ambetter. FROM peach state health plan

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

Exagamglogene Autotemcel (Casgevy)
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:

☐Transfusion-Dependent β-Thalassemia (TDT) ☐ Sickle cell disease (SCD) ☐Other: _____

Prescription Information

MEDICATION	STRENGTH	*DIRECTIONS	QUANTITY	REFILLS
Casgevy (Exagamglogene 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 indicate patient's genotype. ***Mark all that apply***
   ☐β^0/β^0 ☐β^+/β^+ ☐β^0/β^+ (not IVS-1-110) ☐β^0/β^+ (IVS1-110) ☐β^E/β^+ ☐β^E/β^0 ☐β^S/β^S ☐β^S/β^0
   ☐Other: _____
3. Please provide patient's weight: _____ kg
4. Does transplant specialist attest patient understands the risk and benefits of alternative therapeutic options such as allogenic hematopoietic stem cell transplantation (HSCT)? ☐Yes ☐No
5. Does transplant specialist attest patient is clinically stable and eligible to undergo myeloablative conditioning and HSCT?
   ☐Yes ☐No
6. Has patient received prior allogenic HSCT? ☐Yes ☐No
7. Has patient received prior gene therapy? ☐Yes ☐No
8. How many Exa-Cel infusions has patient received? ☐0 ☐1 or more
9. Is there documentation that patient is negative for the presence of the following active infections within the last 6 months?
   ☐Yes ***Mark all that apply*** ☐No
   ☐HIV ☐Hepatitis B virus ☐Hepatitis C virus
10. Is patient negative for advanced liver disease? ☐Yes ***Mark all that apply*** ☐No
    ☐Cirrhosis ☐Bridging or significant fibrosis ☐Active hepatitis
    ☐Persistent aspartate transaminase, alanine transaminase, or direct bilirubin value >3x the upper limit of normal (ULN)
    ☐Baseline prothrombin time or partial thromboplastin time >1.5x ULN ☐Other: _____
11. Does patient currently have malignancy or immunodeficiency disorder?
    ☐Yes, malignancy ☐Yes, immunodeficiency disorder ☐No
12. **For TDT**,
    a. Is there documentation of receipt of ≥ 100 mL/kg or 10 units of packed red blood cells (pRBC) per year during the previous 2 years?
       ☐Yes ***Answer i and ii below*** ☐No
       1. Date: _____ , _____ mL/kg or _____ units pRBC
       2. Date: _____ , _____ mL/kg or _____ units pRBC
    b. Is there documentation of ≥ 8 transfusions of pRBC per year for the previous two years?
       ☐Yes ***Answer i and ii below*** ☐No
       1. Date: _____ , _____ mL/kg or _____ units pRBC

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2. Date: _____ , _____ mL/kg or _____ units pRBC

c. Does patient have any of the following? ☐Yes ***Mark all that apply*** ☐No
☐Associated α-thalassemia and ≥ 1 alpha chain deletion ☐Alpha multiplications ☐Associated sickle cell β-thalassemia

Please continue to page 2.

Patient Name: _____ **DOB:** _____

13. **For SCD**,

a. Is there documentation of ≥ 2 severe vaso-occlusive episodes per year during the previous 2 years?
☐Yes ***Mark all that apply*** ☐No
☐Acute chest syndrome (ACS) date: _____ and _____ episodes
☐Priapism lasting > 2 hours and requiring a visit to a medical facility date: _____ and _____ episodes
☐Splenic sequestration date: _____ and _____ episodes
☐Hepatic sequestration date: _____ and _____ episodes
☐Acute pain event that requires a visit to a medical facility and administration of pain medications (e.g., opioids or intravenous NSAIDS) or packed red blood cell (pRBC) transfusions date: _____ and _____ episodes

b. Has patient failed hydroxyurea at up to the maximally indicated dose for ≥ 6 months?
☐Yes ☐No ☐Contraindicated/intolerant: _____

Complete this section ONLY for indications other than TDT or SCD:

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.603 Exagamglogene Autotemcel (Casgevy)**]
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)