MVP Health Care Medical Policy

Medicare Part B: Lenmeldy

Type of Policy:	Medical Therapy (administered by the pharmacy department)
Prior Approval Date:	NA
Approval Date:	06/01/2024
Effective Date:	06/01/2024
Related Policies:	Medicare Part B: Orphan Drug(s) and Biologicals

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

Drugs Requiring Prior Authorization under the medical benefit

J3490 Lenmeldy (Atidarsagene Autotemcel)

Overview

Lenmeldy is an autologous hematopoietic stem cell-based gene therapy 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). MLD is a rare, autosomal recessive, life-limiting lysosomal storage disease. It is caused by mutations in the arylsulfatase A (ARSA) gene or sphingolipid activator protein B (SAPB) gene which leads to accumulation of sulfatides throughout the body. Sulfatides accumulation is toxic to the nervous system and leads to gait abnormalities, speech regression, functional loss, cognitive loss, and seizures. Atidarsagene autotemcel is intended for one time administration to add functional copies of the ARSA gene into the patient's own hematopoietic stem cells (HSCs).

Indications/Criteria

Metachromatic Leukodystrophy

Lenmeldy may be considered for coverage when:

- Member has a confirmed diagnosis of pre-symptomatic late infantile (PSLI) or pre-symptomatic early juvenile (PSEJ) or early symptomatic early juvenile (ESEJ) metachromatic leukodystrophy (MLD). Diagnosis is confirmed by:
    - Genetic confirmation of mutation in ARSA gene
    - Biochemical testing
        - Sulfatase enzyme activity
        - Urinary sulfatide excretion
    - Brain MRI
        - An MRI can show the presence and absence of myelin. Brain injury accumulates as the disease progresses. An initial MRI in pediatric members can appear normal. Pediatric cases with an initial normal MRI will be reviewed on a case-by-case basis.
- Prescribed by or in consultation with Neurologist or Geneticist
- Chart notes documenting that the member does not have liver or renal impairment which is documented with current renal and liver function tests
- Documentation that the member will not receive live vaccines 6 weeks prior to myeloablative conditioning for Lenmeldy and until hematological recovery following treatment with Lenmeldy
- For female members, a negative serum pregnancy test must be confirmed
- Provider confirmation that member will not use prophylactic HIV anti-retroviral medications at least one month prior to mobilization or for the expected direction of time needed for the elimination of the medications.
    - Note: Anti-retroviral medications may interfere with the manufacturing of Lenmeldy
    - Note: if a child requires anti-retrovirals for HIV prophylaxis, initiation of Lenmeldy treatment should be delayed until confirmation of a negative test for HIV.
- Treatment centers administering Lenmeldy must be appropriately certified to do so. Please see link for treatment centers: LENMELDY(TM) (atidarsagene autotemcel) – Now Available
- Provider confirmation that the manufacturer requirement for a collection of unmanipulated back-up $CD34^+$ cells of at least 2.0×10^6 $CD34^+$ cells/kg is met
- Provider confirmation that full myeloablative conditioning would occur prior to Lenmeldy administration
- Chart notes documenting that the member has a current negative screening for the following: HIV-1, HIV-2, HBV, HCV, HTLV-1, HTLV-2, CMV and mycoplasma infection. Documentation must indicate that the member does not have active HIV-1, HIV-2, HBV, HCV, HTLV-1, HTLV-2, CMV and mycoplasma infection.

- Current documentation that the member does not have any active bacterial, viral, fungal, or parasitic infection(s)

Lenmeldy will be approved as a one-time dose within 6 months. Requests for replacement due to lost or damaged product will not be covered. Coverage is contingent on eligibility at the time of infusion.

Exclusions

The use of Lenmeldy will not be covered for the following situations:

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Diagnosis of late juvenile metachromatic leukodystrophy (MLD).
- Members with renal impairment
- Members with hepatic impairment
- Member has been previously treated with Lenmeldy
- Member is pregnant or planning to become pregnant
- Member has tested positive for or has active HIV-1, HIV-2, HBV, HCV, HTLV-1, HTLV-2, CMV and mycoplasma infection
- Members with active bacterial, viral, fungal, or parasitic infections
- Use in combination with other autologous genome edited hematopoietic stem cell-based gene therapies

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References

1. Lenmeldy suspension for intravenous infusion. Orchard Therapeutics. Boston, MA. Revised March 2024. USPI_final_3-18-24.pdf (orchard-tx.com)

2. Metachromatic Leukodystrophy. The Cleveland Clinic. Revised February 6, 2023. Accessed April 23, 2024. Metachromatic Leukodystrophy: What It Is, Causes & Symptoms (clevelandclinic.org)

3. Metachromatic Leukodystrophy. National Organization for Rare Disorders. Reviewed March 18, 2024. Accessed April 23, 2024. Metachromatic Leukodystrophy - Symptoms, Causes, Treatment | NORD (rarediseases.org)