TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Depemokimab-ulaa (Exdensur)	**CRITERIA ID:** TX.CC.PHAR.62
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy
EFFECTIVE DATE: 08/17/2026	**PRODUCT(S):** STAR, STAR+PLUS, STAR HEALTH, STAR KIDS, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: N/A	**REGULATOR MOST RECENT APPROVAL DATE(S):** N/A

CRITERIA STATEMENT:
The purpose of this clinical criteria is to provide a guide to medical necessity reviews for depemokimab-ulaa (Exdensur).

PURPOSE:
Consistent with the regulation at 42 CFR Section 438.210 and 42 CFR Section 457.1230(d), services covered under managed care contracts, including clinician-administered drugs, must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services specified in the state plan. While MCOs may place appropriate limits on drugs, MCOs may not use a standard for determining medical necessity that is more restrictive than what is used in the state plan, i.e., developed by the Vendor Drug Program. For example, if a member is denied a clinician administered drug in managed care because of the MCO's prior authorization criteria but would have received the drug under the criteria specified in the state plan, then the MCO's prior authorization criteria would violate the amount, duration, and scope requirements cited above. HHSC intends to amend the Managed Care Contracts at the next opportunity to include this requirement. This same standard applies to CHIP formulary and CAD coverage.

Refer to the Outpatient Drug Services Handbook of the Texas Medicaid Provider Procedure Manual for more details on the clinical criteria and prior authorization requirements.

SCOPE:
Superior HealthPlan (SHP), Centene Pharmacy Services (CPS)

DEFINITIONS:
CPS = Centene Pharmacy Services
MCO = Managed Care Organization

POLICY:
It is the policy of Superior HealthPlan and Centene Pharmacy Services to follow state guidance for medical necessity review of depemokimab-ulaa (Exdensur); procedure code: J2361.

Description/Mechanism of Action:
Exdensur is an ultra long acting interleukin-5 (IL-5) antagonist monoclonal antibody.

FDA Approved Indications:
Exdensur 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.

Formulations:
Exdensur is available as a 100 mg/mL solution in a single-dose, prefilled syringe with needle guard.

PROCEDURE:
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

I. Initial Approval Criteria:

A. Severe Asthma (must meet all)**:**

1. The client is 12 years of age or older.
2. The client has a confirmed diagnosis of severe asthma (as defined by the National Heart, Lung, and Blood Institute's Guidelines for the diagnosis and management of asthma) (diagnosis code J4550, J4551, or J8283).
3. The client's asthma is characterized by an eosinophilic phenotype with a baseline blood eosinophilic count of at least 150 cells/microliter or greater.
4. Provider attestation that the client has asthma that is uncontrolled before administration of Exdensur as an add-on treatment.
5. Provider attestation that the client has adhered to at least three consecutive months of inhaled corticosteroid therapy and used at least one additional asthma controller or asthma maintenance medication.
6. Documentation that the client's asthma is inadequately controlled despite the use of controller therapy (i.e., medium- to high-dose inhaled corticosteroid (ICS) plus at least one asthma controller with or without maintenance oral corticosteroids (OCS)), indicated by either of the following within the previous year:
   a. At least two or more asthma exacerbations that required treatment with systemic corticosteroids (SCS); or
   b. Reduced lung function with forced expiratory volume in one second (FEV1) that was less than 80% of predicted.
7. Provider attestation that Exdensur will be used as an add-on maintenance therapy to the client's medication for asthma and may not be used as a single or primary therapy.
8. Provider attestation that Exdensur will not be used in combination with anti-IgE, anti-IL4, or anti-IL5 monoclonal antibody agents, such as Xolair, Fasenra, Nucala, or Cinqair.

Approval duration: 12 months.

REFERENCES:
Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook

ATTACHMENTS:

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Policy	N/A	08/17/2026