ambetter. FROM peach state health plan

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

Lovotibeglogene Autotemcel (Lyfgenia)
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: _____

☐ Sickle cell disease (SCD) ☐ Other: _____

Prescription Information

MEDICATION	STRENGTH	*DIRECTIONS	QUANTITY	REFILLS
Lyfgenia (Lovotibeglogene Autotemcel)				

Clinical Information

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

* **THERAPY Start Date**: _____

1. Is therapy prescribed by or in consultation with a hematologist and transplant specialist?
   ☐ Yes, hematologist and transplant specialist ☐ Yes, hematologist ☐ Yes, transplant specialist ☐ No
2. Please provide the following patient information:
   a. Genotype ***Mark all that apply*** ☐ β^S/β^S ☐ β^S/β^0 ☐ β^S/β^+ ☐ Other: _____
   b. Weight: _____ kg
3. Is there documentation of ≥ 4 severe vaso-occlusive events (VOEs) within the past 24 months?
   ☐ Yes ***Mark all that apply*** ☐ No
   ☐ Acute chest syndrome (ACS) ☐ Acute hepatic sequestration ☐ Acute splenic sequestration
   ☐ An episode of acute pain lasting > 2 hours with no medically determined cause other than vaso-occlusion
   ☐ Priapism required any level of medical attention
   a. *If* yes, did patient require hospitalization or multiple visits to an emergency department/urgent care over 72 hours and received intravenous medications at each visit? Yes ☐ No
4. Has patient failed hydroxyurea at up to the maximally indicated dose for ≥ 6 months?
   ☐ Yes ☐ No ☐ Contraindicated/intolerant
   a. *If contraindicated/intolerant*, please describe: _____
5. Does transplant specialist attest patient understands the risk and benefits of alternative therapeutic options such as allogenic hematopoietic stem cell transplantation (HSCT)? ☐ Yes ☐ No
6. Does transplant specialist attest patient is clinically stable and eligible to undergo myeloablative conditioning and HSCT?
   ☐ Yes ☐ No
7. Has patient received prior allogenic HSCT? ☐ Yes ☐ No
8. Has patient received prior allogenic gene therapy? ☐ Yes ☐ No
9. Does patient have 2 α-globin gene deletions (e.g., alpha-thalassemia trait)? ☐ Yes ☐ No
10. Is there documentation from within the last 6 months that patient is negative for the presence of the following active infections?
    ☐ Yes ***Mark all that apply*** ☐ No
    ☐ HIV ☐ Hepatitis B virus ☐ Hepatitis C virus
11. Does the patient have any advanced liver disease? ☐ Yes ***Mark all that apply*** ☐ No
    ☐ Cirrhosis ☐ Bridging or significant fibrosis ☐ Active hepatitis

☐ Baseline prothrombin time or partial thromboplastin time >1.5x ULN
☐ Persistent aspartate transaminase, alanine transaminase, or direct bilirubin value >3x the upper limit of normal (ULN)

12. Does patient have current malignancy or immunodeficiency disorder? ☐ Yes ☐ No

Please continue to page 2.

Patient Name: _____ **DOB:** _____

13. How many Lyfgenia infusions has patient received? ☐ 0 ☐ ≥ 1

Complete this section ONLY for indications other than SDC:

14. 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.627 Lovotibeglogene Autotemcel (Lyfgenia)**]
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)