COMMUNITY HEALTH CHOICE

Zynteglo® (betibeglogene autotemcel)

Effective Date: 6/1/2024
Medical Care Management Committee Approval: 3/21/2024

Contents

Coverage Policy

This Medical Review Guideline (Guideline) is provided for informational purposes only and does not constitute medical advice. It is intended solely for the use of Community Health Choice, Inc. (Community) clinical staff as a guideline for use in determining medical necessity of requested procedures, medications and therapy. This Guideline does not address eligibility or benefit coverage. Other Policies and Coverage Determination Guidelines may apply. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Medical Review Guideline. If there is a discrepancy between this Guideline and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern. Community reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

This policy applies to the following Zynteglo® (betibeglogene autotemcel) product:

HCPCS Code	Description	Maximum Dosage per Administration
J3590	Unclassified biologics	N/A

Diagnosis-Specific Criteria

Zynteglo® (betibeglogene autotemcel) will be considered medically necessary for members meeting ALL of the following criteria:

1. Member is four years of age or older; AND
2. Member has a documented diagnosis of β-thalassemia and other forms of thalassemia have been ruled out; AND
3. Member is RBC transfusion dependent and has a documented history of receiving RBC transfusions of at least 100 ml per kilogram per year or at least eight or more transfusions of regular RBCs per year for two years; AND
4. Member has not had a prior hematopoietic stem cell transplant (HSCT) and is unable to find a matched related donor; AND
5. Member is stable and eligible for HSCT, according to the following criteria:
   a. No advanced liver disease

b. No human immunodeficiency virus positive diagnosis
c. No hepatitis B virus and hepatitis C virus
d. No prior or current malignancies
e. No bleeding disorders
f. Normal iron levels in the heart
g. Normal levels of white blood cells
h. Normal platelet counts; AND

6. Prescriber attestations for the following:
   a. To avoid the use of anti-retroviral medications or hydroxyurea for one month prior to mobilization and until all cycles of apheresis are completed
   b. To discontinue iron chelators at least seven days prior to initiation of myeloablative conditioning and the use of myelosuppressive iron chelators should be avoided for six months after Zynteglo® infusion; AND
7. Prescribers of Zynteglo® must monitor the following:
   a. The client's platelet count for thrombocytopenia and bleeding during the treatment period with Zynteglo®
   b. The client for at least 15 years post Zynteglo® infusion for possible hematologic malignancies

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive.

HCPCS Code	Description
J3590	Unclassified biologics

Diagnosis Code	Description
D56.1	β-thalassemia

Policy Revision History

Status	Effective Date	Description
Baseline	6/1/2024	Initial version of betibeglogene autotemcel diagnosis specific policy