Cigna Healthcare Gene Therapy Prior Auth Request Form

This therapy requires supportive documentation (chart notes, genetic test results, etc.).

****Due to privacy regulations we will not be able to respond via fax with the outcome of our review unless all asterisked (*) fields on this form are completed****

Gene Therapy Prior Authorization

To allow more efficient and accurate processing of your medication request, please complete this form and fax it back along with copies of all supporting clinical documentation. Fax completed form to Fax# 833-910-1625.

Notice: Failure to complete this form in its entirety may result in delayed processing or an adverse determination for insufficient information.

Gene Therapy Product Name **Zynteglo**

Cigna has designated the above product to be a gene therapy product, which is included in the Cigna Gene Therapy Provider Network.

Questions pertaining to gene therapy may be directed to the dedicated Gene Therapy Program team at 855.678.0051 or email to GeneTherapyProgram@Cigna.com

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 on this form are completed.*		
Specialty:	* DEA, NPI or TIN:				
Office Contact Person:			* Customer Name:		
Office Phone:			* Cigna ID:	*Customer Date of Birth:	
Office Fax: *Is your fax machine kept in a secure location? ☐ Yes ☐ No *May we fax our response to your office? ☐ Yes ☐ No			* Customer/Patient Street Address:		
Office Street Address:			City:	State:	Zip:
City:	State:	Zip:	Patient 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)

Where will this medication be obtained?

☐ CVS Specialty Pharmacy
☐ Other (please specify):

ICD10:

Name of Facility administering medication:
Facility Name: State: Tax ID#:
Address (City, State, Zip Code):

Clinical Information – Zynteglo

Does patient have a documented diagnosis of transfusion dependent Beta Thalassemia?
☐ Yes
☐ No
☐ Unknown

Is patient 4 years of age to 50 years of age?
☐ Yes
☐ No

Is there documentation of beta-globin genotypes confirmed by DNA analysis?
☐ Yes (please include copy of these results)
☐ No
☐ Unknown

Is there documentation of transfusion dependence defined by meeting **ONE** of the following?
☐ Patient received transfusions of at least 100 mL per kg of body weight per year of packed red cells (pRBCs) for the past 2 years?
☐ Patient received eight or more transfusions of pRBCs per year for the past 2 years?

According to prescriber, patient is unable to receive stem cell transplant due to **ONE** of the following:
☐ Patient is without a matched HLA family donor
☐ A matched family donor is unwilling to donate

Is there Documentation of **ALL** of the following? (**please include copy of these results**)
☐ Estimated glomerular filtration rate (eGFR)
☐ White blood cell (WBC) count and date completed
☐ Platelet count and date completed
☐ Diffusion capacity of carbon monoxide (DLCO)
☐ Adequate cardiac function as evidenced by a left ventricular ejection fraction greater than 40%
☐ Prior to collection of cells for manufacturing, your patient is negative for Human Immunodeficiency virus 1 and 2
☐ Prior to collection of cells for manufacturing, your patient is negative for Human T-lymphotropic virus 1 and 2
☐ Your patient was evaluated for AND does not have evidence of severe iron overload
☐ If 16 years of age or older, provide documentation of Karnofsky performance status score of at least 80%
☐ If less than 16 years of age, provide documentation of Lansky performance status score of at least 80%

According to the prescriber, the patient does **NOT** have any of the following:
☐ active bacterial, viral, fungal or parasitic infection
☐ prior or current malignancy or myeloproliferative disorder
☐ familial cancer syndrome or a history of such in their immediate family
☐ an uncorrected bleeding disorder
☐ advanced liver disease

According to the prescriber, hematopoietic stem cell transplantation procedure is appropriate for the individual as required to receive Zynteglo gene therapy?
☐ Yes
☐ No
☐ Unknown

☐ Zynteglo being prescribed by a hematologist and/or a stem cell transplant specialist?
☐ Yes
☐ No
☐ Unknown

Does patient's treatment plan include concurrent use with Reblozyl?
☐ Yes
☐ No
☐ Unknown

Does the patient have a prior history of having a hematopoietic stem cell transplant?
☐ Yes
☐ No
☐ Unknown

Does the patient have prior history of receiving a gene therapy?
☐ Yes

☐ No
☐ Unknown

If any of the requirements listed above are not met and provider feels administration of Zynteglo is medically necessary please provide clinical support and rationale for the use of Zynteglo.

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

Additional CPT and Administration Codes for Consideration Following Medical Necessity Determination

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)
☐ J2562 Injection, plerixafor, 1 mg (Mozobil) Plus
Directions for use: Dose: Quantity: Duration of therapy:
☐ J1442 Injection, filgrastim (G-CSF), excludes biosimilar, 1 mcg
Directions for use: Dose: Quantity: Duration of therapy:
☐ J1447 Injection, tbo-filgrastim, 1 mcg
Directions for use: Dose: Quantity: Duration of therapy:
☐ Q5101 Injection, filgrastim-sndz, biosimilar, (Zarxio), 1 mcg
Directions for use: Dose: Quantity: Duration of therapy:
☐ Q5110 Injection, filgrastim-aafi, biosimilar, (Nivestym), 1 mcg
Directions for use: Dose: Quantity: Duration of therapy:
☐ Q5125 Injection, filgrastim-ayow, biosimilar, (Releuko), 1 mcg
Directions for use: Dose: Quantity: Duration of therapy:
☐ Other
Directions for use: Dose: Quantity: Duration of therapy:

Conditioning Regimen
☐ J0594 Injection, busulfan, 1 mg
Directions for use: Dose: Quantity: Duration of therapy:
☐ Other
Directions for use: Dose: Quantity: Duration of therapy:

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

Additional Attestation required for Embarc Benefit Protection* Criteria when applicable

According to the prescribing physician:
☐ Your patient plans to undergo mobilization, apheresis and myeloablative conditioning
☐ Your patient's hemoglobin level is or will be > 11.0 g/dL within 30 days prior to mobilization
☐ Your patient's hemoglobin level is or will be > 11.0 g/dL within 30 days before myeloablative conditioning
☐ A granulocyte-colony stimulating factor product and Mozobil (plerixafor subcutaneous injection) will be utilized for mobilization
☐ Busulfan will be used for myeloablative conditioning
☐ Your patient is not receiving iron chelation therapy or this therapy will be stopped at least 7 days prior to myeloablative conditioning
☐ The use of iron chelators will be avoided for 6 months after infusion of Zynteglo
☐ Your patient has received or is planning to receive prophylaxis for hepatic veno-occlusive disease/hepatic sinusoidal obstruction syndrome before myeloablative conditioning with busulfan
☐ If your patient is a female of reproductive potential, a negative serum pregnancy test was or will be obtained prior to the start of mobilization and re-confirmed prior to conditioning procedures, as well as before Zynteglo administration
☐ If your patient is a female of reproductive potential, they will use an effective method of contraception from the start of mobilization through at least 6 months after administration of Zynteglo
☐ If your patient is a male, they will be using an effective method of contraception from the start of mobilization through at least 6 months after administration of Zynteglo

**For additional information on Embarc Benefit Protection refer to the Cigna Reference Guide of physicians, physicians, hospitals, ancillaries, and other*

health care providers. This guide is available at CignaforHCP.com > Resources > Reference Guides > Medical Reference Guides: View Documents > Health Care Professional Reference Guides. Providers must log in to access

Agreement and Attestation

Do you and your patient agree to share any required plan specific outcome measures?

☐ Yes
☐ No

Attestation: 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:**_____

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