SENTARA HEALTH PLANS

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 1-844-668-1550**. 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 Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

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

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

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

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

Weight: _____ **Date:** _____

❑ 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]**

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- 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.

- ❑ Member is less than 18 years of age
- ❑ Provider is a specialist in treating patients with metachromatic leukodystrophy (MLD), and/or in multidisciplinary consultation with pediatric neurology, geneticist, physical medicine/rehabilitation, behavioral health specialty, etc.
- ❑ Member has a confirmed diagnosis of MLD (also known as arylsulfatase A deficiency) as evidenced by **ALL** the following biochemical and molecular markers **(NOTE: laboratory documentation and genetic panel results must be submitted with this request)**:
  - ❑ Arylsulfatase A (ARSA) enzyme activity below the normal range in peripheral blood mononuclear cells-leukocytes or fibroblasts
  - ❑ Increased urinary excretion of sulfatides in a 24-hour urine collection
  - ❑ Presence of biallelic ARSA pathogenic mutation of known polymorphisms
- ❑ Provider has performed initial evaluation and has attained all past medical records to confirm and detail the applicable MLD phenotypic subtype and corresponding requirements below:
  - ❑ **PRE-SYMPTOMATIC LATE INFANTILE (PSLI, DEFINED AS ≤ 30 MONTHS)**
    - ❑ Member is absent of disease-related symptoms or neurological examination findings of MLD
  - ❑ **PRE-SYMPTOMATIC, EARLY JUVENILE (PSEJ, DEFINED AS > 30 MONTHS AND < 7 YEARS OF AGE)**
    - ❑ Member must meet **ONE** of the following:
      - ❑ Member is absent of neurological signs and symptoms of MLD
      - ❑ Physical exam findings are limited to abnormal reflexes and/or clonus

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- ❑ **EARLY SYMPTOMATIC, EARLY JUVENILE (ESEJ, DEFINED AS > 30 MONTHS AND < 7 YEARS OF AGE)**
  - ❑ Member's symptomatic status defined as walking independently (Gross Motor Function Classification (GMFC)–MLD Level 0 with ataxia or GMFC–MLD Level 1) **AND** IQ ≥ 85 **(NOTE: submission of cognitive testing and completed gross motor function measure instrument with score and functional class level correlation required)**
- ❑ Member risk factors for thrombosis as well as veno-occlusive disease have been evaluated prior to administration
- ❑ Member has been 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
- ❑ Provider will ensure that the member will **NOT** receive prophylactic HIV anti-retroviral therapy for at least one-month preceding mobilization (NOTE: anti-retrovirals may interfere with manufacturing)
- ❑ Prophylaxis for infection will be followed according to standard institutional guidelines
- ❑ Member 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)
- ❑ Member will have mobilization of stem cells using granulocyte-colony stimulating factor (G-CSF with or without plerixafor)
- ❑ Member will receive Lenmeldy™ as single agent therapy (NOTE: not inclusive of busulfan conditioning regimen)
- ❑ Provider has performed initial evaluation and attained all past medical records to confirm **ONE** of the following patient variables on stem cell transplant history:
  - ❑ Member has **NOT** received a prior allogeneic stem cell transplant
  - ❑ Member has received a prior allogeneic stem cell transplant and the provider has performed the adequate laboratory work to confirm the member is without evidence of residual donor cells present **(NOTE: laboratory documentation required for request submission)**
- ❑ Member is a candidate for autologous stem cell transplantation (e.g., adequate renal and hepatic function)
- ❑ Member has **NOT** received other gene therapy to treat metachromatic leukodystrophy

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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 Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan'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.