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: Zynteglo® (betibeglogene autotemcel) **(J3590/C9399) (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.

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.

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

- ❑ Member is at least 4 years of age
- ❑ Treating specialist(s) will be familiar with treating patients with beta thalassemia, and knowledgeable in conducting safe autologous stem cell transplant procedures
- ❑ Member has a documented diagnosis of beta thalassemia (excludes alpha-thalassemia and hemoglobin S/ß-thalassemia variants) as outlined by at least **ONE** of the following:
  - ❑ Member 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 HbA_2 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 with 8 or more transfusions of pRBCs per year 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)**
- ❑ **ALL** the following have been assessed, and confirmation is noted that 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])
  - Advanced liver disease
  - MRI of the liver with results demonstrating liver iron content ≥ 15 mg/g (unless biopsy confirms absence of advanced disease)
- ❑ Member is of sufficient weight to at least accept the minimum number of cells required to initiate the manufacturing process
- ❑ Member has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), human T-lymphotrophic virus 1 & 2 (HTLV-1/HTLV-2), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis)
- ❑ Member has **NOT** used prophylactic HIV anti-retroviral medication or hydroxyurea within 30 days prior to mobilization (or for the expected duration for elimination of those medications) and until all cycles of apheresis are completed **(Note: if a patient requires anti-retrovirals for HIV prophylaxis, confirm a negative test for HIV before beginning mobilization)**

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- ❑ Iron chelation therapy has been discontinued for at least 7 days prior to initiating myeloablative conditioning therapy and myelosuppressive iron chelators will be avoided for 6 months post-treatment
- ❑ 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 betibeglogene autotemcel
- ❑ 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 does **NOT** have availability of a willing 10/10 HLA-matched sibling donor
- ❑ Member has **NOT** received other gene therapies for the treatment of beta thalassemia

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.