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) **(J3590/C9399) (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:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

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

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

Weight: _____ **Date:** _____

☐ 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 ≥ 12 years of age
- ❑ Treating specialist(s) will be familiar with treating patients with β-thalassemia, and knowledgeable in conducting safe autologous stem cell transplant procedures
- ❑ 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:
  - ❑ Documentation of HBB sequence gene analysis showing biallelic pathogenic variants **[NOTE: α-thalassemia and hemoglobin S/ß-thalassemia variants are excluded from service authorization]**
  - ❑ Medical chart recording 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 **[NOTE: Detailed medical records of transfusion program/schedule recording dates of administration and volume administered are required. Last two (2) years of records MUST be provided]**
- ❑ Member has been screened and found negative for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus 1 & 2 (HIV-1/HIV-2) in accordance with clinical guidelines prior to collection of cells (leukapheresis)
- ❑ Provider must submit documentation to confirm the 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 **[Alanine transaminase (ALT) >3 × the upper limit of normal (ULN) or direct bilirubin value >2.5 × ULN; Baseline prothrombin time (PT) (international normalized ratio [INR]) >1.5 × ULN; History of cirrhosis or any evidence of bridging fibrosis, or active hepatitis on liver biopsy]**
- ❑ Member does **NOT** have a history of hypersensitivity to dimethyl sulfoxide (DMSO) or dextran 40
- ❑ Females of reproductive potential have a negative pregnancy test prior to start of mobilization and re-confirmed prior to conditioning procedures and again before administration of exagamglogene autotemcel
- ❑ Females of childbearing potential and males capable of fathering a child must use effective method of contraception from start of mobilization through at least 6 months after administration of exagamglogene autotemcel

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- ❑ Member is of sufficient weight to at least accept the minimum number of cells required to initiate the manufacturing process
- ❑ Requested medication will be used as single agent therapy (not applicable to lymphodepleting or bridging therapy while awaiting manufacture)
- ❑ Member will receive periodic life-long monitoring for hematological malignancies
- ❑ Member is eligible to undergo hematopoietic stem cell transplant (HSCT) and has **NOT** had prior HSCT or other gene therapy
- ❑ Member has **NOT** received other gene therapies to treat β-thalassemia [e.g., Zynteglo® (betibeglogene autotemcel)]
- ❑ Provider must submit an assessment documenting a Karnofsky performance status of ≥ 80%
- ❑ Member does **NOT** have availability of a willing 10/10 HLA-matched sibling donor

Medication being provided by: Please check applicable box below.

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

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy – Proprium Rx**

For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan'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.****