TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Atidarsagene autotemcel (Lenmeldy)	**CRITERIA ID:** TX.CC.PHAR.52
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy
EFFECTIVE DATE: 7/1/2025	**PRODUCT(S):** STAR, STAR Kids, STAR Health, STAR Plus, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: N/A	**REGULATOR MOST RECENT APPROVAL DATE(S):**

CRITERIA STATEMENT:
The purpose of this clinical criteria is to provide a guide to medical necessity reviews for Atidarsagene autotemcel (Lenmeldy)

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. All Precision Drug medical necessity determinations will be supported by PDAC UM recommendation, utilizing specialist input as directed and allowed by turnaround times.

The procedure code J3391 (used for Lenmeldy®) will be limited to once per lifetime, by any provider. If the code is updated in the future it will still be limited to once per lifetime.

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

DEFINITIONS:
PDAC = Precision Drug Action Committee

UM = Utilization Management
CPS = Centene Pharmacy Service
SHP = Superior HealthPlan
PSLI = Pre-symptomatic late infantile
PSEJ = Presymptomatic early juvenile
ESEJ = Early symptomatic early juvenile
MLD = Metachromatic leukodystrophy
ARSA = Arylsulfatase A
HSCT = Hematopoietic stem cell gene therapy
HIV = Human immunodeficiency virus
HSC = hematopoietic stem cell

POLICY:
It is the policy of Superior HealthPlan (SHP) and Centene Pharmacy Services (CPS) to follow state guidance for medical necessity review of Atidarsagene autotemcel (Lenmeldy); procedure code: J3391.

Description/Mechanism of Action:
Atidarsagene autotemcel is an autologous hematopoietic stem cell (HSC)-based gene therapy that works by inserting one or more functional copies of the human ARSA complementary deoxyribonucleic acid (cDNA) into patients' HSCs through transduction of autologous CD34 positive cells with ARSA lentiviral vector (LVV). After atidarsagene autotemcel infusion, transduced CD34 positive HSCs engraft in bone marrow, repopulate the hematopoietic compartment, and their progeny produce ARSA enzyme. Functional ARSA enzyme can breakdown or prevent the harmful accumulation of sulfatides.

FDA Approved Indications:
Atidarsagene autotemcel (Lenmeldy) is indicated for the treatment of clients with pre-symptomatic late infantile (PSLI), presymptomatic early juvenile (PSEJ), or early symptomatic early juvenile (ESEJ) metachromatic leukodystrophy.

Formulations:
Atidarsagene autotemcel (Lenmeldy) is a single-dose cell suspension for intravenous infusion, composed of one to eight infusion bags which contain 2 to 11.8 × 10^6 cells/mL (1.8 to 11.8 x 106 CD34+ cells/ml) suspended in cryopreservation solution.

Qualified Treatment Centers (QTCs)
- QTCs are medical centers that have been trained to administer Orchard Therapeutics gene therapy.
    - Texas Children's Hospital, Baylor University (Houston)

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. Metachromatic leukodystrophy
      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. Medical necessity determinations will be supported by PDAC UM recommendation. The CPS or SHP pharmacy clinician will review the UM recommendation with the prior authorization request for clinical appropriateness and make a recommendation to the medical director but will not make the ultimate determination on any case.
3. The client is 7 years and younger OR is between the ages 7 to 17 years with onset of symptoms less than 7 years.
4. The client has a diagnosis of one of the following forms of metachromatic leukodystrophy (diagnosis code: E75.25):
    a. Pre-symptomatic late infantile
    b. Pre-symptomatic early juvenile (PSEJ)
    c. Early symptomatic early juvenile (ESEJ)
5. The client's diagnosis is confirmed by all of the following:
    a. Biochemical testing indicating Arylsulfatase A (ARSA) activity below normal range
    b. Genetic testing confirming two disease causing ARSA alleles
    c. If ARSA mutations are present, a 24-hour urine collection showing elevated sulfatide levels
6. The client is a candidate for and has not previously received hematopoietic stem cell gene therapy (HSCT).
7. Prescriber attestation client will not take prophylactic HIV anti-retroviral medications for at least one month prior to mobilization, or for the expected duration of time needed for the elimination of medications.
8. Prescriber attestation to monitor the client for all the following parameters following Lenmeldy (atidarsagene autotemcel) treatment:
    a. Signs and symptoms of encephalitis, thrombocytopenia and/or serious infection
    b. Signs and symptoms of veno-occlusive disease including liver function tests during the first month post Lenmeldy infusion
    c. Life-long hematologic malignancies, including a complete blood count (with differential) annually and integration site analysis, as warranted, for at least 15 years after treatment

Approval duration: 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 Document	N/A	6/26/2025