Exdensur® (depemokimab-ulaa)
(Subcutaneous)

Document Number: M-P0831

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 12 months (365 days).
- Renewal: Prior authorization validity may be renewed every 12 months (365 days) thereafter.

II. Dosing Limits

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

- 100 mg every 6 months

III. Initial Approval Criteria

For Commercial Members Only
• Patient must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of (reslizumab) Cinqair® OR (benralizumab) Fasenra®; **AND** • Patient must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of TWO of the following: mepolizumab (Nucala®), dupilumab (Dupixent®), tezepelumab-ekko (Tezspire®), omalizumab (Xolair®)
For Medicaid Members Only
• Patient must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of (reslizumab) Cinqair® OR (benralizumab) Fasenra®; **AND** • Patient must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of TWO of the following: mepolizumab (Nucala®), dupilumab (Dupixent®), omalizumab (Xolair®)

Target Agent(s) will be approved when ALL of the following are met:

1. ONE of the following:
   A. The requested agent is eligible for continuation of therapy AND ONE of the following:

Agents Eligible for Continuation of Therapy
All target agents are eligible for continuation of therapy

1. The member has been treated with the requested agent (starting on samples is not approvable) within the past 90 days; **OR**
2. The prescriber states the member has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed; **OR**

B. BOTH of the following:
1. ONE of the following:
A. The member has a diagnosis of severe eosinophilic asthma and BOTH of the following:
1. The member's diagnosis has been confirmed by ONE of the following:
A. 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; **OR**
B. The member has a fraction of exhaled nitric oxide (FeNO) of 20 parts per billion or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids; **OR**
C. The member has sputum eosinophils 2% or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids; **AND**
2. ONE of the following:
A. The member has a history of uncontrolled asthma while on asthma control therapy (e.g., inhaled corticosteroid [ICS]/long-acting beta-2 agonist [LABA] combination therapy) as demonstrated by ONE of the following:
1. Frequent severe asthma exacerbations requiring two or more courses of systemic corticosteroids (steroid burst) within the past 12 months; **OR**
2. Serious asthma exacerbations requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the past 12 months; **OR**
3. Controlled asthma that worsens when the doses of inhaled and/or systemic corticosteroids are tapered; **OR**
4. Baseline (prior to therapy with the requested agent) Forced Expiratory Volume (FEV1) that is less than 80% of predicted; **OR**

B. The member's medication history (excluding sample use) indicates use of a biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of asthma within the past 12 months; **OR**

B. The member has another FDA labeled indication for the requested agent and route of administration; **AND**

2. If the member has an FDA labeled indication, then ONE of the following:
   A. The member's age is within FDA labeling for the requested indication for the requested agent; **OR**
   B. There is support for using the requested agent for the member's age for the requested indication; **OR**

C. The member has another indication that is supported in compendia for the requested agent and route of administration; **AND**

2. If the member has a diagnosis of severe eosinophilic asthma, then ALL of the following:
   A. ONE of the following:
      1. The member is NOT currently treated with a biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of asthma (including the requested agent) AND is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months AND has been adherent for 90 days within the past 120 days; **OR**
      2. The member is currently treated with a biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of asthma (including the requested agent) AND ONE of the following:
         A. The member is currently treated with an inhaled corticosteroid for at least 3 months that is adequately dosed to control symptoms AND has been adherent for 90 days within the past 120 days; **OR**
         B. The member is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months AND has been adherent for 90 days within the past 120 days; **OR**
      3. The member has an intolerance or hypersensitivity to therapy with ONE inhaled corticosteroid; **OR**
      4. The member has an FDA labeled contraindication to ALL inhaled corticosteroids; **AND**
   B. ONE of the following:
      1. The member is currently treated for at least 3 months AND has been adherent for 90 days within the past 120 days with ONE of the following:
         A. A long-acting beta-2 agonist (LABA); **OR**
         B. A long-acting muscarinic antagonist (LAMA); **OR**
         C. A leukotriene receptor antagonist (LTRA); **OR**

D. Theophylline; **OR**

2. The member has an intolerance or hypersensitivity to therapy with ONE long-acting beta-2 agonist (LABA), long-acting muscarinic antagonist (LAMA), leukotriene receptor antagonist (LTRA), or theophylline; **OR**
3. The member has an FDA labeled contraindication to ALL long-acting beta-2 agonists (LABA) AND long-acting muscarinic antagonists (LAMA); **AND**

C. The member will continue asthma control therapy (e.g., ICS, ICS/LABA, LTRA, LAMA, theophylline) in combination with the requested agent; **AND**

3. The prescriber is a specialist in the area of the member's diagnosis (e.g., asthma: allergist, immunologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the member's diagnosis **AND**
4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table):
   A. The member will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR**
   B. The member will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:
      1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND**
      2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, or guidelines required) **AND**
5. The member does NOT have any FDA labeled contraindications to the requested agent

Compendia Allowed: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use

IV. Renewal Criteria

Target Agent(s) will be approved 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; **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 prescriber is a specialist in the area of the member's diagnosis (e.g., asthma: allergist, immunologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the member's diagnosis; **AND**
5. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table):

A. The member will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors); **OR**

B. The member will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:

1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent; **AND**
2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, or guidelines required); **AND**

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

Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly Abrilada (adalimumab-afzb) Actemra (tocilizumab) Adalimumab Adbry (tralokinumab-ldrm) Amjevita (adalimumab-atto) Arcalyst (rilonacept) Avsola (infliximab-axxq) Avtozma (tocilizumab-anoh) Benlysta (belimumab) Bimzelx (bimekizumab-bkzx) Cibinqo (abrocitinib) Cimzia (certolizumab) Cinqair (reslizumab) Cosentyx (secukinumab) Cyltezo (adalimumab-adbm) Dupixent (dupilumab) Ebglyss (lebrikizumab-lbkz) Enbrel (etanercept) Entyvio (vedolizumab) Exdensur (depemokimab-ulaa) Fasenra (benralizumab) Hadlima (adalimumab-bwwd) Hulio (adalimumab-fkjp) Humira (adalimumab) Hyrimoz (adalimumab-adaz) Idacio (adalimumab-aacf) Ilaris (canakinumab)

Contraindicated as Concomitant Therapy
Ilumya (tildrakizumab-asmn)
Imuldosa (ustekinumab-srlf)
Inflectra (infliximab-dyyb)
Infliximab
Kevzara (sarilumab)
Kineret (anakinra)
Leqselvi (deuruxolitinib)
Litfulo (ritlecitinib)
Nemluvio (nemolizumab-ilto)
Nucala (mepolizumab)
Olumiant (baricitinib)
Omlyclo (omalizumab-igec)
Omvoh (mirikizumab-mrkz)
Opzelura (ruxolitinib)
Orencia (abatacept)
Otezla (apremilast)
Otezla XR (apremilast extended-release)
Otulfi (ustekinumab-aauz)
Pyzchiva (ustekinumab-ttwe)
Remicade (infliximab)
Renflexis (infliximab-abda)
Rhapsido (remibrutinib)
Riabni (rituximab-arrx)
Rinvoq (upadacitinib)
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)
Ruxience (rituximab-pvvr)
Saphnelo (anifrolumab-fnia)
Selarsdi (ustekinumab-aekn)
Siliq (brodalumab)
Simlandi (adalimumab-ryvk)
Simponi (golimumab)
Simponi ARIA (golimumab)
Skyrizi (risankizumab-rzaa)
Sotyktu (deucravacitinib)
Spevigo (spesolimab-sbzo) subcutaneous injection
Starjemza (ustekinumab-hmny)
Stelara (ustekinumab)
Steqeyma (ustekinumab-stba)

Contraindicated as Concomitant Therapy
Taltz (ixekizumab) Tezspire (tezepelumab-ekko) Tofacitinib Tofidence (tocilizumab-bavi) Tremfya (guselkumab) Truxima (rituximab-abbs) Tyenne (tocilizumab-aazg) Tyruko (natalizumab-sztn) Tysabri (natalizumab) Ustekinumab Velsipity (etrasimod) Wezlana (ustekinumab-auub) Xeljanz (tofacitinib) Xeljanz XR (tofacitinib extended release) Xolair (omalizumab) Yesintek (ustekinumab-kfce) Yuflyma (adalimumab-aaty) Yusimry (adalimumab-aqvh) Zeposia (ozanimod) Zymfentra (infliximab-dyyb)

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):

- J3590 – Unclassified biologics
- C9399 – Unclassified drugs or biologicals (Hospital Outpatient Use Only)

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

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