



Medical Assistance BULLETIN

ISSUE DATE November 10, 2025	EFFECTIVE DATE January 5, 2026	NUMBER *See below
SUBJECT Prior Authorization of Lyfgenia (lovotibeglogene autotemcel) – Pharmacy Services		BY  Sally Kozak Deputy Secretary Office of Medical Assistance Programs

IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISe to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: <https://www.pa.gov/en/agencies/dhs/resources/for-providers/provider-enrollment-information/provider-enrollment-documents.html>.

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Lyfgenia (lovotibeglogene autotemcel) submitted for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program. The guidelines to determine the medical necessity of Lyfgenia (lovotibeglogene autotemcel) will be utilized in the fee-for-service and managed care delivery systems. Providers rendering services to MA beneficiaries in the managed care delivery system should address any questions related to the prior authorization of Lyfgenia (lovotibeglogene autotemcel) to the appropriate managed care organization.

BACKGROUND/DISCUSSION:

The Department of Human Services (Department) is updating the medical necessity guidelines for Lyfgenia (lovotibeglogene autotemcel) as follows:

*01-26-27	09-26-27	27-26-27	33-26-27
02-26-27	11-26-27	30-26-27	
03-26-27	14-26-27	31-26-27	
08-26-27	24-26-27	32-26-27	

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

Fee-for-Service Provider Service Center: 1-800-537-8862

Visit the Office of Medical Assistance Programs website at:

<https://www.pa.gov/en/agencies/dhs/departments-offices/omap-info.html>

- Deletion of the guideline that the beneficiary is not a prior recipient of gene therapy or an allogeneic hematopoietic stem cell transplant.
- Addition of a guideline that the beneficiary is clinically stable for transplantation based on the prescriber's assessment.
- Clarification of the guideline related to genetic testing for sickle cell disease.

The revisions to the guidelines to determine medical necessity of prescriptions for Lyfgenia (lovotibeglogene autotemcel) were subject to public review and comment and subsequently approved for implementation by the Department.

PROCEDURE:

The procedures for prescribers to request prior authorization of Lyfgenia (lovotibeglogene autotemcel) are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to Lyfgenia [lovotibeglogene autotemcel]) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs and products that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

RESOURCES:

Prior Authorization of Pharmaceutical Services Handbook – SECTION I
Pharmacy Prior Authorization General Requirements

<https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/pharmacy-prior-authorization-general-requirements.html>

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines

<https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/clinical-guidelines.html>

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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

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PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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.

E. References

1. Lyfgenia [prescribing information]. Somerville, MA: bluebird bio, Inc; December 2023.
2. The National Institutes of Health – National Heart, Lung, and Blood Institute Evidence-Based Management of Sickle Cell Disease, Expert Panel Report, 2014. Available at: https://www.nhlbi.nih.gov/sites/default/files/media/docs/sickle-cell-disease-report%20020816_0.pdf. Accessed March 2024.
3. Connor RF, Fosmarin AG, Tirnauer JS. What's new in hematology. UpToDate [internet database]. Waltham, MA: UpToDate Inc. Updated February 29, 2024. Accessed March 18, 2024.
4. Fitzjugh C. Investigational therapies for sickle cell disease. UpToDate [internet database]. DeBaun MR, Tirnauer JS, eds. Waltham, MA: UpToDate Inc. Updated December 22, 2023. Accessed March 15, 2024.