Atidarsagene Autotemcel (Lenmeldy)

Prior Authorization Form/Prescription

peach state health plan

Telephone: (800) 514-0083 option 2
Fax: (866) 374-1579

Date: _____ Date Medication Required: _____
Ship to: ❍ Physician ❍ Patient's Home ❍ Other _____

Patient Information

*Last Name:	*First Name:	Middle:	*DOB: ____/____/_____
Daytime Phone:	Evening Phone:	*Sex: ☐ Male ☐ Female	

Insurance Information (*Attach copies of cards*)

*Primary Insurance:		Secondary Insurance:	
*ID #:	Group #:	ID #:	Group #:

Physician Information

*Name:	*Specialty:	NPI:
*Phone #:	Secure Fax #:	Office Contact:

Procedural Hospital

*Hospital Name:

Primary Diagnosis

*ICD-10 Code: _____

☐Metachromatic Leukodystrophy (MLD) ☐Other: _____

Prescription Information

MEDICATION	STRENGTH	*DIRECTIONS	QUANTITY	REFILLS
Lenmeldy (Atidarsagene Autotemcel)				

Clinical Information ***** *Please submit supporting clinical documentation* *****

* **THERAPY TYPE (choose one):** ☐INITIAL THERAPY ☐CONTINUATION OF THERAPY

Therapy start date: _____

If prescribed dose exceeds the FDA maximum recommended dose, please submit supporting practice guidelines/peer-reviewed literature

1. Is therapy prescribed by or in consultation with a medical geneticist or neurologist? ☐Yes ☐No
2. Is MLD confirmed by the following? ☐Yes ***Mark all that apply*** ☐No
   - ☐Arylsulfatase A (ARSA) activity below the normal range in peripheral blood mononuclear cells or fibroblasts
   - ☐Presence of two disease-causing mutations of either known or novel alleles
   - ☐Presence of sulfatides in a 24-hour urine collection
   - ☐Other: _____
3. Does patient have 1 of the following forms of MLD? ☐Yes ***Mark all that apply*** ☐No
   - ☐Late infantile: pre-symptomatic (patients without neurological impairment (disease-related symptoms))
   - ☐Early juvenile: pre- or early-symptomatic (IQ ≥ 70 and the ability to walk independently for ≥ 10 steps)
   - a. *If yes*, do any of the following apply to patient? ☐Yes ***Mark all that apply*** ☐No
     - ☐Age at onset of symptoms in patient ≤ 30 months
     - ☐Age at onset of symptoms in older sibling(s) ≤ 30 months
     - ☐Age at onset of symptoms in older sibling(s) ≤ 30 months & < 7 years
     - ☐Peripheral neuropathy at electroneurography (ENG) study
     - ☐Peripheral neuropathy at electroneurography (ENG) study with null (0) or residual (R) alleles referring to either known or novel mutations
     - ☐2 null (0) mutant ARSA alleles
     - ☐1 null (0) and 1 residual (R) mutant ARSA alleles
4. Does patient have clinical manifestations of the disease? ☐Yes ***Answer a and b below*** ☐No
   - a. How many steps can the patient walk independently? ☐0-9 ☐≥ 10
   - b. Does the patient have cognitive decline (intelligence quotient (IQ) ≥ 70? ☐Yes IQ: _____ ☐No
5. Has patient previously received either of the following? ☐Yes ***Mark all that apply*** ☐No
   - ☐Hematopoietic stem cell gene therapy ☐Allogeneic transplant
6. How many Lenmeldy infusions has the patient received? ☐0 ☐1 ☐2+

Complete this section ONLY for indications <u>other</u> than MLD:

7. Has patient tried and failed, or is contraindicated to, accepted standards of care? ☐Yes ☐No
   If yes, submit documentation and answer the following:

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a. Please list all previous therapies: _____

Please continue to page 2.

Patient Name: _____ **DOB:** _____

b. Was patient adherent to previously tried therapies? ☐Yes ☐No ☐No, patient intolerant to drug

Physician's Signature: _____ **Date:** _____ ☐DAW

INFORMATION BELOW IS TO BE COMPLETE BY THE HEALTH PLAN/ CPS PA STAFF

Authorization Information

***Authorization number:**	***Decision Due Date:**
***J-Code:**	***Coverage:** ☐ State excludes ☐ COB (secondary)
* **Line of Business:** ☐ Commercial ☐ Health Insurance Marketplace ☐ Medicaid ☐ Medicare	* **Benefit:** ☐ Medical ☐ Pharmacy

*** Choose one criteria option below based on line of business:**

Medicare Criteria Only:

☐ Medicare Local Coverage Decision (LCD) specific for your region
Please include policy of link to LCD, followed by any applicable Medicare Part B step therapy requirements in MCPB.ST.00. _____

☐ Medicare National Coverage Decision (NCD).
Please include policy of link to NCD, followed by any applicable Medicare Part B step therapy requirements in MCPB.ST.00. _____

Medicaid, Commercial, Exchange (Ambetter) Criteria:

☐ Centene Policy [**CP.PHAR.602 Atidarsagene Autotemcel (Lenmeldy)**]
Date Policy last reviewed/approved by plan (we want to be sure we are using the version approved by your plan):
_____

OR

☐ State or Health Plan Specific (please include policy) _____