An Important Message from

The Texas Health and Human Services Commission (HHSC)

Prior Authorization Criteria for High-Cost Clinician Administered Drug (HCCAD) Lenmeldy Effective July 1, 2025

Background:
On July 1, 2025, Lenmeldy, will become a benefit of Medicaid and CHIP. HHSC requires prior authorization for Lenmeldy (procedure code J3391) for Medicaid and CHIP, effective for dates of service on or after Aug. 1, 2025.

Key Details:
Lenmeldy (atidarsagene autotemcel) is an autologous hematopoietic stem cell-based gene therapy indicated for the treatment of clients with pre-symptomatic late infantile (PSLI), pre-symptomatic early juvenile (PSEJ), or early symptomatic early juvenile (ESEJ) metachromatic leukodystrophy.

HHSC will reimburse Lenmeldy as non-risk and designated it as a high-cost clinician-administered drug. The HHSC-approved clinical prior authorization is mandatory for MCOs.

Action:

Prior Authorization Requirements
Prior authorization approval for a one-time Lenmeldy (atidarsagene autotemcel) J3391 infusion therapy will be considered when all the following criteria are met:

- The client is 7 years and younger OR is between the ages 7 to 17 years with onset of symptoms less than 7 years;
- The client has a documented biochemical and molecular diagnosis of one of the following forms of metachromatic leukodystrophy (diagnosis code: E75.25):
    - Pre-symptomatic late infantile
    - Pre-symptomatic early juvenile (PSEJ)
    - Early symptomatic early juvenile
- MLD diagnosis is confirmed by:
    - Biochemical testing indicating Arylsulfatase A (ARSA) activity below normal range,
    - Genetic testing confirming two disease causing ARSA alleles, and
    - If ARSA mutations are present, a 24-hour urine collection showing elevated sulfatide levels.
- The client is a candidate for and has not previously received hematopoietic stem cell gene therapy (HSCT); and
- The 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

Lenmeldy (atidarsagene autotemcel), J3391 is limited to one transfusion treatment per lifetime.

Required Monitoring Parameters
MCOs must require providers to monitor the client for the parameters listed below following Lenmeldy (atidarsagene autotemcel) treatment:

- Signs and symptoms of encephalitis, thrombocytopenia and/or serious infection;
- Signs and symptoms of veno-occlusive disease including liver function tests during the first month post Lenmeldy infusion; and
- 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.

Questions?
Please contact UnitedHealthcare Customer Service at 888-887-9003, 8 a.m.–6 p.m. CT, Monday–Friday.