

Last review date: 8/20/2024

Applicable Products:
Lenmeldy (Atidarsagene Autotemcel)

Initial Approval Criteria:

- Patient has a diagnosis of metachromatic leukodystrophy (MLD) confirmed by all of the following:
 - Gene testing shows presence of two disease-causing arylsulfatase A gene (ARSA) alleles; **AND**
 - ARSA activity is below normal range (31-198 nmol/mg/h); **AND**
- Patient has one of the following MLD subtypes:
 - Pre-symptomatic (PS); **AND**
 - Patient is > 30 months and <7 years old; **OR**
 - Early symptomatic (ES); **AND**
 - Patient is > 30 months and <7 years old; **OR**
 - Late infantile (LI); **AND**
 - ≤ 30 months of age; **AND**
- Patient has not received prior allogeneic hematopoietic stem cell transplantation; **AND**
- Prescribed by or in consultation with a hematologist or specialist; **AND**
- If applicable: Trial and failure, intolerance, or a contraindication to the preferred products as listed in the medical drug list

Renewal Criteria:

None

Length of Authorization:

1 dose per lifetime

This policy is designed to address medical guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Each person's unique clinical or other circumstances may warrant individual consideration, based on review of applicable medical records, as well as other regulatory, contractual and/or legal requirements.

Medical policies do not constitute medical advice, nor are they intended to govern the practice of medicine. They are intended to reflect reimbursement and coverage guidelines. Coverage for services may vary for individual members, based on the terms of the benefit contract.