ambetter. FROM peach state health plan

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

Atidarsagene Autotemcel (Lenmeldy)
PDAC Drug Review Form

The information below can be completed by the Health Plan and/or Centene Pharmacy Services (CPS) staff

Patient Information

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

Insurance Information

*Primary Insurance (Health Plan Name and State)	*ID #:

Physician Information

*Name:	*Specialty:	*Phone #:

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 Start Date**: _____

1. Is therapy prescribed by or in consultation with a medical geneticist, neurologist, or physician specialized in bone marrow transplantation (e.g., hematologist/oncologist)? ☐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 2 disease-causing mutations of either known or novel alleles
   - ☐If novel alleles identified, elevated sulfatide levels in a 24-hour urine collection
   - ☐Other: _____
3. What age was the patient's onset of symptoms? ☐< 7 ☐> 7
4. What age was the patient's older siblings onset of symptoms? ***Mark all that apply*** ☐≤ 30 months ☐< 7 ☐> 7
5. Does patient have pre-symptomatic late infantile (PSLI), pre-symptomatic earl juvenile (PSEJ), or early symptomatic early juvenile (ESEJ) form of MLD as defined by any of the following? ☐Yes ***Mark all that apply*** ☐No
   - ☐2 null (0) mutant ARSA alleles
   - ☐Abnormal reflexes
   - ☐Peripheral neuropathy at electroneurography (ENG) study
   - ☐Without neurological impairment (disease-related symptoms)
   - ☐Peripheral neuropathy at ENG study with null (0) or residual (R) alleles referring to either known or novel mutations
   - ☐Abnormalities on brain magnetic resonance imaging abnormalities on nerve conduction tests not associated with functional impairment (e.g., no tremor, no peripheral ataxia)
6. Please provide the following patient information:
   a. Intelligence quotient (IQ): _____
   b. Weight: _____ kg
7. Please indicate patient's ability to walk independently as defined by gross motor function classification for MLD (GMFC-MLD)?
   - ☐Walking without support quality of performance normal for age
   - ☐Walking without support but with reduced quality of performance
   - ☐Walking with support, walking without support not possible
   - ☐Sitting without support and locomotion such as crawling or rolling, walking without support not possible
   - ☐Sitting without support but no locomotion or sitting without support not possible but locomotion such as crawling or rolling
   - ☐No locomotion nor sitting without support but head control is possible
   - ☐Loss of any locomotion as well as loss of any head and trunk control
8. Has patient previously received hematopoietic stem cell gene therapy? ☐Yes ☐No
9. Has patient previously received allogeneic hematopoietic stem cell transplant? ☐Yes ***Answer a and b below*** ☐No
   a. Has it been > 6 months since the transplant? ☐Yes ☐No

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b. Is there evidence of residual cells of donor origin? ☐Yes ☐No
10. How many Lenmeldy infusions has the patient received? ☐0 ☐1 ☐2+

Please continue to page 2.

Patient Name: _____ **DOB**: _____

Complete this section ONLY for indications other than MLD:

11. Has patient tried and failed, or is contraindicated to, accepted standards of care? ☐Yes ☐No

If yes, submit documentation and answer the following:

a. Please list all previous therapies: _____
b. Was patient adherent to previously tried therapies? ☐Yes ☐No ☐No, patient intolerant to drug

Information	
***Number**:	***Date of Request**:
***HCPCS Code**:	***Decision Due Date**:
* **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)