Highmark Wholecare
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

I. Requirements for Prior Authorization of Lyfgenia (lovotibeglogene autotemcel)

A. Prescriptions That Require Prior Authorization

All prescriptions for Lyfgenia (lovotibeglogene autotemcel) must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for Lyfgenia (lovotibeglogene autotemcel), the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed Lyfgenia (lovotibeglogene autotemcel) for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling; **AND**

2. Is age-appropriate according to FDA-approved package labeling; **AND**

3. Is prescribed a dose and number of treatments that are consistent with FDA-approved package labeling; **AND**

4. Is prescribed Lyfgenia (lovotibeglogene autotemcel) by a specialist at a qualified treatment center for Lyfgenia (lovotibeglogene autotemcel); **AND**

5. Does not have a contraindication to the prescribed drug; **AND**

6. Is clinically stable for transplantation based on the prescriber's assessment; **AND**

7. For treatment of sickle cell disease, **both** of the following:

    a. Has sickle cell disease with confirmatory genetic testing

    b. **One** of the following:

        i. Has a history of vaso-occlusive episodes (e.g., pain crises, acute chest syndrome, splenic sequestration, priapism) that required a medical facility visit (e.g., emergency department, hospital)
        ii. Is currently receiving chronic transfusion therapy for recurrent vaso-occlusive episodes.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for Lyfgenia (lovotibeglogene autotemcel). If the guidelines in Section B. are met, the reviewer will

prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Requests for prior authorization of Lyfgenia (lovotibeglogene autotemcel) will be approved for 18 months.

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LYFGENIA (lovotibeglogene autotemcel) PRIOR AUTHORIZATION FORM *(form effective 1/5/2026)*

Beneficiary name:	Beneficiary ID#:	Beneficiary DOB:
Prescriber name:		Prescriber NPI:
Prescriber address (street/city/state/zip):		
Prescriber specialty:	Prescriber phone:	Prescriber fax:
Office contact name:	Office contact phone:	Office contact fax:
Service provider name:		Service provider MA ID:
Service provider address (street/city/state/zip):		

Drug name: **Lyfgenia**	Beneficiary's weight (kg):	Dose: _____ x 10^6 CD34+ cells/kg
Place of service:		Anticipated date of infusion:
Diagnosis *(submit documentation)*:	Dx code (*required*):	HCPCS code *(required)*:

Check all that apply and submit documentation (e.g., recent chart/clinic notes, diagnostic evaluations, test results, etc.) for each item.

- ☐ Is clinically stable for transplantation based on the prescriber's assessment.
- ☐ Has NOT received a prior allogeneic hematopoietic stem cell transplant.
- ☐ Has sickle cell disease with confirmatory genetic testing.
- ☐ At least one of the following:
  - ☐ Has a history of vaso-occlusive episodes (e.g., pain crises, acute chest syndrome, splenic sequestration, priapism) that required a medical facility visit (e.g., emergency department, hospital).
  - ☐ Is currently receiving chronic transfusion therapy for recurrent vaso-occlusive episodes.

PLEASE FAX COMPLETED FORM WITH SUPPORTING CLINICAL DOCUMENTATION

Prescriber Signature:	**Date**: