Effective Date: 05/30/2026
Current Effective Date: 05/30/2026
Last P&T Approval/Version: 04/29/2026
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Policy Number: C30602-A

Exdensur (depemokimab-ulaa)

PRODUCTS AFFECTED

Exdensur (depemokimab-ulaa)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Severe asthma with an eosinophilic phenotype

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. This clinical policy will be reviewed along with state and federal requirements, the benefit being administered and formulary preferencing. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available. The Pharmacy and Therapeutics Committee has determined that biosimilars may be preferred.

A. SEVERE ASTHMA WITH EOSINOPHILIC PHENOTYPE:
   1. Documented diagnosis of moderate to severe asthma
      AND

2. Exdensur (depemokimab-ulaa) is NOT being used as monotherapy for asthma (must be prescribed as add-on maintenance to be used in combination with other medications for long-term control of asthma)
   AND
3. Documentation member has eosinophilic phenotype or predominantly eosinophil-driven disease with blood eosinophil counts: ≥150 cells/microliter at initiation of therapy (within 6 weeks of request) OR ≥ 300 cells/microliter in the prior 12 months [DOCUMENTATION REQUIRED]
   AND
4. Documentation member has experienced exacerbation(s) or hospitalization(s), within the last 12 months as evidenced by ANY of the following:
   i. Two or more exacerbations requiring treatment with systemic corticosteroids (intramuscular, intravenous, or oral) despite the use of high- dose inhaled corticosteroids in the past 12 months
   ii. One or more exacerbation requiring hospitalization
   iii. Two-fold increase or greater in the dose of systemic corticosteroid treatment for asthma exacerbations
   iv. Asthma worsens upon tapering of oral corticosteroid therapy
   v. Mechanical ventilation in the past 12 months
   vi. Poor symptom control indicated by Asthma Control Questionnaire (ACQ) score consistently greater than 1.5 or Asthma Control Test (ACT) score consistently less than 20
   vii. Forced expiratory volume in 1 second (FEV1) < 80% predicted
   viii. FEV1/forced vital capacity (FVC) < 0.80
   AND
5. Documentation of adherence to ONE of the following regimens of at least 3 months (within the past 90 days) and symptoms inadequately controlled (as documented in criteria above):
   (a) Medium or High dose ICS- LABA combination product AND one additional asthma controller medication (LAMA, LTRA, Low dose azithromycin), preferably a LAMA- per GINA guideline
   OR
   (b) Medium or High dose ICS- LABA combination product AND oral corticosteroids [see appendix for product classes]
   MOLINA REVIEWER NOTE: Verify pharmacy claims for adherence with the combination therapy above within the last 90 days. For new members to Molina Healthcare, confirm medication use in medical chart history. Non-adherence, which can be documented by review of the prescription fill history, would not constitute therapeutic failure.
   AND
6. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or serious side effects to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. Submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s). [DOCUMENTATION REQUIRED]
   MOLINA REVIEWER NOTE: For Illinois Marketplace, please see Appendix.

CONTINUATION OF THERAPY:

A. SEVERE ASTHMA WITH EOSINOPHILIC PHENOTYPE:
   1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
      AND
   2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or unacceptable toxicity from the drug [e.g., symptoms of anaphylaxis (bronchospasm, hypotension, syncope, urticaria, and/or angioedema), malignancy, symptoms similar to serum sickness (fever, arthralgia, and rash); parasitic (helminth) infection, eosinophilic conditions (e.g., vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy), especially upon reduction of oral corticosteroids]
      AND

