Cigna Healthcare Casgevy Gene Therapy Prior Auth
Sickel Cell Disease
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 Sickle Cell Disease**

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="3">PHYSICIAN INFORMATION</th><th colspan="3">PATIENT INFORMATION</th></tr>
<tr><td colspan="3">*Physician Name:</td><td colspan="3" 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>Specialty:</td><td colspan="2">*DEA, NPI or TIN:</td></tr>
<tr><td colspan="3">Office Contact Person:</td><td colspan="3">*Customer Name:</td></tr>
<tr><td colspan="3">Office Phone:</td><td>*Cigna ID:</td><td colspan="2">*Customer Date of Birth:</td></tr>
<tr><td colspan="3">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="3">*Customer / Patient Street Address:</td></tr>
<tr><td colspan="3">Office Street Address:</td><td>City:</td><td>State:</td><td>Zip:</td></tr>
<tr><td>City:</td><td>State:</td><td>Zip:</td><td colspan="3">Patient Phone:</td></tr>
</table>

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?
☐Buy and Bill / Office Stock
☐ Other

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:

Casgevy is considered medically necessary for treatment of Sickle Cell Disease when the following criteria are met, check all that apply:

☐ Patient is ≥ 12 years of age; AND

☐Patient has not received a gene therapy for sickle cell disease in the past **[verification in claims history required]**; AND
Note: If no claim for Casgevy or Lyfgenia (lovotibeglogene 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 Lyfgenia.

☐ According to the prescribing physician, a hematopoietic stem cell transplantation is appropriate for the patient; AND

☐ 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; AND

☐ Genetic testing **[documentation required]** indicates the patient has ONE of the following sickle cell disease genotypes (i, ii, or iii):
- ☐ i. β^S/β^S genotype; OR
- ☐ ii. β^S/β^0 genotype; OR
- ☐ iii. β^S/β^+ genotype; AND

Note: Other genotypes will be reviewed by the Medical Director on a case-by-case basis.

☐ Patient has tried at least ONE pharmacologic treatment for sickle cell disease **[documentation required]**; AND
Note: Examples of pharmacologic treatment for sickle cell disease include hydroxyurea, L-glutamine, Adakveo (crizanlizumab-tmca intravenous infusion), and Oxbryta (voxelotor tablets and tablets for oral suspension).

☐ While receiving appropriate standard treatment for sickle cell disease, patient had at least four severe vaso-occlusive crises or events in the previous 2 years, as defined by the following (i, ii, iii, iv, or v):

- ☐ i. An episode of acute pain that resulted in a visit to a medical facility which required administration of at least ONE of the following (a or b) **[documentation required]**:
  - ☐ a.) Intravenous opioid; OR
  - ☐ b.) Intravenous nonsteroidal anti-inflammatory drug; OR
- ☐ ii. Acute chest syndrome **[documentation required]**; OR
  Note: Acute chest syndrome is defined by the presence of a new pulmonary infiltrate associated with pneumonia-like symptoms (e.g., chest pain, fever [> 99.5°F], tachypnea, wheezing or cough, or findings upon lung auscultation).
- ☐ iii. Acute hepatic sequestration **[documentation required]**; OR
  Note: Acute hepatic sequestration is defined by a sudden increase in liver size associated with pain in the right upper quadrant, abnormal results of liver function test not due to biliary tract disease, and the reduction of hemoglobin concentration by ≥ 2 g/dL below the baseline value.
- ☐ iv. Acute splenic sequestration **[documentation required]**; OR
  Note: Acute splenic sequestration is defined by an enlarged spleen, left upper quadrant pain, and an acute decrease in hemoglobin concentration of ≥ 2 g/dL below the baseline value.
- ☐ v. Acute priapism lasting > 2 hours and requiring a visit to a medical facility **[documentation required]**; AND

☐ Patient does **NOT** have the following (i, ii, iii, and iv):

- ☐ i. Clinically significant and active bacterial, viral, fungal, or parasitic infection; AND
- ☐ ii. Advanced liver disease **[documentation required]**; AND
  Note: Examples of advanced liver disease include alanine transaminase > 3 times upper limit of normal; direct bilirubin value > 2.5 times upper limit of normal; baseline prothrombin time (international normalized ratio [INR]) > 1.5 times upper limit of normal; cirrhosis; bridging fibrosis; or active hepatitis.
- ☐ iii. Severe cerebral vasculopathy as defined by history of untreated Moyamoya disease or presence of Moyamoya disease that puts the patient at risk of bleeding, per the prescribing physician; AND
- ☐ iv. Prior or current malignancy, myeloproliferative disorder, or significant immunodeficiency disorder; AND

☐ According to the prescribing physician, patient will have been discontinued from the following medications (for the duration noted) [i and ii]:

- ☐ i. Disease-modifying therapies for sickle cell disease for at least 2 months before the planned start of mobilization and conditioning; AND
  Note: Examples of disease-modifying therapies for sickle cell disease include hydroxyurea, Adakveo, L-glutamine, and Oxbryta.
- ☐ ii. 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** the following (i, ii, iii, and iv):

- ☐ i. Patient will undergo mobilization, apheresis, and myeloablative conditioning; AND
- ☐ ii. A hematopoietic stem cell mobilizer will be utilized for mobilization; AND
  Note: Mozobil (plerixafor subcutaneous injection) is an example of a hematopoietic stem cell mobilizer.
- ☐ iii. Busulfan will be used for myeloablative conditioning; AND
- ☐ iv. Sickle hemoglobin level will be < 30% of total hemoglobin with total hemoglobin concentration ≤ 11 g/dL at BOTH of the following timepoints (a **and** b):
  - ☐ a) Prior to planned start of mobilization; AND
  - ☐ b) Until initiation of myeloablative conditioning; AND

☐ Prior to collection of cells for manufacturing, cellular screening is negative for ALL of the following (i, ii, iii, and iv):

- ☐ i. Human immunodeficiency virus-1 and -2 **[documentation required]**; AND
- ☐ ii. Hepatitis B virus **[documentation required]**; AND
  Note: A patient who has been vaccinated against hepatitis B virus (HBV) [HBV surface antibody-positive] who is negative for other markers of prior HBV infection (e.g., negative for HBV core antibody) is eligible; a patient with past exposure to HBV is also eligible as long as patient is negative for HBV DNA.
- ☐ iii. Hepatitis C virus **[documentation required]**; AND
- ☐ iv. Human T-lymphotrophic virus-1 and -2 **[documentation required]**; AND

☐ 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; AND
  - ☐ 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; AND

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

☐ 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.

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)

Any other use is considered experimental, investigational, or unproven, including the following, check all that apply:

☐ Prior Receipt of Gene Therapy. Prior receipt of gene therapy was a reason for patient exclusion in the pivotal study.

If any of above apply to your customer, please provide clinical support and rationale for the use of Casgevy.

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

Additional Attestation required for Embarc Benefit Protection*:
The prescribing physician confirms that the patient has not previously received Casgevy?

☐ Yes

☐ No

☐ Unknown

**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

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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