Cigna®

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 Lyfgenia®
## (lovotibeglogene 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?**
☐ Accredo
☐ 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):
☐ Hospital Inpatient

**What is the indication or diagnosis?**
☐ Sickle Cell Disease
☐ 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 ≥ 12 years of age |
| ☐ | Patient has not received Lyfgenia for sickle cell disease in the past |
| ☐ | Patient has not received Casgevy for sickle cell disease 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. | 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 |
| | Genetic testing [documentation required] indicates the patient has ONE of the following sickle cell disease genotypes (i, ii, or iii): |
| ☐ i. | i. $\beta^S/\beta^S$ genotype |
| ☐ ii. | ii. $\beta^S/\beta^0$ genotype |
| ☐ iii. | iii. $\beta^S/\beta^+$ genotype |
| | *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]** |
| | *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 **[documentation required]** |
| | *Note: Examples of severe vaso-occlusive crises or events include the following:*<br>*•An episode of acute pain that resulted in a visit to a medical facility which required administration of an intravenous opioid and/or intravenous nonsteroidal anti-inflammatory drug*<br>*•Acute chest syndrome, which 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)*<br>*•Acute hepatic sequestration, which 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*<br>*•Acute splenic sequestration, which 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*<br>*•Acute priapism lasting > 2 hours and requiring a visit to a medical facility* |
| | Patient does not have the following (i, ii, iii, iv, and v): |
| ☐ i. | i. More than two α-globin gene deletions **[documentation required]** |
| ☐ ii. | ii. Clinically significant and active bacterial, viral, fungal, or parasitic infection |
| ☐ iii. | iii. Advanced liver disease **[documentation required]** |
| | *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.* |
| ☐ iv. | iv. 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<br>prior or current malignancy or myeloproliferative disorder or significant immunodeficiency disorder |
| | According to the prescribing physician, patient will have been discontinued from the following medications (for the duration noted) prior to mobilization (i, ii, iii, and iv): |
| ☐ i. | i. Disease-modifying therapies for sickle cell disease for at least 2 months *Note: Examples of disease-modifying therapies for sickle cell disease include hydroxyurea, Adakveo, L-glutamine, and Oxbryta.* |
| ☐ ii. | ii. Erythropoietin for at least 2 months |
| ☐ iii. | iii. Iron chelation therapy for at least 7 days *Note: Examples of iron chelators used for this condition include deferoxamine injection, deferiprone tablets or solution, and deferasirox tablets.* |
| ☐ iv. | iv. Anti-retrovirals (prophylactic for human immunodeficiency virus [HIV]) for at least 1 month *Note: Examples of anti-retrovirals for HIV include abacavir, emtricitabine, lamivudine, and zidovudine.* |
| | According to the prescribing physician, patient meets ALL of the following (i, ii, iii, and iv): |
| ☐ i. | i. Patient will undergo mobilization, apheresis, and myeloablative conditioning |
| ☐ ii. | ii. A hematopoietic stem cell mobilizer will be utilized for mobilization<br>*Note: Mozobil (plerixafor subcutaneous injection) is an example of a hematopoietic stem cell mobilizer.* |
| ☐ iii. | iii. Busulfan will be used for myeloablative conditioning |
| | 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): |
| ☐ iv.a. | a) Prior to planned start of mobilization |
| ☐ iv.b. | b) Until initiation of myeloablative conditioning |
| | Patient screening is negative for ALL of the following (i, ii, iii, and iv): |
| ☐ i. | i. Human immunodeficiency virus-1 and -2 **[documentation required]** |
| ☐ ii. | ii. Hepatitis B virus **[documentation required]**<br>*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. | iii. Hepatitis C virus **[documentation required]** |

| | |
|---|---|
| ☐ iv. | iv. Human T-lymphotrophic virus-1 and -2 **[documentation required]** |
| | According to the prescribing physician, a patient of reproductive potential meets ONE of the following (i or ii):<br>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 each mobilization cycle 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 Lyfgenia |
| ☐ 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 Lyfgenia |
| ☐ | 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]**<br>Date obtained: |
| ☐ | Patient had prior hematopoietic stem cell transplantation. |
| ☐ | Patient had prior receipt of gene therapy |

**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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