3. Documentation that Exdensur (depemokimab-ulaa) therapy has resulted in clinical improvement as documented by ONE or more of the following from baseline [DOCUMENTATION REQUIRED]:
   a) Improvement in lung function (increase in percent predicted FEV1 or PEF)
   OR
   b) Decreased utilization of rescue medications, decreased frequency of exacerbations (defined as worsening of asthma that requires increase in inhaled corticosteroid dose or treatment with systemic corticosteroids)
   OR
   c) Decreased frequency of unscheduled clinic, urgent care, or emergency department visits
   OR
   d) Reduction in reported symptoms: chest tightness, coughing, shortness of breath, nocturnal wakening, wheezing, sustained improvement in Asthma Control Test (ACT) scores
   OR
   e) Decreased or stopped oral treatments (including oral corticosteroids and other add on medications, if applicable), or reduced ICS-LABA dose (to at least moderate)
   MOLINA REVIEWER NOTE: For members with unclear response after initial use, see Background (GINA 2025).
   AND
4. Documentation member is currently treated and is adherent with standard therapy (e.g., inhaled corticosteroids, long-acting beta-2 agonist (LABA), leukotriene receptor antagonist (LTRA), long-acting muscarinic antagonist (LAMA)) within the past 90 days

DURATION OF APPROVAL:
Initial authorization: 6 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:
Prescribed by, or in consultation with, a board-certified allergist, immunologist, pulmonologist or physician experienced in the management of asthma [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
12 years of age and older

QUANTITY:
100 mg once every 6 months

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy or medical benefit coverage and the subcutaneous injectable products administered in a place of service that is a non-hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Subcutaneous

DRUG CLASS:
Interleukin-5 Antagonists (IgG1 kappa)

FDA-APPROVED USES:
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.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

State Specific Information

State Marketplace

Illinois (Source: Illinois General Assembly)

"(215 ILCS 134/45.1) Sec. 45.1. Medical exceptions procedures required. (c) An off-formulary exception request shall not be denied if: (1) the formulary prescription drug is contraindicated; (2) the patient has tried the formulary prescription drug while under the patient's current or previous health insurance or health benefit plan and the prescribing provider submits evidence of failure or intolerance; or (3) the patient is stable on a prescription drug selected by his or her health care provider for the medical condition under consideration while on a current or previous health insurance or health benefit plan. (d) Upon the granting of an exception request, the insurer, health plan, utilization review organization, or other entity shall authorize the coverage for the drug prescribed by the enrollee's treating health care provider, to the extent the prescribed drug is a covered drug under the policy or contract up to the quantity covered. (e) Any approval of a medical exception request made pursuant to this Section shall be honored for 12 months following the date of the approval or until renewal of the plan."

APPENDIX 1:

Asthma Controller medications: suppress the inflammatory causes of asthma to provide clinical control over the long term, whereas reliever medications relieve bronchoconstriction quickly. Controller medications include inhaled glucocorticoids, long-acting beta-agonists (LABAs) and Leukotriene receptor antagonists (LTRA). Theophylline (Theo-24, Uniphyl, TheoChron ER, generics) is also a controller agent, however, it is not as efficacious as LABAs and not recommended for treatment.

Anticholinergic (LAMA)

Tiotropium bromide monohydrate (Spiriva Respimat)

Inhaled Corticosteroids (ICS) (list not all inclusive):

Beclometasone dipropionate (QVAR), Fluticasone furoate (Arnuity Ellipta), Budesonide DPI (Pulmicort Flexhaler), Fluticasone propionate (Flovent Diskus), Budesonide nebules (Pulmicort Respules), Fluticasone propionate (Flovent HFA), Ciclesonide (Alvesco), Fluticasone propionate (ArmonAir Digihaler), Flunisolide (Aerospan), Mometasone furoate (Asmanex Twisthaler), Mometasone furoate (Asmanex HFA)*

*HFA: hydrofluoroalkane propellant metered dose inhaler
*DPI: dry powder inhaler

Combination Long-Acting Bronchodilator and Corticosteroid (ICS+ LABA) (list not all inclusive):

Budesonide/formoterol fumarate dihydrate (Symbicort)
Fluticasone propionate/salmeterol (Advair Diskus/ Adair HFA/ AirDuo/ AirDuo RespiClick/Wixela Inhub)
Fluticasone furoate/vilanterol(Breo Ellipta)
Mometasone furoate/formoterol fumarate dihydrate (Dulera)

Combination Anticholinergic and Corticosteroid and long-acting bronchodilator (ICS+ LAMA+ LABA)

