

Betibeglogene autotemcel (Zynteglo®)

Place of Service
Hospital Administration

HCPCS: J3590

NDC: 73554-3111-1 (20 mL infusion bag, overwrap, and metal cassette)

- A single dose of Zynteglo contains a minimum of 5.0×10^6 CD34+ cells/kg of body weight, in up to four infusion bags
- Zynteglo is available in 20 mL infusion bags

Condition(s) listed in policy (see criteria for details)

- [Transfusion-dependent beta-thalassemia \(TDT\)](#)

AHFS therapeutic class: Gene therapy

Mechanism of action: Autologous hematopoietic stem cell-based gene therapy containing transgene that encodes for $\beta^{A-T787Q}$ -globin.

(1) Special Instructions and Pertinent Information

Covered under the medical benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Zynteglo® (betibeglogene autotemcel) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Transfusion-dependent beta-thalassemia (TDT)

1. Transfusion dependence, defined as at least 8 transfusions of packed red blood cell (pRBC) in previous 12 months, AND
2. Both of the following:
 - a. Patient ≤ 50 years of age, and
 - b. If < 5 years of age: minimum weight of 6 kg, and able to provide minimum number of cells to perform apheresis (e.g., needed to manufacture product)

AND

3. Patient is clinically stable and eligible to undergo myeloablative conditioning before infusion of Zynteglo, AND
4. White blood cell (WBC) count $\geq 3 \times 10^9$ /L, AND
5. Platelet count $\geq 100 \times 10^9$ /L (unless related to hypersplenism), AND
6. Patient is negative for HIV-1, HIV-2, hepatitis B virus (HBV), and hepatitis C virus (HCV), AND
7. Patient does not have any of the following:
 - a. Uncorrected bleeding disorder, and
 - b. Any prior or current malignancy (with the exception of adequately treated cone-biopsied in situ carcinoma of the cervix uteri and basal or squamous cell carcinoma of the skin), and
 - c. History of major organ damage (e.g., advanced liver disease, cardiac T2 < 10 ms by MRI), and
 - d. Severe iron overload that warrants exclusion in the provider's opinion

Covered Doses

Up to four infusions bags, which contain 2.0 to 20×10^6 cells/mL, as a single-dose intravenous (IV) infusion

Coverage period

One-time treatment per lifetime

ICD-10:

D56.1

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Zynteglo® (betibeglogene autotemcel) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s):

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

- Provided as a single dose for infusion containing a suspension of CD34+ cells in one or more (up to 4) infusion bags. The minimum recommended dose of ZYNTGLO is 5.0×10^6 CD34+ cells/kg.
- Zynteglo is shipped from the manufacturing facility to the treatment center storage facility in a cryoshipper, which may contain multiple metal cassettes intended for a single patient.

(6) References

- AHFS®. Available by subscription at <http://www.lexi.com>
- DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
- Zynteglo® (betibeglogene autotemcel) [Prescribing Information]. Somerville, MA: bluebird bio, Inc.; 08/2022.

(7) Policy Update

Date of last review: 4Q2023

Date of next review: 4Q2024

Changes from previous policy version:

- No clinical change to policy following routine annual review.

*BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee*