) (go to #5)
- Please specify location of administration if hospital outpatient infusion: _____
- Please specify location of administration if hospital inpatient infusion: _____
- Please provide the NPI number for the place of administration: _____
- Initiation AND Continuation of therapy:**
 - What is the patient's diagnosis? _____
 - What other medication has the patient received for their condition? Please list _____
 - Please describe the response to previous therapies: _____
 - Will the patient be receiving any other treatment for the listed condition while on this medication? Please list: _____
 - Please list any labs values important for diagnosing or monitoring this patient's condition: _____
- Continuation of therapy:**
 - Has the patient progressed while on this medication? ☐ yes ☐ no
 - How has the patient's condition changed while on this medication?

☐ Improved: Please describe: _____
 ☐ Stable: please describe: _____
 ☐ Worsened; Please describe: _____
 ☐ Other; Please describe: _____

Chart notes are required for the processing of all requests. Please add any other supporting medical information necessary for our review (required)

Coverage will not be provided if the prescribing physician's signature and date are not reflected on this document.

☐ Request for expedited review: I certify that applying the standard review time frame may seriously jeopardize the life or health of the member or the member's ability to regain maximum function

Physician's Name	Physician Signature	Date
Step 2: Checklist	☐ Form Completely Filled Out ☐ Provide chart notes	☐ Attach test results
Step 3: Submit	By Fax: BCBSM Specialty Pharmacy Mailbox 1-877-325-5979	By Mail: BCBSM Specialty Pharmacy Program P.O. Box 312320, Detroit, MI 48231-2320

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7/26/2018, 9/18/2018; 1/31/2020; 3/17/2020; 8/9/2021