Fluticasone/umeclidnium/vilanterol (Trelegy Elipta) Budesonide/glycopyrrolate/formoterol (Breztri Aerosphere)

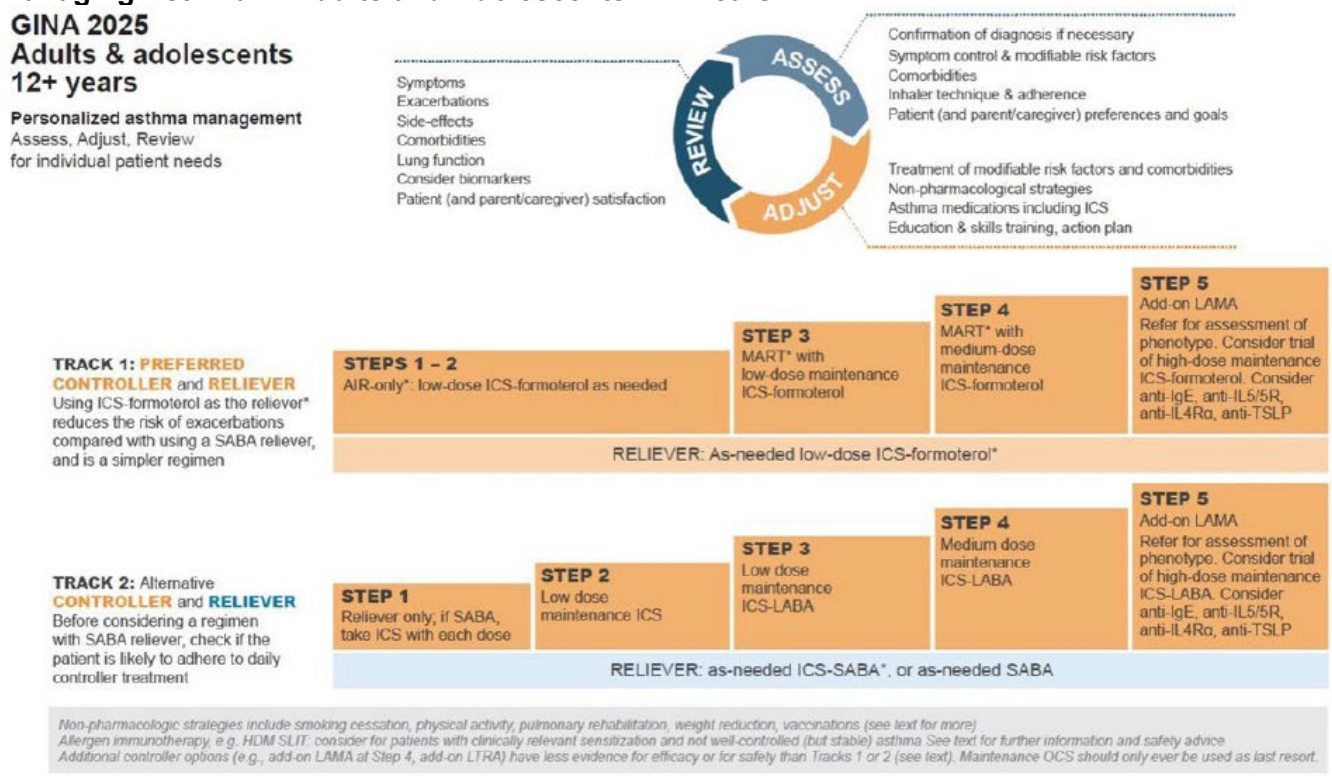
Leukotriene receptor antagonist (LTRA) (list not all inclusive):

Montelukast (Singulair), Zafirlukast (Accolate), Zileuton (Zyflo)

APPENDIX 2:

- FEV1 (forced expiratory volume in 1 second): A measure of airway obstruction determined using spirometry. Individual FEV1 values are compared to predicted values based on age, height, sex and race.
- PEF (peak expiratory flow): PEF is often described as a percent of personal best measurement. Personal best PEF is the highest PEF value attained after 2 to 3 weeks of testing when asthma is in good control.

