SENTARA COMMUNITY PLAN
(MEDICAID)

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 1-844-305-2331**. 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**.

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 Name/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 containing a minimum of 3.0×10^6 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 3.0×10^6 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 at least 12 years of age at the expected time of gene therapy administration
- ❑ CGT Product is prescribed by or in consultation with a board-certified hematologist with SCD expertise
- ❑ Member has a documented medical diagnosis of SCD by either confirmatory genetic testing or hemoglobin fractionation
- ❑ Failure or intolerance to hydroxyurea (defined as being unable to take hydroxyurea per health care professional judgement) at any point in the past
- ❑ CGT Product will be administered in a qualified treatment center
- ❑ Member meets **ONE** of the following (based on provider attestation):
  - ❑ Currently receiving chronic transfusion therapy for recurrent Vaso-Occlusive Events (VOEs)
  - ❑ Experienced four (4) or more VOEs in previous twenty-four (24) months as determined by the Eligible Beneficiary's treating clinician

Medication being provided by: Please check applicable box below.

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

  NPI or DEA # of administering location: _____

  OR
- ❑ **Specialty Pharmacy – PropriumRx**

For urgent reviews: Practitioner should call Sentara Health Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health'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.*

***Approved by Pharmacy and Therapeutics Committee**: ~~1/18/2024;~~ **11/21/2024**
REVISED/UPDATED/REFORAMATTED: 2/29/2024, 11/19/2024; 6/10/2026, **8/11/2026**