Fax completed form to designated gene therapy fax (833) 910-1625
For Urgent requests please outreach to Cigna Gene Therapy Program at (855) 678-0051 or email to GeneTherapyProgram@Cignahealthcare.com

Gene Therapy Zynteglo™

(betibeglogene autotemcel intravenous infusion)

PHYSICIAN INFORMATION			PATIENT INFORMATION		
* Physician Name:			*Due to privacy regulations, we will not be able to respond via fax with the outcome of our review unless all asterisked (*) items under physician and patient information are completed.		
Specialty:	* DEA, NPI or TIN:				
Office Contact Person:			* Patient Name:		
Office Phone:			* Cigna ID:	* Date of Birth:	
Office Fax:			* Patient Street Address:		
Office Street Address:			City:	State:	Zip:
City:	State:	Zip:	Patient Phone:		

FACILITY BILLING INFORMATION FOR PAYMENT SUPPORT

Billing Office Contact Name: Billing Office Phone:

Urgency:
☐ Standard ☐ Urgent (In checking this box, I attest to the fact that applying the standard review time frame may seriously jeopardize the customer's life, health, or ability to regain maximum function)

Medication Request Detail:

ICD10: HCPCS Code

NDC: Additional Comment:

New Start: Continuation:

Where will this medication be obtained?
☐ CVS Specialty
☐ Other (please specify):
☐ Physician's office stock (billing on a medical claim form)

Facility and/or doctor administering medication:
Facility Name: State: Tax ID#:
Address (City, State, Zip Code):

Where will this drug be administered?
☐ Hospital Outpatient
☐ Other (please specify):
☐ Physician's Office

What is the indication or diagnosis?
☐ Transfusion-Dependent Beta-Thalassemia
☐ other

Clinical Information. **Documentation is required for use of this gene therapy. Documentation may include, but is not limited to, chart notes, laboratory results, medical test results, claims records, prescription receipts, and/or other information. All documentation must include patient-specific identifying information.**

Check all that apply:

☐	Patient is ≥ 4 years of age
☐	Prescribing physician confirms that the patient has not previously received Zynteglo
☐	Prescribing physician confirms that the patient has not previously received Casgevy
☐	According to the prescribing physician, a hematopoietic stem cell transplantation is appropriate for the patient