APPENDIX 3:
Managing Asthma in Adults and Adolescents 12+ Years



ABBREVIATIONS: AIR: anti-inflammatory reliever; HDM: house dust mite; ICS: inhaled corticosteroid; LABA: long-acting beta2-agonist; Ig: immunoglobulin; IL: interleukin; LAMA: long-acting muscarinic antagonist; LTRA: Leukotriene Receptor Antagonist; MART: maintenance-and-reliever therapy with ICS-formoterol; OCS: oral corticosteroids; SABA: short-acting beta2-agonist; SLIT: sublingual immunotherapy; TSLP: thymic stromal lymphopoietin
REFERENCE: Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2025. Available from: www.ginasthma.org

APPENDIX 4: SUGGESTED TOTAL DAILY DOSAGES for INHALED CORTICOSTEROIDS (ICS) IN ADULTS AND ADOLESCENTS (12 years and older):

Inhaled Corticosteroid	Low Dose ICS (mcg)	Medium Dose ICS (mcg)	High Dose ICS (mcg)
Beclometasone dipropionate (pMDI, standard particle, HFA)	200-500	>500-1000	>1000
Beclometasone dipropionate (DPI or pMDI, extrafine particle, HFA)	100-200	>200-400	>400
Budesonide (DPI, or pMDI, standard particle, HFA)	200-400	>400-800	>800
Ciclesonide (pMDI, extrafine particle, HFA)	80-160	>160-320	>320
Fluticasone furoate (DPI)	100	100-200	200
Fluticasone propionate (DPI)	100-250	>250-500	>500
Fluticasone propionate (pMDI, standard particle, HFA)	100-250	>250-500	>500
Mometasone furoate (DPI)	Depends on DPI device – see product information		
Mometasone furoate (pMDI, standard particle, HFA)	200-400	200-400	>400

Reference: Box 4-2. Low, medium, and high daily metered doses of inhaled corticosteroids (alone or with LABA) Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2025. Available from: www.ginasthma.org

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Asthma is a heterogeneous disease marked by chronic airway inflammation. According to the Global Initiative for Asthma (GINA), “asthma is defined by the history of respiratory symptoms such as wheeze, shortness of breath, chest tightness, and cough that vary over time and in intensity, together with variable expiratory airflow”. The estimated U.S. prevalence of asthma is 8.2%, or about 26.8 million people.

Symptoms of asthma can range from mild to severe and may be frequent or infrequent. Severe asthma is defined as uncontrolled asthma despite optimized high-dose inhaled corticosteroid (ICS)/long-acting beta2-agonist (LABA) treatment or that worsens when high-dose treatment is decreased. The true prevalence of severe asthma is unknown; however, based on various definitions, it is estimated that 3%–10% of patients with asthma have severe disease; of these, 20% to 50% are considered uncontrolled, meaning that they have asthma-related healthcare encounters and/or require corticosteroids. Severe disease is the driver of morbidity in asthma and accounts for more than 60% of asthma-related spending.

Type 2 (T2) inflammation is present in more than one-half of patients with asthma and is a key driver of disease severity and exacerbation risk. It is typically characterized by elevated blood eosinophils (known as eosinophilic asthma) or elevated fractional exhaled nitric oxide (FeNO). The definition of eosinophilic asthma varies but is usually considered blood eosinophil levels of ≥150 cells/μL or sometimes ≥300 cells/μL. Patients with T2-high asthma have a higher likelihood of severe exacerbations and healthcare utilization. While T2 inflammation generally responds to ICSs, a subset of patients with severe asthma remain inadequately controlled despite high-dose ICS + LABA therapy. For these patients, guidelines recommend add-on biologic therapies targeting T2 inflammatory pathways to reduce exacerbations and improve disease control.

In December 2025, the FDA approved Exdensur (depemokimab-ulaa), an IL-5 antagonist, for treating severe eosinophilic asthma in patients aged 12 and older. It is the first ultra–long-acting biologic approved for twice-yearly dosing in asthma. The recommended dosage is 100 mg given subcutaneously once every 6 months.

