MASSACHUSETTS

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# Prior Authorization Request Form for Gene Therapies for Thalassemia – Zynteglo (Betibeglogene automeucel) #216

## Medical Policy #215 Gene Therapy for Thalassemia – Zynteglo

Please use this form to assist in identifying members who meet Blue Cross Blue Shield of Massachusetts' (BCBSMA's) medical necessity criteria for Gene Therapies for Thalassemia – Zynteglo (Betibeglogene automeucel) therapy. For members who do not meet the criteria, submit a letter of medical necessity with a request for Clinical Exception (Individual Consideration).

**Once completed, please fax to: 888-973-0726**

**CLINICAL DOCUMENTATION**
Copies of clinical documentation that supports the medical necessity criteria for Zynteglo must be submitted with this form. If the patient does not meet all the criteria listed below, please submit a letter of medical necessity explaining why an exception is justified.

| **Patient Information** | |
|---|---|
| Patient Name: | Today's Date: |
| BCBSMA ID#: | Date of Treatment: |
| Date of Birth: | Place of Service: Outpatient ❒ Inpatient ❒<br><br>Distributor: |

| **Physician Information** | **Facility Information** |
|---|---|
| Name: | Name: |
| Address: | Address: |
| Phone #: | Phone #: |
| Fax#: | Fax#: |
| NPI#: | NPI#: |

| **Please check off if the patient has the following diagnosis:** | |
|---|---|
| Documented diagnosis of β-thalassemia by globin gene testing | ❒ |

| **Please check off that the patient meets ALL the following criteria:** | |
|---|---|
| Is adult (age <65 years) or child (age ≥3 years) | ❒ |
| Patient requires regular peripheral blood transfusions to maintain target hemoglobin levels | ❒ |
| Documented history of receiving transfusions of ≥100 ml per kilogram of body weight of packed red cells per year or who had disease that had been managed under standard thalassemia guidelines with ≥8 transfusions per year in the previous 2 years at the time of treatment decision | ❒ |
| Karnofsky performance status of ≥80 for adults (≥16 years of age) or a Lansky performance status of ≥80 for adolescents (<16 years of age) | ❒ |
| Negative serologic test for HIV infection (as per US FDA prescribing label, apheresis material from individuals with a positive test for HIV will not be accepted for Betibeglogene autotemcel manufacturing) | ❒ |

**CONTRAINDICATIONS**

| **Please check off that the patient DOES NOT HAVE ANY of the following contraindications:** | |
|---|---|
| Individual does not have any of the following:<br>i. Availability of human leukocyte antigen-identical or human leukocyte antigen-matched donor; **OR**<br>ii. T2*-weighted magnetic resonance imaging measurement of myocardial iron of less than 10 msec or other evidence of severe iron overload in the opinion of treating physician; **OR**<br>iii. Advanced liver disease (meets any one of the following):<br>a. Persistent aspartate transaminase, alanine transaminase, or direct bilirubin value greater than 3 times the upper limit of normal; **OR**<br>b. Baseline prothrombin time or partial thromboplastin time greater than 1.5 times the upper limit of normal; **OR**<br>c. Magnetic resonance imaging of the liver demonstrating clear evidence of cirrhosis; **OR**<br>d. Liver biopsy demonstrating cirrhosis, any evidence of bridging fibrosis, or active hepatitis; **OR**<br>iv. Baseline estimated glomerular filtration rate less than 70 mL/min/1.73 $m^2$; **OR**<br>v. History of receiving prior gene therapy or allogenic hematopoietic stem cell transplant; **OR**<br>vi. 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) or myeloproliferative or significant immunodeficiency disorder; **OR**<br>vii. Any immediate family member (i.e. parent or siblings) with a known Familial Cancer Syndrome (including but not limited to hereditary breast and ovarian cancer syndrome, hereditary nonpolyposis colorectal cancer syndrome and familial adenomatous polyposis); **OR**<br>viii. Active, uncontrolled HCV or HBV infection; **OR**<br>ix. Contraindication to the use of granulocyte colony stimulating factor (G-CSF), plerixafor, busulfan, or any other medicinal products required during myeloablative conditioning, including hypersensitivity to the active substances or to any of the excipients; **OR**<br>x. A white blood cell count less than 3 X $10^9$/L, and/or platelet count less than 100 X $10^9$/L not related to hypersplenism. | ❒ |

| **HCPCS Codes** | **Code Description** |
|---|---|
| C9399 | Unclassified drugs or biological |
| J3490 | Unclassified drugs |
| J3590 | Unclassified biologics |

**Providers should enter the relevant diagnosis code(s) below:**

| **Code** | **Description** | |
|---|---|---|
| | | ❒ |
| | | ❒ |

**Providers should enter other relevant code(s) below:**

| **Code** | **Description** | |
|---|---|---|
| | | ❒ |
| | | ❒ |