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.

Authorization Criteria: Coverage will be provided for one treatment course (1 dose of Lyfgenia) and may NOT be renewed.

- ❑ Member is ≥12 years of age
- ❑ Treating specialist(s) will be familiar with treating patients with sickle cells disease, and knowledgeable in conducting safe autologous stem cell transplant procedures
- ❑ Member has a diagnosis of sickle cell disease (SCD) as confirmed by the **ALL** the following:
  - ❑ Genetic panel confirming one of the following genotypes: βS/βS, βS/β0, βS/β+ **(documentation required identifying biallelic *HBB* pathogenic variants where at least one allele is the p.Glu6Val pathogenic variant on molecular genetic testing)**
  - ❑ Genetic panel confirming the member does **NOT** have more than two α-globin gene deletions, or carry the α-thalassemia trait, -α3.7/-α3.7
  - ❑ Medical chart notes detailing history of sickle cell disease (this will include documented history of crises as noted below)
- ❑ Provider must submit chart notes which contain detailed patient history and document **ALL** the following:
  - ❑ Interval treatment history demonstrating inadequate control to a least hydroxyurea and **ONE** of the following therapies approved to prevent complications of SCD, or reduce VOCs:
    - ❑ Endari® (glutamine)
    - ❑ Adakveo® (crizanlizumab)
  - ❑ While receiving appropriate standard treatment for sickle cell disease, member has had at least **FOUR** severe vaso-occlusive crises or events in the previous 2 years, as defined by at least **ONE** of the following **(check all that apply)**:
    - ❑ 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)**
    - ❑ Acute priapism lasting > 2 hours and requiring a visit to a medical facility

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- ❑ All other therapies for crises (e.g., Endari® (glutamine), Adakveo® (crizanlizumab), and hydroxyurea will be discontinued
- ❑ Member is HIV negative as confirmed by a negative HIV test prior to mobilization **[NOTE: Patients who have received Lyfgenia® are likely to test positive by polymerase chain reaction (PCR) assays for HIV due to integrated BB305 LVV proviral DNA, resulting in a possible false-positive PCR assay test result for HIV. Therefore, patients who have received Lyfgenia should not be screened for HIV infection using a PCR-based assay.]**
- ❑ **ALL** the following have been assessed, and confirmation is noted that the member does **NOT** have any of the following:
  - ❑ Severely elevated iron in the heart (i.e., patients with cardiac T2* less than 10 msec by magnetic resonance imaging [MRI])
  - ❑ Advanced liver disease, defined as:
    - Persistent aspartate transaminase, alanine transaminase, or direct bilirubin value > 3 x the upper limit of normal (ULN), **OR**
    - Baseline prothrombin time or partial thromboplastin time >1.5 x ULN, suspected of arising from liver disease, **OR**
    - MRI of the liver demonstrating clear evidence of cirrhosis, **OR**
    - Liver biopsy shows any evidence of cirrhosis, bridging fibrosis, or significant active hepatitis
  - ❑ MRI of the liver with results demonstrating liver iron content ≥ 15 mg/g (unless biopsy confirms absence of advanced disease)
- ❑ Member does **NOT** have a history of hypersensitivity to dimethyl sulfoxide (DMSO) or dextran 40
- ❑ Member does **NOT** have a history of untreated Moyamoya disease, or presence of Moyamoya disease that the provider believes will put the patient at risk of bleeding
- ❑ A transcranial doppler (TCD) ultrasonogrphy has been performed at baseline demonstrating a normal TCD velocity (time-averaged mean of the maximum velocity [TAMMV] <170 cm/sec in the middle cerebral artery (MCA) and the internal carotid artery **[NOTE: Members with a history of abnormal TCD (TAMMV ≥200 cm/sec) excluded from service authorization; other history of severe cerebral vasculopathy, defined by any history of: overt ischemic or hemorrhagic stroke, occlusion or stenosis in the circle of Willis are also excluded]**
- ❑ Females of reproductive potential have a negative pregnancy test prior to start of mobilization and re-confirmed prior to conditioning procedures and again before administration of lovotibeglogene autotemcel
- ❑ Females of childbearing potential and males capable of fathering a child must use effective method of contraception from start of mobilization through at least 6 months after administration of lovotibeglogene autotemcel
- ❑ Member is of sufficient weight to at least accept the minimum number of cells required to initiate the manufacturing process
- ❑ Requested medication will be used as single agent therapy (not applicable to lymphodepleting or bridging therapy while awaiting manufacture)

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- ❑ Member will receive periodic life-long monitoring for hematological malignancies
- ❑ Member is eligible to undergo hematopoietic stem cell transplant (HSCT) and has **NOT** had prior HSCT or other gene therapy
- ❑ Member has **NOT** received other gene therapies to treat sickle cell disease [e.g., Casgevy™ (exagamglogene autotemcel)]
- ❑ Provider must submit an assessment documenting a Karnofsky performance status of ≥ 60% for members ≥16 years of age, or a Lansky performance status of ≥ 60% for members <16 years of age
- ❑ Member does **NOT** have availability of a willing 10/10 HLA-matched sibling donor

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.