Pharmacy Drug Policy & Procedure

Policy Name:	Lenmeldy (atidarsagene autotemcel)	Policy#:	2777P

Purpose of the Policy

The purpose of this policy is to define coverage criteria for Lenmeldy (atidarsagene autotemcel)

Statement of the Policy

Health Alliance Medical Plans will approve the use of Lenmeldy (atidarsagene autotemcel) under the specialty medical benefit if the following criteria are met.

Criteria

1. 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 ≤ 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

2. Exclusion Criteria

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).

3. Approval Period

3.1 One time approval over 6 months

3.2 Limit one infusion per lifetime

4. Referral to Care Coordination

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

1. Lenmeldy (atidarsagene autotemcel) [prescribing information]. Boston, MA: Orchard Therapeutics North America; March 2024.
2. Fumagalli F, et al. Lentiviral haematopoietic stem-cell gene therapy for early-onset metachromatic leukodystrophy: long-term results from a non-randomised, open-label, phase 1/2 trial and expanded access. Lancet. 2022;399(10322):372-383.

Created Date: 10/02/24
Effective Date: 10/02/24
Posted to Website: 10/02/24
Revision Date: