

Last review date: 3/23/2024

Applicable Products:
Zynteglo (betibeglogene autotemcel)

Initial Approval Criteria:

Coverage may be approved if all of the following are met:

- Must have a diagnosis of transfusion-dependent  $\beta$ -thalassemia confirmed by both of the following:
  - Genetic testing confirming diagnosis of  $\beta$ -thalassemia; **AND**
  - Documentation of transfusion-dependent disease defined as one of the following:
    - History of  $\geq 8$  transfusions of packed red blood cells (pRBC) per year in the previous two years; **OR**
    - History of  $\geq 100$  mL/kg/year of pRBCs in the previous two years; **AND**
- Must be prescribed by or in consultation with a hematologist; **AND**
- Must be age 4 years or older; **AND**
- Patient does not currently have an active bacterial, viral, fungal, or parasitic infection as determined by the prescribing physician; **AND**
- One of the following:
  - For patients 18 years of age or older: Must have an attestation from the provider that the member is eligible to undergo hematopoietic stem cell transplant (HSCT); **OR**
  - For patients 17 years of age or younger: Must have an attestation from the prescriber that a suitable and willing fully matched sibling donor is not available for allogeneic hematopoietic stem cell transplant (HSCT); **AND**
- Patient must not have any of the following:
  - Cardiomyopathy or severe congestive heart failure (NYHA class III or IV)
  - Advanced liver disease
  - Advanced kidney disease
  - Hypersplenism
  - Evidence of active infection including hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV)
  - Prior HSCT or gene therapy; **AND**
- Must be administered at a Zynteglo Qualified Treatment Center (QTC); **AND**
- If applicable: Trial and failure, intolerance, or a contraindication to the preferred products as listed in the medical drug list

Renewal Criteria:

None

Length of Authorization:

1 dose per lifetime

*This policy is designed to address medical guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Each person's unique clinical or other circumstances may warrant individual consideration, based on review of applicable medical records, as well as other regulatory, contractual and/or legal requirements.*

*Medical policies do not constitute medical advice, nor are they intended to govern the practice of medicine. They are intended to reflect reimbursement and coverage guidelines. Coverage for services may vary for individual members, based on the terms of the benefit contract.*