Cigna Healthcare Lyfgenia Gene Therapy Prior Auth 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: **Lyfgenia**

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?
☐ Buy and Bill / Office Stock
☐ Accredo
☐ Other (please specify):

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

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 Lyfgenia 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.

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

☐ Patient is ≥ 12 years of age;

☐ Patient has not received a gene therapy 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. 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;

☐ Genetic testing **[documentation required]** indicates the patient has ONE of the following sickle cell disease genotypes (i, ii, or iii):
- ☐ i. βS/βS genotype; OR
- ☐ ii. βS/β0 genotype; OR
- ☐ iii. βS/β+ genotype;

NOTE: other genotypes will be reviewed 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 sever vaso-occlusive crises or events include the following:
- An episode of acute pain that that resulted in a visit to a medical facility which required administration of an intravenous opioid and/or intravenous nonsteroidal anti-inflammatory drug;
- 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);
- 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;
- 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;
- 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. More than two α-globin gene deletions **[documentation required];**
- ☐ ii. Clinically significant and active bacterial, viral, fungal, or parasitic infection;
- ☐ 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. 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;
- ☐ v. 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. 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. Erythropoietin for at least 2 months;
☐ 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. Anit-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. Patient will undergo mobilization, apheresis, and myeloablative conditioning;
☐ ii. A hematopoietic stem cell mobilizer will be utilized for mobilization;
Note: Mozobil (plerixafor subcutaneous injection) is an example of a hematopoietic stem cell mobilizer.
☐ 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 both of the following timepoints (a and b)
☐ a. Prior to planned start of mobilization;
☐ b. Until initiation of 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]**;
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]**;
☐ 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):

☐ 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 Lyfgenia; OR
☐ ii. A male** of reproductive potential (i.e., capable of fathering a child) will use an effective method of contraception from the start of mobilization through at least 6 months after administration of Lyfgenia
☐ 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]**;

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

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

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

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

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

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