Reference number(s)
6440-A

SPECIALTY GUIDELINE MANAGEMENT

LENMELDY (atidarsagene autotemcel)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Lenmeldy is indicated for the treatment of children with pre-symptomatic late infantile (PSLI), pre-symptomatic early juvenile (PSEJ) or early symptomatic early juvenile (ESEJ) metachromatic leukodystrophy (MLD).

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
Chart notes, medical records, or lab results documenting all of the following:
A. PSLI, PSEJ, or ESEJ classification of MLD.
B. Variant(s) in the *ARSA* gene.
C. Deficiency of arylsulfatase A (ARSA) on biochemical testing.
D. Elevated sulfatide levels based on 24-hour urine collection, if applicable.

III. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a physician who specializes in the treatment of metachromatic leukodystrophy (MLD).

IV. CRITERIA FOR INITIAL APPROVAL

Metachromatic Leukodystrophy (MLD)
Authorization of 3 months for a one-time administration may be granted for treatment of metachromatic leukodystrophy (MLD) when all of the following criteria are met:
A. Member must have one of the following types of MLD:
    1. Pre-symptomatic late infantile (PSLI).
    2. Pre-symptomatic early juvenile (PSEJ).
    3. Early symptomatic early juvenile (ESEJ).
B. The diagnosis was confirmed by all of the following:
    1. Biochemical testing documenting ARSA activity below the normal range for the laboratory performing the test.
    2. The presence of two disease-causing ARSA alleles, either known or novel mutations, identified on genetic testing.
    3. If novel mutations are identified, a 24-hour urine collection showing elevated sulfatide levels.

C. Member has not received Lenmeldy or any other gene therapy previously.
D. Member does not have evidence of residual cells of donor origin if the member has received a prior allogeneic hematopoietic stem cell transplant (allo-HSCT).

V. REFERENCES

1. Lenmeldy [package insert]. Boston, MA: Orchard Therapeutics North America.; March 2024.
2. Gomez-Ospina N. Arylsulfatase A Deficiency. 2006 May 30 [Updated 2024 Feb 8]. In: Adam MP, Feldman J, Mirzaa GM, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2024. Available from: https://www.ncbi.nlm.nih.gov/books/NBK1130/. Accessed March 19, 2024.