RX.PA.116.MPC Exdensur (depemokimab-ulaa)

The purpose of this policy is to define the prior authorization process for Exdensur (depemokimab-ulaa), indicated for the treatment of:

- Add-on maintenance therapy of severe asthma characterized by an eosinophilic phenotype in adults and pediatric patients 12 years and older

PROCEDURE

A. Initial Authorization Criteria

1. Severe Eosinophilic Asthma

- Must have documentation of a diagnosis of severe eosinophilic asthma
    - Note: Exdensur is not indicated for relief of acute bronchospasm or status asthmaticus
- Must be 12 years of age or older
- Must have had 2 or more asthma exacerbations requiring treatment with systemic corticosteroids in the past 12 months OR one or more asthma exacerbations requiring hospitalization or an emergency department visit in the past 12 months
- The member has inadequate asthma control despite being currently compliant with the following regimen for at least 3 months:
    - Medium to high dose inhaled corticosteroids (ICS) + at least one additional asthma controller
    - Note: Asthma controller (i.e. long acting beta2 agonist, long acting muscarinic antagonist, leukotriene modifier, theophylline)
- Provider attestation that Exdensur will be used concurrently as an add on therapy in combination with an inhaled corticosteroid (ICS) or inhaled corticosteroid-containing combination inhaler
- Must have a documented baseline blood eosinophil count greater than or equal to 150 cells/microliter (within the past 60 days of the request)
- Must have documentation of an FEV1/forced vital capacity (FVC) less than 0.8 (within 60 days of the request)
- Must not use Exdensur in combination with another anti-interleukin (IL) monoclonal antibody
    - Note: Examples of anti-IL monoclonal antibodies are Nucala, Cinqair, and Dupixent (dupilumab subcutaneous injection)

- Provider attestation of patient evaluation for helminth infections before initiating therapy and during treatment with Exdensur
- Must have documentation of an adequate trial (at least 4 months), intolerance to, or contraindication to Nucala
- Must have documentation of an adequate trial (at least 4 months), intolerance to, or contraindication to Fasenra
- Must have documentation of an adequate trial (at least 4 months), intolerance to, or contraindication to Dupixent
- Must be prescribed by or in consultation with a pulmonologist or allergist/immunologist

B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.

C. Exdensur treatments will be considered investigational or experimental for any other use and will not be covered.

D. <u>Reauthorization Criteria:</u>

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals.

- MPC Renewal:
  - Documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.
- Renewal from Previous Insurer:
- Members who have received prior approval (from insurer other than MPC), or have been receiving medication samples, should be considered under criterion A (Initial Authorization Criteria).
  - Provider has documented positive clinical response to therapy for the member from baseline

Length of Authorization (if above criteria met)	
Initial Authorization	6 months
Reauthorization	12 months

APPLICABLE CODES

Code	Description
J3590	Unclassified biologics

References

1. Exdensur [package insert]. Philadelphia, PA; GlaxoSmithKline LLC; April 2026.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
New Policy	*04/2026*