The approval of Exdensur is supported by results from the Phase 3 SWIFT-1 (NCT04719832) and SWIFT-2 (NCT04718103) clinical trials. These clinical trials demonstrated that the rate of asthma exacerbations was

significantly lower in patients receiving Exdensur compared to placebo. During the 52-week treatment period, fewer patients experienced exacerbations in the Exdensur group (32% and 32%) compared to the placebo group (46% and 50%) in SWIFT-1 and SWIFT-2, respectively. The percentage of patients with exacerbations requiring hospitalization and/or Emergency Department visit was numerically lower for patients treated with Exdensur (1% and 4%) compared with placebo (8% and 10%) in SWIFT-1 and SWIFT-2, respectively. Additionally, the time to first clinically significant exacerbation was longer for EXDENSUR compared to placebo.

In SWIFT-1 and SWIFT-2, Exdensur was well tolerated, with patients experiencing a similar rate and severity of side effects as those receiving placebo. The most common adverse reactions (incidence ≥4% and more common than placebo) were upper respiratory tract infection, allergic rhinitis, influenza, arthralgia, and pharyngitis. In the pooled safety population, injection site reactions occurred in 1% and <1% patients receiving Exdensur and placebo, respectively.

Global Initiative for Asthma (GINA, 2025)

Add-on biologic therapy: options recommended by GINA for patients with uncontrolled severe asthma despite optimized maximal therapy include:

- Add-on anti-immunoglobulin E treatment (omalizumab [Xolair]) for patients age > 6 years with **severe allergic asthma** (Evidence A)
- Add-on anti-interleukin- 5/5R treatment (SC mepolizumab [Nucala] for patients age > 6 years; IV reslizumab [Cinqair] for ages >18 years or SC benralizumab [Fasenra] for ages >12 years), with **severe eosinophilic asthma** (Evidence A)
- Add-on anti-interleukin-4Rα treatment (SC dupilumab[Dupixent]) for patients aged > 6 years with **severe eosinophilic/type 2 asthma** or for **patients requiring treatment with maintenance OCS** (Evidence A)
- Add-On anti-thymic stromal lymphopoietin (anti TSLP) treatment (subcutaneous tezepelumab [Tezspire]) for patients aged >12 years with **severe asthma** (Evidence A)
- Suggested initial trial of add-on anti-IL5 for severe eosinophilic asthma is at least 4 months. At that point, response to initial trial of add-on therapy should be reviewed. There are no well-defined criteria for good response, but exacerbations, symptom control, lung function, side effects, treatment intensity, and patient satisfaction should be considered. If the response is unclear, consider extending the trial to 6-12 months. If there is no response, stop the biologic therapy and consider switching to a different targeted therapy, if available.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Exdensur (depemokimab-ulaa) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Exdensur (depemokimab-ulaa) include: no labeled contraindications.

Exclusions/Discontinuation:
Hypersensitivity reactions, including anaphylaxis, can occur after administration of Exdensur (depemokimab-ulaa). If a hypersensitivity reaction occurs, discontinue Exdensur and initiate appropriate therapy.

Treat pre-existing helminth infections before initiating therapy with Exdensur. If a patient become infected while receiving treatment with Exdensur and does not respond to anti-helminth treatment, discontinue Exdensur until the parasitic infection resolves.

OTHER SPECIAL CONSIDERATIONS:
Do not abruptly discontinue systemic or inhaled corticosteroids upon initiation of therapy with Exdensur (depemokimab-ulaa). Reduce corticosteroid dose gradually, if appropriate.

Placental transfer of Exdensur increases throughout pregnancy and is highest in the third trimester.YTE modification (a process used in the development of Exdensur) may lead to prolonged and increased exposure of the infant exposed in utero, and the potential of clinical impact is unknown and should be considered.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Exdensur SOSY 100MG/ML single-dose prefilled syringe

REFERENCES

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SUMMARY OF REVIEW/REVISIONS	DATE
NEW CRITERIA CREATION	Q1 2026