SENTARA COMMUNITY PLAN
(MEDICAID)

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-305-2331**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

Drug Requested: Casgevy™ (exagamglogene autotemcel) (J3392) (Medical) β - Thalassemia

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

- ❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Dosing Limits

A. **Quantity Limit (max daily dose) [NDC Unit]:**

- Casgevy is supplied in one or more vials (one carton contains a single lot consisting of 1 to 9 vials) containing a frozen suspension of genome edited autologous CD34+ cells in a cryo-preservative medium containing 5% DMSO and dextran 40 **[NDC 51167-290-09]**
- The minimum recommended dose of Casgevy is 3×10^6 CD34+ cells per kg of body weight

B. **Max Units (per dose and over time) [HCPCS Unit]**:

- One treatment (dose) per lifetime

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Authorization Criteria: Coverage will be provided for one treatment course (1 dose of Casgevy) and may NOT be renewed.

- ❑ Member is 2 years of age or older
- ❑ Member has a documented diagnosis of homozygous beta thalassemia or compound heterozygous beta thalassemia including β-thalassemia/hemoglobin E (HbE) as outlined by **ONE** of the following:
  - ❑ Diagnosis is confirmed by HBB sequence gene analysis showing biallelic pathogenic variants
  - ❑ Member has severe microcytic hypochromic anemia, absence of iron deficiency, anisopoikilocytosis with nucleated red blood cells on peripheral blood smear, and hemoglobin analysis that reveals decreased amounts or complete absence of hemoglobin A (HbA) and increased HbA2 with or without increased amounts of hemoglobin F (HbF);
- ❑ Member has transfusion-dependent disease defined as a history of transfusions of at least 100 mL/kg/year of packed red blood cells (pRBCs) or ≥10 units/year of packed red blood cells (pRBCs) in the 2 years preceding therapy
- ❑ Member will be transfused prior to apheresis to a total Hb ≥ 11 g/dL for 60 days prior to myeloablative conditioning
- ❑ Member does **NOT** have any of the following:
  - ❑ Severely elevated iron in the heart (i.e., patients with cardiac T2* less than 10 msec by magnetic resonance imaging [MRI], or left ventricular ejection fraction [LVEF] < 45% by echocardiogram)
  - ❑ Advanced liver disease (i.e., AST or ALT > 3 times the upper limit of normal [ULN], or direct bilirubin value > 2.5 times the ULN, or if a liver biopsy demonstrated bridging fibrosis or cirrhosis)

Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy – PropriumRx**

For urgent reviews: Practitioner should call Sentara Health Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****

***Approved by Pharmacy and Therapeutics Committee**: 3/21/2024
REVISED/UPDATED/REFORMATTED: ~~5/15/2024; 6/8/2026;~~ **9/3/2026**