

Zynteglo® (Betibeglogene Autotemcel) Prior Authorization Form

Member Name: _____ Date of Birth: _____ Member ID#: _____

Drug Information

Physician billing (HCPCS code: _____) Start Date: _____

Billing Provider Information

Provider NPI: _____ Provider Name: _____

Provider Phone: _____ Provider Fax: _____

Prescriber Information

Prescriber NPI: _____ Prescriber Name: _____

Prescriber Phone: _____ Prescriber Fax: _____ Specialty: _____

Criteria

For Authorization: (Only one Zynteglo® infusion will be approved per member per lifetime):

1. Please indicate the member's diagnosis:
 - Beta Thalassemia
 - Other: _____
2. Does the member require regular red blood cell (RBC) transfusions as demonstrated by one of the following?
 - History of ≥100mL/kg/year transfusions of packed RBCs in the last 2 years.
 - ≥8 transfusions of packed RBCs per year in the last 2 years.
3. Please provide the member's weight: _____
4. Is the prescriber a hematologist with expertise in the treatment of beta thalassemia and the administration of Zynteglo®? Yes___ No___
5. Does the member have a known and available human leukocyte antigen (HLA)-matched sibling donor? Yes___ No___
6. Does the member have a prior history of hematopoietic stem cell transplantation (HSCT)? Yes___ No___
7. Does the member have a negative serology test for human immunodeficiency virus (HIV) prior to apheresis? Yes___ No___
8. Has the prescriber verified the member is clinically stable and eligible to undergo HSCT? Yes___ No___
9. If member is female:
 - A. Is member pregnant? Yes___ No___
 - B. Will member have a negative pregnancy test prior to the start of mobilization, prior to conditioning procedures, and prior to Zynteglo® administration? Yes___ No___
10. If member is of reproductive potential, will they use an effective method of contraception from the start of mobilization through at least 6 months after administration of Zynteglo®? Yes___ No___
11. If member is of reproductive potential, has the prescriber counseled them on the potential effects of myeloablative conditioning on fertility, and the potential risk of infertility is acceptable to the member? Yes___ No___
12. Will the prescriber evaluate the potential for drug interactions, according to package labeling, prior to and after administration of Zynteglo®? Yes___ No___
13. Will member be monitored for hematologic malignancies lifelong, with a complete blood count (with differential) performed at month 6 and month 12 after treatment with Zynteglo®, then at least annually thereafter for at least 15 years, and with integration site analysis at months 6,12, and as warranted? Yes___ No___

PLEASE PROVIDE THE INFORMATION REQUESTED AND RETURN TO:

University of Oklahoma College of Pharmacy
Pharmacy Management Consultants
Product Based Prior Authorization Unit
Fax: 1-800-224-4014
Phone: 1-800-522-0114 Option 4

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Criteria

Page 2 of 2—Please complete and return all pages. Failure to complete all pages will result in processing delays.
For Authorization, continued:

- 14. Will Zynteglo® be administered at a Zynteglo® qualified treatment center? Yes ___ No ___
A. Please provide name of treatment center: _____
- 15. Does the receiving facility have a mechanism in place to track the patient-specific Zynteglo® dose from receipt to storage to administration? Yes ___ No ___
A. Please provide name of facility: _____

Additional information: _____

Prescriber Signature: _____ Date: _____

I certify that the indicated treatment is medically necessary and all information is true and correct to the best of my knowledge.
Failure to complete this form in full and attach requested clinical notes will result in processing delays.

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