SENTARA HEALTH PLANS

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 1-844-668-1550**. 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**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Zynteglo™ (betibeglogene autotemcel) **(J3393) (Medical)**

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]:

- Zynteglo™ up to 4 infusion bags, 20 mL/infusion bag, overwrap, and metal cassette: 73554-3111-xx
- A single dose of Zynteglo™ containing a minimum of 5.0×10^6 CD34+ cells/kg of body weight, in one or more infusion bags

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

- A single dose of Zynteglo™ containing a minimum of 5.0×10^6 CD34+ cells/kg of body weight, in one or more infusion bags

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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.

Coverage will be provided for one treatment course and may NOT be renewed.

- ❑ Member is ≥ 4 years of age
- ❑ Medication is prescribed by a hematologist or a stem cell transplant physician
- ❑ Member has **NOT** received a gene therapy for beta-thalassemia in the past **(verified by medical paid claims)** [**NOTE**: If no claim for Zynteglo™ or Casgevy® (exagamglogene autotemcel intravenous infusion) is present (or if claims history is not available), the prescribing physician confirms that the member has not previously received Zynteglo™ or Casgevy®]
- ❑ According to the prescribing physician, a hematopoietic stem cell transplantation is appropriate for the member
- ❑ Member meets **ONE** of the following:
  - ❑ Member does **NOT** have a Human Leukocyte Antigen (HLA)-matched donor
  - ❑ Member has an HLA-matched donor, but the individual is not able or is not willing to donate
- ❑ Member has **ONE** of the following genotypes as confirmed by genetic testing **(submit documentation)**:
  - ❑ Non-β^0/β^0 genotype (e.g., β^0/β^+, β^E/β^0, and β^+/β^+)
  - ❑ β^0/β^0 genotypes (e.g., $\beta^0/\beta^{+(IVS\text{-}I\text{-}110)}$ and $\beta^{+(IVS\text{-}I\text{-}110)}/\beta^{+(IVS\text{-}I\text{-}110)}$)
- ❑ Member is transfusion-dependent, as defined by meeting **ONE** of the following **(submit documentation)**:
  - ❑ Receipt of transfusions of ≥ 100 mL of packed red cells per kg of body weight per year in the previous 2 years
  - ❑ Receipt of transfusions eight or more times per year in the previous 2 years
- ❑ Member meets **BOTH** of the following **(submit documentation)**:
  - ❑ Member has been evaluated for the presence of severe iron overload
  - ❑ Member does **NOT** have evidence of severe iron overload [**NOTE**: Examples include abnormal myocardial iron results (a T2*-weighted magnetic resonance imaging measurement of myocardial iron of less than 10 msec), high liver iron concentration (≥ 15 mg/g), liver biopsy results suggest abnormalities, or clinical evidence of organ damage (e.g., endocrine comorbidities)]
- ❑ Member does **NOT** currently have an active bacterial, viral, fungal, or parasitic infection
- ❑ Member does **NOT** have any of the following:
  - Prior or current malignancy, myeloproliferative disorder, or significant immunodeficiency disorder [**NOTE**: This does not include adequately treated cone biopsied in situ carcinoma of the cervix uteri and basal or squamous cell carcinoma of the skin]
  - Advanced liver disease **(submit documentation)** [**NOTE**: Examples include alanine transaminase or aspartate transaminase greater than three times upper limit of normal, direct bilirubin value greater than three times upper limit of normal, active hepatitis, extensive bridging fibrosis, or cirrhosis]

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- ❑ According to the prescribing physician, member will have been discontinued from iron chelation therapy for at least 7 days prior to myeloablative conditioning [**NOTE**: Examples of iron chelators used for this condition include deferoxamine injection, deferiprone tablets or solution, and deferasirox tablets]
- ❑ According to the prescribing physician, member meets **ALL** the following:
  - ❑ Member will undergo mobilization, apheresis, and myeloablative conditioning
  - ❑ A granulocyte-colony stimulating factor product and a hematopoietic stem cell mobilizer will be utilized for mobilization [**NOTE**: Filgrastim products are examples of a granulocyte-colony stimulating factor therapy and Mozobil® (plerixafor subcutaneous injection) is an example of a hematopoietic stem cell mobilizer]
  - ❑ Busulfan will be used for myeloablative conditioning
  - ❑ Total hemoglobin level is ≥ 11.0 g/dL at **BOTH** of the following timepoints:
    - ❑ Prior to mobilization
    - ❑ Prior to myeloablative conditioning
- ❑ Prior to collection of cells for manufacturing, member cellular screening is negative for **ALL** the following **(submit documentation)**:
  - ❑ Human immunodeficiency virus-1 and -2
  - ❑ Hepatitis B virus
  - ❑ Hepatitis C virus
  - ❑ Human T-lymphotropic virus-1 and -2
- ❑ According to the prescribing physician, member meets **ONE** of the following:
  - ❑ Member is a female of reproductive potential and meets **BOTH** of the following:
    - ❑ A negative serum pregnancy test will be confirmed prior to the start of mobilization and re-confirmed prior to myeloablative conditioning
    - ❑ Member will use an effective method of contraception from the start of mobilization through at least 6 months after administration of Zynteglo™
  - ❑ Member is a male of reproductive potential and will use an effective method of contraception from the start of mobilization through at least 6 months after administration of Zynteglo™
- ❑ Member's current body weight has been obtained within 30 days **(submit documentation)**

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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.

***Approved by Pharmacy and Therapeutics Committee**: ~~11/18/2022;~~ ~~9/26/2024;~~ **1/23/2025**
REVISED/UPDATED/REFORMATTED: ~~11/29/2022; 10/15/2024;~~ **01/02/2025**