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

Documentation is required for use of [Zynteglo] as noted in the criteria as [documentation required]. Documentation may include, but is not limited to, chart notes, laboratory results, medical test results, claims records, prescription receipts, and/or other information.

Zynteglo is considered medically necessary when the following criteria are met, check all that apply:

☐ Is patient 4 years of age?

☐ Patient has not received a gene therapy for beta-thalassemia in the past

☐ 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. Non-β0/β0 genotype [documentation required]; OR
Note: Examples include β0/β+, βE/β0, and β+/β+.
☐ ii. β0/β0 genotypes [documentation required]; AND
Note: Other examples include β0/β+(IVS-I-110) and β+(IVS-I-110)/β+(IVS-I-110).

Patient is transfusion-dependent, as defined by meeting ONE of the following (i or ii):
☐ 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]; OR
☐ 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. Patient has been evaluated for the presence of severe iron overload [documentation required]
☐ 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. . Prior or current malignancy, myeloproliferative disorder, or significant immunodeficiency disorder; AND
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.
☐ Advanced liver disease [documentation required]; AND
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; AND
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 of the following (i, ii, iii, and iv):
☐ i. Patient will undergo mobilization, apheresis, and myeloablative conditioning
☐ ii. A granulocyte-colony stimulating factor product, and a hematopoietic stem cell mobilizer will be utilized for mobilization; AND
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. 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):
☐ a) Prior to mobilization
☐ b) Prior to myeloablative conditioning

Patient screening is negative for ALL the following (i, ii, iii, and iv):
☐ i. Human immunodeficiency virus-1 and -2 [documentation required]
☐ ii. Hepatitis B virus [documentation required]
☐ iii. Hepatitis C virus [documentation required]
☐ 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):
  - ☐ a) A negative serum pregnancy test will be confirmed prior to the start of mobilization and re-confirmed prior to myeloablative conditioning
  - ☐ b) Patient will use an effective method of contraception from the start of mobilization through at least 6 months after administration of Zynteglo; OR
- ☐ 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

☐ 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]

If any of the requirements listed above are not met and provider feels the 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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Address: Cigna Pharmacy Services, PO Box 42005, Phoenix AZ 85080-2005