TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Eladocagene exuparvovec-tneq (Kebilidi)	**CRITERIA ID:** TX.CC.PHAR.61
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy
EFFECTIVE DATE: 07/14/2026	**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 eladocagene exuparvovec-tneq (Kebilidi).

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.

This medication is a non-risk based (NRB) payment drug and should follow state guidance for medical necessity review for Medicaid/CHIP due to the manner in which it is reimbursed. All determinations will be performed by a Medical Director. A pharmacy clinician will review the prior authorization request and make a recommendation to the Medical Director but will not make the ultimate determination on any case.

Additionally, this medication is a Precision Drug. Centene's Precision Drug Action Committee (PDAC) creates a standardized approach for Centene to manage Precision Drugs and the associated costs for their administration, prior to members presenting with a request for one of these agents. All Precision Drug requests or potential requests must be reported to the PDAC for tracking, regardless of whether agents are carved out, passed through, etc.

The procedure code J3590 (used for Kebilidi) will be limited to one approval per lifetime, by any provider.

This medication is designated by HHSC as a high-cost clinician-administered drug (HCCAD), allowing separate reimbursement for inpatient use. When inpatient use is required, the drug may be billed on a separate outpatient claim or through specialty pharmacy billing, when available.

SCOPE:
This criteria applies to all directors, officers, and employees of Centene Corporation, its affiliates, health plans, and subsidiary companies (collectively, the "Company").

DEFINITIONS:
CPS = Centene Pharmacy Services
NRB = Non-Risk Based
PDAC = Precision Drug Action Committee
SHP = Superior HealthPlan
UM = Utilization Management

POLICY:
It is the policy of Superior HealthPlan and Centene Pharmacy Services to follow state guidance for medical necessity review of eladocagene exuparvovec-tneq (Kebilidi); procedure code: J3590.

Description/Mechanism of Action:
Kebilidi is an adeno-associated virus (AAV) vector-based gene therapy.

FDA Approved Indications:
Kebilidi is indicated for the treatment of adult and pediatric patients with aromatic L-amino acid decarboxylase (AADC) deficiency.

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. Aromatic L-amino acid decarboxylase (AADC) deficiency :

1. A Medical Director is required to review and approve or deny all requests. A pharmacy clinician will make a recommendation on the prior authorization, but ultimate determination will be made by the Medical Director only.
2. The client is 16 months of age or older.
3. The client has a confirmed diagnosis of AADC deficiency (diagnosis code: E70.81).
4. The client has biallelic mutations in the DDC gene identified by molecular genetic testing.
5. Documentation of a skull assessment confirming the client has achieved skull maturity by neuroimaging, necessary for stereotactic neurosurgical administration of Kebilidi therapy.
6. The client has not previously received Kebilidi infusion for AADC deficiency.
7. Provider attestation to monitoring for all of the following:
    a. Post-procedural complications, which may include respiratory and cardiac arrest following Kebilidi administration.
    b. Additional procedure-related adverse events, such as cerebrospinal fluid leak, intracranial bleeding, neuroinflammation, acute infarction, and infection.
    c. Signs of dyskinesia or involuntary movements of face, arms, legs, or entire body (e.g., fidgeting, writhing, wriggling, head bobbing, or body swaying) following administration of Kebilidi.

Approval duration: 12 months (only 1 dose per lifetime will be provided on this drug regardless of provider).

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

ATTACHMENTS:

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Policy	N/A	07/14/2026