Highmark Wholecare
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

Requirements for Prior Authorization of Zynteglo (betibeglogene autotemcel)

A. Prescriptions That Require Prior Authorization

All prescriptions for Zynteglo (betibeglogene autotemcel) must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for Zynteglo (betibeglogene autotemcel), the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed Zynteglo (betibeglogene autotemcel) for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling; **AND**
2. Is age-appropriate according to FDA-approved package labeling; **AND**
3. Is prescribed a dose and number of treatments that are consistent with FDA-approved package labeling; **AND**
4. Is prescribed Zynteglo (betibeglogene autotemcel) by a specialist at a qualified treatment center for Zynteglo (betibeglogene autotemcel); **AND**
5. Does not have a contraindication to the prescribed medication; **AND**
6. Is not a prior recipient of gene therapy or an allogeneic hematopoietic stem cell transplant; **AND**
7. For treatment of transfusion-dependent β-thalassemia, **both** of the following:
    i. Has genetic testing confirming diagnosis of β-thalassemia
    ii. Has a history of at least 100 mL/kg/year or 8 transfusion episodes/year of packed red blood cell transfusions in the prior 2 years.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for Zynteglo (betibeglogene autotemcel). If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Requests for prior authorization of Zynteglo (betibeglogene autotemcel) will be approved for 18 months for 1 infusion.

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ZYNTEGLO (betibeglogene autotemcel) PRIOR AUTHORIZATION FORM *(form effective 7/15/2024)*

Beneficiary name:	Beneficiary ID#:	Beneficiary DOB:
Prescriber name:		Prescriber NPI:
Prescriber address (street/city/state/zip):		
Prescriber specialty:	Prescriber phone:	Prescriber fax:
Office contact name:	Office contact phone:	Office contact fax:
Billing provider name:		Billing provider NPI:
Billing provider address:		

Drug name: **Zynteglo**	Beneficiary's weight (kg):	Dose: _____ x 10^6 CD34+ cells/kg
Place of service:		Anticipated date of infusion:
Diagnosis *(submit documentation)*:		Dx code (*required*):

Check all that apply and submit documentation (e.g., recent chart/clinic notes, diagnostic evaluations, test results, etc.) for each item.

- ☐ Has NOT received prior gene therapy.
- ☐ Has NOT received a prior allogeneic hematopoietic stem cell transplant.
- ☐ Has genetic testing confirming the diagnosis of β-thalassemia.
- ☐ Has a history of at least 100 mL/kg/year or 8 transfusion episodes/year of packed red blood cell transfusions in the prior 2 years.

PLEASE FAX COMPLETED FORM TO HIGHMARK WHOLECARE

Prescriber Signature:	**Date**: