Cigna Healthcare Casgevy Gene Therapy Prior Auth Transfusion-Dependent Beta-Thalassemia

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

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: **Casgevy for Transfusion-Dependent Beta-Thalassemia**

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

<table>
<tr><th colspan="4">PHYSICIAN INFORMATION</th><th colspan="4">PATIENT INFORMATION</th></tr>
<tr><td colspan="4">*Physician Name:</td><td colspan="4" rowspan="2">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.</td></tr>
<tr><td colspan="2">Specialty:</td><td colspan="2">*DEA, NPI or TIN:</td></tr>
<tr><td colspan="4">Office Contact Person:</td><td colspan="4">*Customer Name:</td></tr>
<tr><td colspan="4">Office Phone:</td><td colspan="2">*Cigna ID:</td><td colspan="2">*Customer Date of Birth:</td></tr>
<tr><td colspan="4">Office Fax:
*Is your fax machine kept in a secure location:
☐ Yes
☐ No

*May we fax our response to your office?
☐ Yes
☐ No</td><td colspan="4">*Customer / Patient Street Address:</td></tr>
<tr><td colspan="4">Office Street Address:</td><td>City:</td><td>State:</td><td colspan="2">Zip:</td></tr>
<tr><td>City:</td><td>State:</td><td colspan="2">Zip:</td><td colspan="4">Patient Phone:</td></tr>
<tr><td colspan="8">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)</td></tr>
<tr><td colspan="8">Where will this medication be obtained?
☐ Buy and Bill / Office Stock
☐ Orsini
☐ Other</td></tr>
</table>

Where will this medication be administered?
Facility Name:
Address: State:

Tax ID#:

What location will this medication be administered?
☐ Outpatient Hospital ☐ Inpatient Hospital ☐ MD Office / Clinic
☐ Home ☐ Other

ICD 10 Associated with the Indication of this request:

Documentation is required for use of Casgevy 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.

Casgevy is considered medically necessary to treat Transfusion-Dependent Beta-Thalassemia when the following criteria are met, check all that apply:

☐ Patient is ≥ 12 years of age

☐ Patient has not received a gene therapy for beta-thalassemia in the past
Note: If no claim for Casgevy or Zynteglo (betibeglogene autotemcel intravenous infusion) is present (or if claims history is not available), the prescribing physician confirms that the patient has not previously received Casgevy or Zynteglo.

☐ 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. Patient does not have a Human Leukocyte Antigen (HLA)-matched donor; OR
- ☐ 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. Non-β^0/β^0 genotype **[documentation required]**; OR
  Note: Examples include β^0/β^+, β^E/β^0, and β^+/β^+.
- ☐ ii. β^0/β^0 genotypes **[documentation required]**; AND
  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. Receipt of transfusions of ≥ 100 mL per kg of body weight of packed red blood cells per year in the previous 2 years **[documentation required]**; OR
- ☐ ii. Receipt of transfusions of ≥ 10 units of packed red blood cells 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 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.
- ☐ 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. Patient will undergo mobilization, apheresis, and myeloablative conditioning; AND
- ☐ 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; AND
- ☐ iv. Total hemoglobin level is ≥ 11 g/dL at BOTH of the following timepoints (a **and** b):
  - ☐ a) Prior to mobilization; AND
  - ☐ b) Prior to myeloablative conditioning

☐ Patient screening is negative for ALL of 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, patient 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 each mobilization cycle 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 Casgevy; 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 Casgevy

☐ The medication is prescribed by a hematologist or a stem cell transplant physician

☐ Current patient body weight has been obtained within 30 days **[documentation required]**

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

Conditions Not Covered

Casgevy for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

☐ **Prior Hematopoietic Stem Cell Transplantation.**
Note: Prescribing physician must confirm that the patient has not received a prior hematopoietic stem cell transplantation.
Casgevy has not been studied in a patient who has received a prior allogeneic or autologous hematopoietic stem cell transplant. Treatment with Casgevy is not recommended.

☐ **Prior Receipt of Gene Therapy.** Casgevy has not been studied in a patient who has received prior gene therapy such as Lyfgenia® (lovotibeglogene autotemcel intravenous infusion) and Zynteglo® (betibeglogene autotemcel intravenous infusion). Treatment with Casgevy is not recommended.

☐ **Concurrent Use with Reblozyl® (luspatercept-aamt subcutaneous injection).** Reblozyl was not utilized with Casgevy in the pivotal trial assessing the efficacy of Casgevy in patients with transfusion-dependent beta-thalassemia

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). 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: _____

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