Clinical Policy: Lovotibeglogene autotemcel (Lyfgenia)

Reference Number: PA.CP.PHAR.627
Effective Date: 07/15/2024
Last Review Date: 11/2025

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Lovotibeglogene autotemcel (Lyfgenia) is **medically necessary** when the following criteria are met:

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 member:

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 medication; 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 member does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the member, 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 a 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 member

D. Approval Duration:
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.
5. ClinicalTrials.gov. A Study Evaluating the Safety and Efficacy of bb1111 in Severe Sickle Cell Disease. Last updated August 23, 2023. Available at: https://clinicaltrials.gov/ct2/show/NCT02140554. Accessed November 18, 2024.

6. Kanter J, Liem RI, Bernaudin F, et al. American Society of Hematology 2021 guidelines for sickle cell disease: stem cell transplantation. *Blood Adv*. 2021;5(18):3668-3689. doi:10.1182/bloodadvances.2021004394C
7. Kanter J, Walters MC, Krishnamurti L, et al. Biologic and Clinical Efficacy of LentiGlobin for Sickle Cell Disease. *N Engl J Med*. 2022;386(7):617-628. doi:10.1056/NEJMoa2117175
8. Yawn BP, Buchanan GR, Afenyi-Annan AN, et al. Evidence-based management of sickle cell disease: Expert Panel Report, 2014. National Heart, Lung, and Blood Institute (NHLBI). Available at: https://www.nhlbi.nih.gov/sites/default/files/media/docs/sickle-cell-disease-report%20020816_0.pdf. Accessed November 18, 2024.
9. Clinical Pharmacology [database online]. Philadelphia, PA: Elsevier. Updated periodically. Available at: http://www.clinicalkey.com/pharmacology. Accessed November 18, 2024.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3394	Injection, lovotibeglogene autotemcel, per treatment

Reviews, Revisions, and Approvals	Date
Policy created	07/2024
1Q 2025 annual review: Added HCPCS code [J3394] and removed HCPCS codes [J3590, C9399]; references reviewed and updated.	07/2025
Q1 2026: policy revised according to DHS revisions effective 01/05/2026.	11/2025