

POLICY NAME	Lenmeldy (atidarsagene autotemcel)	POLICY #	2777P
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Criteria

Coverage Criteria

- ☐ **1.1** Diagnosis of metachromatic leukodystrophy (MLD) confirmed by ALL of the following:
 - Molecular genetic testing confirms mutation in the arylsulfatase A (ARSA) gene
 - ARSA activity below the normal range in peripheral blood
 - Elevated sulfatide levels above the normal laboratory reference range
- ☐ **1.2** Disease is categorized as pre-symptomatic late infantile (PSLI) as confirmed by disease onset \leq 30 months and one of the following:
 - Absence of nerve related signs and symptoms of MLD (e.g., peripheral nerve pain, walking difficulties, muscle weakness)
 - Abnormal reflexes or abnormalities on brain magnetic resonance imaging (MRI) and/or nerve conduction tests not associated with functional impairment (e.g., no tremor, no loss of muscle function)
- ☐ **1.3** Prescribed by or in consultation with a neurologist (nervous system doctor), geneticist (genetic condition doctor), or specialist in the treatment of MLD at an authorized treatment center (authorized treatment centers are defined by the manufacturer)
- ☐ **1.4** Age less than 18 years
- ☐ **1.5** Review of clinical information confirming that patient has met all of the above requirements for treatment completed by both a pharmacist and medical director

Exclusion Criteria – Any of the following prevents coverage

- ☐ **2.1** MLD of any other category or sub-type (such as pre-symptomatic early-juvenile or early-symptomatic early-juvenile)
 - Clinical benefit was not as prevalent or is not supported in these patients and is excluded from coverage.
- ☐ **2.2** History of hematopoietic stem cell transplant (HSCT)
 - Patients with prior stem cell transplant were excluded from clinical trials. Safety and efficacy of Lenmeldy in patients with a history of stem cell transplant has not been established and treatment is not recommended in these patients (package insert).

Referral to Care Coordination

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4.1 Referral to care coordination will be placed to encourage collaboration with medical management to ensure treatment is received at a qualified treatment center and any appropriate follow-up care is provided CPT Codes HCPCS Codes References