	Patient meets ONE of the following (i or ii):
☐ i.	i. Patient does not have a Human Leukocyte Antigen (HLA)-matched donor
☐ ii.	ii. Patient has an HLA-matched donor, but the individual is not able or is not willing to donate
	Patient has ONE of the following genotypes as confirmed by genetic testing (i or ii):
☐ i.	i.Non-β^0/β^0 genotype **[documentation required]** *Note: Examples include β^0/β^+, β^E/β^0, and β^+/β^+*
☐ ii.	ii. β^0/β^0 genotypes **[documentation required]** *Note: Other examples include $\beta^0/\beta^{+(IVS\text{-}I\text{-}110)}$ and $\beta^{+(IVS\text{-}I\text{-}110)}/\beta^{+(IVS\text{-}I\text{-}110)}$*
	Patient is transfusion-dependent, as defined by meeting ONE of the following (i or ii):
☐ i.	i. Receipt of transfusions of ≥ 100 mL of packed red cells per kg of body weight per year in the previous 2 years **[documentation required]**
☐ ii.	ii. Receipt of transfusions eight or more times per year in the previous 2 years **[documentation required]**
	Patient meets BOTH of the following (i and ii):
☐ i.	i. Patient has been evaluated for the presence of severe iron overload **[documentation required]**
☐ ii.	ii. Patient does not have evidence of severe iron overload *Note: Examples include abnormal myocardial iron results (a T2*-weighted magnetic resonance imaging measurement of myocardial iron of less than 10 msec), high liver iron concentration (≥ 15 mg/g), liver biopsy results suggest abnormalities, or clinical evidence of organ damage (e.g., endocrine comorbidities).*
☐	Patient does not currently have an active bacterial, viral, fungal, or parasitic infection
	Patient does not have any of the following (i and ii):
☐ i.	i. Prior or current malignancy, myeloproliferative disorder, or significant immunodeficiency disorder *Note: This does not include adequately treated cone biopsied in situ carcinoma of the cervix uteri and basal or squamous cell carcinoma of the skin.*
☐ ii.	ii. Advanced liver disease **[documentation required]** *Note: Examples include alanine transaminase or aspartate transaminase greater than three times upper limit of normal, direct bilirubin value greater than three times upper limit of normal, active hepatitis, extensive bridging fibrosis, or cirrhosis.*
☐	According to the prescribing physician, patient will have been discontinued from iron chelation therapy for at least 7 days prior to myeloablative conditioning *Note: Examples of iron chelators used for this condition include deferoxamine injection, deferiprone tablets or solution, and deferasirox tablets.*
	According to the prescribing physician, patient meets ALL the following (i, ii, iii, and iv):
☐ i.	i. Patient will undergo mobilization, apheresis, and myeloablative conditioning
☐ ii.	ii. A granulocyte-colony stimulating factor product, and a hematopoietic stem cell mobilizer will be utilized for mobilization *Note: Filgrastim products are examples of a granulocyte-colony stimulating factor therapy and Mozobil (plerixafor subcutaneous injection) is an example of a hematopoietic stem cell mobilizer.*
☐ iii.	iii. Busulfan will be used for myeloablative conditioning
	iv. Total hemoglobin level is ≥ 11.0 g/dL at BOTH of the following timepoints (a and b):
☐ iv.a.	a) Prior to mobilization
☐ iv.b.	b) Prior to myeloablative conditioning
	Patient screening is negative for ALL the following (i, ii, iii, and iv):
☐ i.	i. Human immunodeficiency virus-1 and -2 **[documentation required]**
☐ ii.	ii. Hepatitis B virus **[documentation required]**
☐ iii.	iii. Hepatitis C virus **[documentation required]**
☐ iv.	iv. Human T-lymphotropic virus-1 and -2 **[documentation required]**
	According to the prescribing physician, a patient of reproductive potential meets ONE of the following (i or ii): i. A female† of reproductive potential meets BOTH of the following (a and b):
☐ i.a.	a) A negative serum pregnancy test will be confirmed prior to the start of mobilization and re-confirmed prior to myeloablative conditioning
☐ i.b.	b) Patient will use an effective method of contraception from the start of mobilization through at least 6 months after administration of Zynteglo
☐ ii.	ii. A male† of reproductive potential will use an effective method of contraception from the start of mobilization through at least 6 months after administration of Zynteglo *(†) is noted next to the specified gender. In this context, the specified gender is defined as follows: females/males are defined as individuals with the biological traits of a woman/man, regardless of the individual's gender identity or gender expression.*
☐	The medication is prescribed by a hematologist or a stem cell transplant specialist physician
☐	Current patient body weight has been obtained within 30 days **[documentation required]** Date obtained:
☐	Prior has hematopoietic stem cell transplantation.
☐	Prior has receipt of gene therapy
☐	Concurrent Use with Aqvesme™ (mitapivat tablets)
☐	Concurrent Use with Reblozyl (luspatercept-aamt subcutaneous injection).

If any of the requirements listed above are not met and you feel administration of the requested gene therapy is medically necessary, please provide clinical support and rationale for the use of this gene therapy.

Additional pertinent information: (including recent history and physical, recent lab work, disease stage, prior therapy, performance status, and names/doses/admin schedule of any agents to be used concurrently)

Additional CPT and/or Administration Codes for Billing.

Cell Collection
☐ 96372 Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
☐ 38206 Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; autologous
☐ Other

Select applicable G-CSF (Cigna preferencing may apply). Include dose, quantity, duration
☐ J2562 Injection, plerixafor, 1mg (Mozobil) Plus
☐ J1442 Injection, filgrastim (G-CSF), excludes biosimilar, 1 mcg
☐ J1447 Injection, tbo-filgrastim, 1 mcg
☐ Q5101 Injection, filgrastim-sndz, biosimilar (Zarxio), 1 mcg
☐ Q5110 Injection, filgrastim-aafi, biosimilar (Nivestym), 1 mcg
☐ Other

Conditioning Regimen
☐ J0594 Injection, bulsulfan, 1 mg
☐ Other

Please indicate any other CPT codes that will be billed for administration.
☐ Other

Agreement and Attestation:

Do you and your patient agree to share any required plan specific outcome measures? ☐ Yes ☐ No

I attest the information provided is true and accurate to the best of my knowledge. I understand that the Health Plan or insurer its designees may perform a routine audit and request the medical information necessary to verify the accuracy of the information reported on this form.

Prescriber Signature:_____ **Date:**_____

Our standard response time for prescription drug coverage requests is 5 business days. If your request is urgent, it is important that you call us to expedite the request. View our Coverage Policies online at cigna.com.

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