Louisiana Medicaid
Atidarsagene autotemcel (Lenmeldy™)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for atidarsagene autotemcel (Lenmeldy™).

Additional Point-of-Sale edits may apply.

By submitting the authorization request, the prescriber attests to the conditions available HERE.

Approval Criteria

- The recipient has documented biochemical and molecular diagnosis of metachromatic leukodystrophy (MLD) based on ARSA activity below the normal range and identification of two disease-causing ARSA alleles, either known or novel mutations. In the case of a novel mutation(s), a 24-hour urine collection shows elevated sulfatide levels; **AND**
- **ONE** of the following:
    - Pre-symptomatic late infantile (PSLI) MLD with the following:
        - The recipient has an older sibling with a diagnosis of MLD whose age at symptom onset was ≤ 6 years of age (i.e., had not celebrated their 7th birthday); **OR**
        - The recipient has an ARSA genotype consistent with LI MLD; **AND**
        - The recipient has no neurological signs or symptoms of MLD [abnormal reflexes or abnormalities on brain magnetic resonance imaging and/or nerve conduction tests not associated with functional impairment (e.g., no tremor, no peripheral ataxia) are allowed]; **OR**
    - Pre-symptomatic early juvenile (PSEJ) MLD with the following:
        - The recipient has an older sibling with a diagnosis of MLD whose age at symptom onset was ≤ 6 years of age (i.e., had not celebrated their 7th birthday); **OR**
        - The recipient has an ARSA genotype consistent with EJ MLD; **AND**
        - The recipient has no neurological signs and symptoms of MLD **OR** physical exam findings are limited to abnormal reflexes and/or clonus [abnormal reflexes or abnormalities on brain magnetic resonance imaging and/or nerve conduction tests not associated with functional impairment (e.g., no tremor, no peripheral ataxia) are allowed]; **OR**
    - Early symptomatic early juvenile (ESEJ) MLD with **ALL** of the following:
        - Age of disease onset **before** 7 years of age (i.e., has not celebrated their 7th birthday); **AND**
        - The recipient is walking independently (GMFC-MLD Level 0 with ataxia or GMFC-MLD Level 1); **AND**

        - The recipient has normal cognitive function as defined by an IQ ≥ 85 on age-appropriate cognitive scales; **AND**
- The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a neurologist or other physician experienced in the diagnosis and treatment of MLD; **AND**
- **ALL** of the following are true and are **stated on the request**:
    - The recipient does not have the late juvenile form of the disease (disease onset ≥7 years of age and <17 years of age); **AND**
    - The recipient does not have HIV-1 or HIV-2; **AND**
    - The recipient does not have HTLV-1 or HTLV-2; **AND**
    - The recipient does not have active Hepatitis B or C infection; **AND**
    - The recipient does not have active mycoplasma infection; **AND**
    - The recipient does not have renal or hepatic impairment; **AND**
    - The recipient **has never received a dose** of any gene therapy.

Duration of approval: 6 months – allow 1 dose per lifetime

Reference

ClinicalTrials.gov. A Safety and Efficacy Study of Cryopreserved OTL-200 for Treatment of Metachromatic Leukodystrophy (MLD) https://clinicaltrials.gov/study/NCT03392987?cond=OTL-200&viewType=Table&limit=100&rank=2&a=9

Lenmeldy (atidarsagene autotemcel) [package insert]. Boston, MA: Orchard Therapeutics North America; March 2024. https://orchard-tx.com/lenmeldy_uspi

Revision / Date	Implementation Date
Policy Created / May 2024	