RX.PA.071.CCH Zynteglo (betibeglogene autotemcel)

The purpose of this policy is to define the prior authorization process for Zynteglo (betibeglogene autotemcel) for the treatment of adult and pediatric patients with β-thalassemia who require regular red blood cell (RBC) transfusions.

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.

The drug, Zynteglo (betibeglogene autotemcel), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all the criteria listed under the respective diagnosis:

- Must be prescribed by, or in consultation with, a hematologist or transplant specialist
- Member is ≥ 4 years of age and < 65 years of age
- Must have a diagnosis of β-thalassemia confirmed by genetic testing
- Must be transfusion dependent as evidenced by ONE of the following occurring within the last 2 years preceding this request:
    - History of receiving at least 100 mL/kg/year of packed red blood cells (pRBCs) transfusions
    - History of ≥8 transfusions of pRBCs per year
- Must submit laboratory screening/results or imaging documentation of ALL the following, **collected within the last 3 months:**
    - Negative HIV-1 and HIV-2 screening
    - Negative hepatitis B and C screening
    - Negative Human T lymphocytic virus type (HTLV) 1 or 2
    - Complete Blood Count (CBC) with white blood cell (WBC) count $>3\times10^9$/L and platelet count $>100\times10^9$
        - *EXCEPTION*: If CBC results are below thresholds, results can be acceptable if attributable to hypersplenism
    - Baseline creatinine clearance ≥70 mL/min/1.73m2

  - Liver function tests and any associated imaging that rules out advanced liver disease (i.e., bridging fibrosis, cirrhosis, active hepatitis)
  - MRI scan of the liver
    - *Members ≥18 years of age:* If the MRI results demonstrate liver iron content ≥15 mg/g, liver biopsy results are required to rule out advanced liver disease
    - *Members <18 years of age*: If the MRI results demonstrate liver iron content ≥15 mg/g, the request is denied
  - MRI scan of the heart showing a cardiac T2* >10ms
  - Diffuse capacity of carbon monoxide (DLcO) >50% predicted
- Must have chart note documentation or an attestation from the provider of all the following:
  - The member does not have hemoglobin S/β-thalassemia or α-thalassemia
  - If applicable, antiretrovirals and hydroxyurea will be discontinued at least 1 month prior to mobilization and until all cycles of apheresis have been completed
  - If applicable, iron chelation therapy will be discontinued at least 7 days prior to initiation of conditioning
  - If member is female of child-bearing age: a negative serum pregnancy test will be confirmed prior to the start of mobilization and re-confirmed prior to conditioning procedures and before ZYNTEGLO administration
  - The member does not have a history of an uncontrolled bleeding disorder
  - The member does not have any prior or current malignancies OR myeloproliferative or significant immunodeficiency disorders
  - The member does not have an immediate family member with a known Familial Cancer Syndrome
  - The member does not have an uncontrolled seizure disorder
  - The member does not have a clinically significant and active bacterial, viral, fungal, or parasitic infection
  - The member has not received prior gene therapy or a hematopoietic stem cell transplant

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	6 months
Reauthorization	N/A

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

Codes:

CPT Codes / HCPCS Codes / ICD-10 Codes		
Code	Brand	Description
J3393	Zynteglo	Injection, betibeglogene autotemcel, per treatment

References:

1. Zynteglo [package insert]. Somerville, MA: bluebird bio, Inc.; August 2022
2. Locatelli F, Thompson AA, Kwiatkowski JL, et al. Betibeglogene autotemcel gene therapy for non-β0/β0 genotype β-thalassemia. N Engl J Med. 2022;386(5):415-427. doi:10.1056/NEJMoa2113206 [PubMed 34891223]

Revision History

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
New Policy	08/2024

Record Retention

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

Disclaimer

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CountyCare reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and

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