AvMed

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-877-535-1391**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Lenmeldy™ (atidarsagene autotemcel) **(J3590, C9399) (Medical)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Lenmeldy™ is supplied in one to eight infusion bags which contain 2 to 11.8×10^6 cells/mL (1.8 to 11.8 x 10^6 $CD34^+$ cells/mL) suspended in cryopreservation solution **[NDC 83222-0200-01]**

(Continued on next page)

- The minimum/maximum recommended dose of Lenmeldy™ is based on the number of $CD34^+$ cells in the infusion bag(s) per kg of body weight and MLD disease subtype:

MLD Subtype	Minimum Recommended Dose ($CD34^+$ cells/kg)	Maximum Recommended Dose ($CD34^+$ cells/kg)
Pre-symptomatic late infantile	4.2×10^6	30×10^6
Pre-symptomatic early juvenile	9×10^6	30×10^6
Early symptomatic early juvenile	6.6×10^6	30×10^6

B. Max Units (per dose and over time) [HCPCS Unit]:

- One treatment (dose) per lifetime, 1 billable unit: a single dose of Lenmeldy™, 2 to 11.8×10^6 cells/mL (1.8 to 11.8×10^6 $CD34^+$ cells/mL) suspended in one to eight patient-specific infusion bags

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Coverage will be provided for one treatment course and may NOT be renewed.

- ❑ Medication is prescribed by a hematologist, a neurologist, a medical geneticist physician, or a stem cell transplant specialist physician
- ❑ Member has **ONE** of the following metachromatic leukodystrophy (MLD) phenotypic subtypes and meets all corresponding requirements:
  - ❑ Member has presymptomatic late infantile (PSLI) MLD and meets **ALL** the following **(submit documentation)**:
    - ❑ Member has an arylsulfatase A (*ARSA*) genotype consistent with presymptomatic late infantile MLD
    - ❑ Disease onset was at ≤ 30 months of age
    - ❑ Provider confirms member is presymptomatic [**NOTE**: Presymptomatic status is defined as the absence of neurological signs and symptoms of MLD. However, presymptomatic children are allowed to have abnormal reflexes or abnormalities on brain magnetic resonance imaging and/or nerve conduction tests not associated with functional impairment (e.g., no tremor, no peripheral ataxia)]
  - ❑ Member has presymptomatic early juvenile (PSEJ) MLD and meets **ALL** the following **(submit documentation)**:
    - ❑ Member has an arylsulfatase A (*ARSA*) genotype consistent with presymptomatic early juvenile MLD
    - ❑ Disease onset was between > 30 months and < 7 years of age
    - ❑ Provider confirms member is presymptomatic [**NOTE**: Presymptomatic status is defined as the absence of neurological signs and symptoms of MLD or physical examination findings limited to abnormal reflexes and/or clonus. However, presymptomatic children were allowed to have abnormal reflexes or abnormalities on brain magnetic resonance imaging and/or nerve conduction tests not associated with functional impairment (e.g., no tremor, no peripheral ataxia)]

(Continued on next page)

- ❑ Member has early symptomatic early juvenile (ESEJ) metachromatic leukodystrophy (MLD) and meets **ALL** the following **(submit documentation)**:
  - ❑ Member has an arylsulfatase A (*ARSA*) genotype consistent with early symptomatic early juvenile MLD
  - ❑ Disease onset was between > 30 months and < 7 years of age
  - ❑ Member has early symptomatic status as confirmed by **BOTH** of the following:
    - ❑ Member is walking independently as defined as being at gross motor function classification for metachromatic leukodystrophy [GMFC-MLD] Level 0 (with or without ataxia) or GMFC-MLD Level 1
    - ❑ Member has an intelligence quotient ≥ 85
- ❑ Member has **NOT** received Lenmeldy™ in the past **(verified by medical paid claims)** [**NOTE**: If no claim for Lenmeldy™ is present (or if claims history is not available), the prescribing physician confirms that the member has not previously received Lenmeldy™]
- ❑ Member has low arylsulfatase A (*ARSA*) activity indicative of metachromatic leukodystrophy (MLD) (submit documentation) [**NOTE**: Normal laboratory reference range for *ARSA* activity in the peripheral blood mononuclear cells is 31 to 198 nmol/mg/hour. In patients with MLD, *ARSA* activity is 0% to less than or equal to 13%]
- ❑ Member has elevated sulfatide levels above the normal laboratory reference range as evaluated by 24-hour urine collection **(submit documentation)**
- ❑ According to the prescribing physician, a hematopoietic stem cell transplantation is appropriate for the member
- ❑ According to the prescribing physician, member meets **ALL** the following:
  - ❑ Member will undergo mobilization, apheresis, and myeloablative conditioning
  - ❑ A granulocyte-colony stimulating factor product with or without a hematopoietic stem cell mobilizer will be utilized for mobilization [**NOTE**: Filgrastim products are examples of a granulocyte-colony stimulating factor therapy and Mozobil® (plerixafor subcutaneous injection) is an example of a hematopoietic stem cell mobilizer]
  - ❑ Busulfan will be used for myeloablative conditioning
- ❑ Prior to collection of cells for manufacturing, member cellular screening is negative for **ALL** the following **(submit documentation)**:
  - ❑ Human immunodeficiency virus (HIV)-1 and HIV-2
  - ❑ Hepatitis B virus
  - ❑ Hepatitis C virus
  - ❑ Human T-lymphotrophic virus (HTLV)-1 and HTLV-2
  - ❑ Cytomegalovirus
  - ❑ Mycoplasma
- ❑ Member's current body weight has been obtained within 30 days **(submit documentation)**

(Continued on next page)

Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy – Proprium Rx**

For urgent reviews: Practitioner should call AvMed Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. AvMed's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.*