SENTARA HEALTH PLANS

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Lyfgenia™ (lovotibeglogene autotemcel) **(J3394) (Medical)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

☐ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Lyfgenia™ up to 4 infusion bags, approximately 20 mL/infusion bag, overwrap, and metal cassette: 73554-1111-xx
- A single dose of containing a minimum of 3×10^6 CD34+ cells/kg of body weight, in one or more infusion bags

B. Max Units (per dose and over time) [HCPCS Unit]:

- A single dose of Lyfgenia™ containing a minimum of 3×10^6 CD34+ cells/kg of body weight, in one or more infusion bags
- 1 treatment = 1 billable unit

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Coverage will be provided for one treatment course and may NOT be renewed.

- ❑ Member is ≥ 12 years of age
- ❑ Medication is prescribed by a hematologist or a stem cell transplant physician
- ❑ Member has **NOT** received a gene therapy for sickle cell disease in the past **(verified by medical paid claims)** [**NOTE**: If no claim for Lyfgenia™ or Casgevy® (exagamglogene autotemcel intravenous infusion) is present (or if claims history is not available), the prescribing physician confirms that the member has not previously received Lyfgenia™ or Casgevy®]
- ❑ According to the prescribing physician, a hematopoietic stem cell transplantation is appropriate for the member
- ❑ Member meets **ONE** of the following:
  - ❑ Member does **NOT** have a Human Leukocyte Antigen (HLA)-matched donor
  - ❑ Member has an HLA-matched donor, but the individual is not able or is not willing to donate
- ❑ Genetic testing indicates the member has **ONE** of the following sickle cell disease genotypes **(submit documentation)**:
  - ❑ β^S/β^S genotype
  - ❑ β^S/β^0 genotype
  - ❑ β^S/β^+ genotype
- ❑ Member has tried at least **ONE** pharmacologic treatment for sickle cell disease **(submit documentation)** [**NOTE**: Examples of pharmacologic treatment for sickle cell disease include hydroxyurea, L-glutamine, Adakveo® (crizanlizumab-tmca intravenous infusion)]
- ❑ While receiving appropriate standard treatment for sickle cell disease, member had at least four severe vaso-occlusive crises or events in the previous 2 years, as defined by at least **ONE** of the following **(submit documentation)**
  - ❑ An episode of acute pain that resulted in a visit to a medical facility which required administration of at least **ONE** of the following:
    - ❑ Intravenous opioid
    - ❑ Intravenous nonsteroidal anti-inflammatory drug
  - ❑ Acute chest syndrome [**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)]
  - ❑ Acute hepatic sequestration **[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]
  - ❑ Acute splenic sequestration [**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]

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- ❑ Acute priapism lasting > 2 hours and requiring a visit to a medical facility

❑ Member does **NOT** have the following:
- More than two α-globin gene deletions **(submit documentation)**
- Clinically significant and active bacterial, viral, fungal, or parasitic infection
- Advanced liver disease **(submit documentation)** [**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]
- 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
- Prior or current malignancy or myeloproliferative disorder or significant immunodeficiency disorder

❑ According to the prescribing physician, member will have been discontinued from the following medications (for the duration noted) prior to mobilization:
- 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]
- Erythropoietin for at least 2 months
- 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]
- 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, member meets **ALL** the following:
- ❑ Member will undergo mobilization, apheresis, and myeloablative conditioning
- ❑ A hematopoietic stem cell mobilizer will be utilized for mobilization [**NOTE**: Mozobil® (plerixafor subcutaneous injection) is an example of a hematopoietic stem cell mobilizer]
- ❑ Busulfan will be used for myeloablative conditioning
- ❑ Sickle hemoglobin level will be < 30% of total hemoglobin with total hemoglobin concentration ≤ 11 g/dL at **BOTH** of the following timepoint:
  - ❑ Prior to planned start of mobilization
  - ❑ Until initiation of myeloablative conditioning

❑ Prior to collection of cells for manufacturing, member cellular screening is negative for **ALL** the following **(submit documentation)**:
- ❑ Human immunodeficiency virus-1 and -2
- ❑ Hepatitis B virus [**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]
- ❑ Hepatitis C virus
- ❑ Human T-lymphotrophic virus-1 and -2

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- ❑ According to the prescribing physician, member meets **ONE** of the following:
  - ❑ Member is a female of reproductive potential and meets **BOTH** of the following:
    - ❑ A negative serum pregnancy test will be confirmed prior to the start of mobilization and re-confirmed prior to myeloablative conditioning
    - ❑ Member will use an effective method of contraception from the start of mobilization through at least 6 months after administration of Lyfgenia™
  - ❑ Member is a male of reproductive potential and will use an effective method of contraception from the start of mobilization through at least 6 months after administration of Lyfgenia™
- ❑ Member's current body weight has been obtained within 30 days **(submit documentation)**

Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy – Proprium Rx**

For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.