

lovotibeglogene autotemcel (Lyfgenia)**Medical Benefit Drug Policy**Place of Service

Hospital Administration

Hospital Outpatient Facility

Drug Details**USP Category:** GENETIC OR ENZYME OR PROTEIN DISORDER: REPLACEMENT, MODIFIERS, TREATMENT**Mechanism of Action:** Adds functional copies of a modified beta(A)-globin gene into patients' hematopoietic stem cells (HSCs) through transduction of autologous CD34+ cells with BB305LVV**HCPCS:**

J3394:Injection, lovotibeglogene autotemcel, per treatment

How Supplied:

- Supplied in one to four infusion bags containing a frozen suspension of genetically modified autologous cells, enriched for CD34+ cells
- Each bag contains approximately 20 mL. Each infusion bag is individually packed within an overwrap in a metal cassette.

Condition(s) listed in policy *(see coverage criteria for details)*

- Sickle Cell Disease

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Coverage Criteria**The following condition(s) require Prior Authorization/Preservice.****Sickle Cell Disease****Meets medical necessity if all the following are met:**

1. Diagnosis of sickle cell disease
2. Age is consistent with FDA-approved indication
3. Prescribed by or in consultation with a hematologist or transplantation specialist

4. Inadequate response, intolerable side effect, or contraindication to hydroxyurea
5. Patient has experienced at least four vaso-occlusive events (VOEs) in the past 2 years
6. Patient does not have alpha-thalassemia trait (two α -globin gene deletions)
7. Patient is clinically stable and eligible to undergo myeloablative conditioning and hematopoietic stem cell transplantation
8. Patient does not have a readily available matched sibling donor
9. Patient has not previously received allogeneic hematopoietic stem cell transplantation
10. Patient has not previously received gene therapy
11. Patient does not have any prior or current malignancy or immunodeficiency disorder, with the exception of non-melanoma skin cancers or immediate family member with a known or suspected Familial Cancer Syndrome
12. Patient does not have advanced liver disease (e.g., liver cirrhosis, active hepatitis, significant fibrosis, liver iron concentration of ≥ 15 mg/g)
13. Patient does not have evidence of chronic kidney disease
14. Patient does not have history of iron overload (e.g., serum ferritin levels >1000 ng/mL, cardiac T2 <10 ms on MRI)
15. Patient does not have severe cerebral vasculopathy (e.g., history of overt ischemic or hemorrhagic stroke, $>50\%$ stenosis or occlusion in the circle of Willis, Moyamoya disease)
16. Patient does not have any of the following viruses:
 - a. HIV-1 or HIV-2
 - b. Hepatitis B virus (HBV), unless one of the following:
 - i. Patient has received previous vaccination against hepatitis B (e.g., positive for hepatitis B surface antibody) AND has negative markers of hepatitis B (e.g., negative for hepatitis B core antibody)
 - ii. Patient has previous HBV exposure (e.g., positive for hepatitis B core antibody or hepatitis B e antibody) AND negative for HBV DNA
 - c. Hepatitis C virus (HCV), OR undetectable hepatitis C viral load if patient is positive for anti-hepatitis C antibody

Covered Doses:

- The minimum recommended dose is 3×10^6 CD34+ cells/kg
- Dosing is based on the number of CD34+ cells in the infusion bag(s) per kg of body weight.

Coverage Period:

One-time single-dose treatment

ICD-10:

D57.1

References

1. AHFS. Available by subscription at <http://www.lexi.com>
2. DrugDex. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
3. Lyfgenia (lovotibeglogene autotemcel) Prescribing Information. bluebird bio, Inc., Somerville, MA: 12/2023.

Review History

Date of Last Annual Review: 1Q2025

Changes from previous policy version:

- No clinical change following annual review.

*Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee*