Medical Policy:

Lenmeldy™ (atidarsagene autotemcel) intravenous infusion

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.414	July 31, 2024	July 31, 2024

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Lenmeldy is an autologous hematopoietic stem cell (HSC)–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).

Length of Authorization

Lenmeldy is given as a **one-time dose (once per lifetime)** by IV infusion.

Dosing Limits [Medical Benefit]

Lenmeldy is given as a **one-time dose (once per lifetime)** by IV infusion.
(A single dose of Lenmeldy contains 2 to 11.8× 10^6 cells/mL (1.8 to 11.8 x 10^6 CD34+ cells/mL) suspended in one or more patient-specific infusion bags)
Dosing of Lenmeldy is based on the number of CD34+ cells in the infusion bag(s) per kg of body weight.

- Presymptomatic late infantile: IV infusion: Minimum dose: 4.2×10^6 CD34+ cells/kg as a single dose; maximum dose: 30×10^6 CD34+ cells/kg.
- Presymptomatic early juvenile: IV infusion: Minimum dose: 9×10^6 CD34+ cells/kg as a single dose; maximum dose: 30×10^6 CD34+ cells/kg.
- Early symptomatic early juvenile: IV infusion: Minimum dose: 6.6×10^6 CD34+ cells/kg as a single dose; maximum dose: 30×10^6 CD34+ cells/kg.

Guideline

I. INITIAL CRITERIA

Coverage is provided in the following conditions:

1. Patient age is less than 18 years; **AND**
2. Patient is screened and found to be negative for hepatitis B virus (HBV), hepatitis C virus (HCV), human T-lymphotrophic virus 1 & 2 (HTLV-1/HTLV-2), human immunodeficiency virus 1 & 2 (HIV-1/HIV-2), and mycoplasma infection before collection of cells for manufacturing; **AND**
3. Patient will not be administered vaccinations during the 6 weeks preceding the start of myeloablative conditioning, and until hematological recovery following treatment *(Note: Where feasible, administer childhood vaccinations prior to myeloablative conditioning);* **AND**
4. Patient risk factors for thrombosis as well as veno-occlusive disease have been evaluated prior to administration; **AND**
5. Prophylaxis for infection will be followed according to standard institutional guidelines; **AND**
6. Patient will be monitored for hematological malignancies periodically after treatment; **AND**
7. Patients will not receive prophylactic HIV anti-retroviral therapy for at least one-month preceding mobilization (Note: anti-retrovirals may interfere with manufacturing); **AND**
8. Patient will have mobilization of stem cells using granulocyte-colony stimulating factor (G-CSF with or without plerixafor); **AND**
9. Used as single agent therapy (Note: not inclusive of busulfan conditioning regimen); **AND**
10. Patient has not received a prior allogeneic stem cell transplant (or has, but is without evidence of residual donor cells present), and is a candidate for autologous stem cell transplantation (e.g., adequate renal and hepatic function); **AND**
11. Patient does not have a known 10/10 human leukocyte antigen matched related donor willing to participate in an allogeneic HSCT; **AND**
12. Patient has not received other gene therapy for MLD; **AND**

1. <u>Metachromatic Leukodystrophy (MLD)</u>

A. Patient has a confirmed diagnosis of MLD (also known as arylsulfatase A deficiency) as evidenced by the following biochemical and molecular markers:
   i. Arylsulfatase A (ARSA) enzyme activity below the normal range in peripheral blood mononuclear cells-leukocytes or fibroblasts **OR**
   ii. Increased urinary excretion of sulfatides; **AND**

B. Presence of biallelic ARSA pathogenic mutation of known polymorphisms *(Note: Patients with novel mutations, a 24-hour urine collection must show elevated sulfatide levels);* **AND**

C. Patient has pre-symptomatic late infantile (PSLI), presymptomatic, early juvenile (PSEJ) or early symptomatic early juvenile (ESEJ) disease

Applicable Procedure Codes

Code	Description
J3590	Unclassified biologics

Applicable NDCs

Code	Description
83222-0200-01	Lenmeldy Intravenous Suspension

ICD-10 Diagnoses

Code	Description
E75.25	Metachromatic Leukodystrophy

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	07/31/2024	New Policy

References

1. Lenmeldy™ intravenous infusion [prescribing information]. Boston, MA: Orchard; March 2024.