ambetter. FROM peach state health plan

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

Elivaldogene autotemcel (Skysona)
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:

☐ Cerebral adrenoleukodystrophy (CALD) ☐ Other: _____

Prescription Information

MEDICATION	STRENGTH	*DIRECTIONS	QUANTITY	REFILLS
Skysona (Elivaldogene autotemcel)				

Clinical Information

***** *Please submit supporting clinical documentation* *****

* **THERAPY Start Date**: _____

1. Is therapy prescribed by or in consultation with a neurologist and a transplant specialist? ☐Yes ☐No
2. Is CALD confirmed by the following? ☐Yes ****Mark all that apply**** ☐No
   - ☐Genetic confirmation of ABCD1 mutation
   - ☐Elevated levels of very long chain fatty acids (VLCFA): _____ µmol/L or _____ : _____ ratio
3. Is patient a biologic male? ☐Yes ☐No
4. Please provide patient's weight: _____ kg
5. Is early, active CNS disease established by brain MRI demonstrating the following? ☐Yes ****Mark all that apply**** ☐No
   - ☐Loes score ≥ 0.5 and ≤ 9 on the 34-point scale: _____ Loes score
   - ☐Gadolinium enhancement of demyelinating lesions on MRI ☐Other: _____
6. Does patient have a neurologic function score (NFS) ≤ 1? ☐Yes: _____ ☐No
7. Does patient have no available HLA (human leukocyte antigen)-matched (i.e., full HLA-matching of all evaluated alleles) donor? ☐Yes ☐No
8. Does patient have an available HLA-matched donor? ☐Yes ****Answer a and b below**** ☐No
   a. Is there medical rationale that allogeneic hematopoietic stem cell transplantation (HSCT) is not feasible (e.g., donor unable to undergo donation procedure because of medical impairments? ☐Yes ****Submit documentation**** ☐No
   b. Does patient understand the risks and benefits of alternative therapeutic options such as allogeneic HSCT? ☐Yes ☐No
9. Does transplant specialist attest that patient is clinically stable and eligible to undergo myeloablative conditioning and HSCT? ☐Yes ☐No
10. Has patient received prior allogeneic HSCT? ☐Yes ☐No
11. Has patient received prior gene therapy? ☐Yes ☐No
12. Does patient have isolated pyramidal tract disease? ☐Yes ☐No
    a. *If yes*, does hematology specialist attest to the following? ☐Yes ****Mark all that apply**** ☐No
       - ☐Patient understands the potential increased risk of malignancy associated with Skysona treatment
       - ☐Applicable hematology assessments have been performed: _____
13. Is patient positive for the presence of HIV type 1 or 2? ☐Yes ☐No
14. How many Skysona infusions has patient received? ☐0 ☐1 ☐>1

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Complete this section ONLY for indications other than cerebral adrenoleukodystrophy:

15. 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

Please continue to page 2.

Patient Name: _____ **DOB**: _____

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.556 Elivaldogene autotemcel (Skysona)]**

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)