lovotibeglogene autotemcel (Lyfgenia®)

Medical Benefit Drug Policy

Place of Service
Hospital Administration
Hospital Outpatient Facility

Limited Distribution (subject to change): City of Hope Children's Cancer Center, Loma Linda University

Drug Details

USP Category: UNCATEGORIZED
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:
C9399:Unclassified drugs or biolog
J3490:Drugs unclassified injection
J3590:Unclassified biologics
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.

- NDC 73554-1111-1 (20 mL infusion bag, overwrap, and 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 Health and Safety Code section 1367.21 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.

The following condition(s) require Prior Authorization/Preservice:

Sickle cell disease

1. Diagnosis of sickle cell disease, AND
2. Age consistent with FDA-approved indication, AND
3. Prescribed by or in consultation with a hematologist or transplantation specialist, AND
4. Inadequate response, intolerable side effect, or contraindication to hydroxyurea, AND
5. Patient has experienced at least four vaso-occlusive events (VOEs) in the past 2 years, AND
6. Patient does not have alpha-thalassemia trait (two α-globin gene deletions), AND
7. Patient is clinically stable and eligible to undergo myeloablative conditioning and hematopoietic stem cell transplantation, AND
8. Patient does not have a readily available matched sibling donor, AND
9. Patient has not previously received allogeneic hematopoietic stem cell transplantation, AND
10. Patient has not previously received gene therapy, AND
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, and
12. Patient does not have advanced liver disease (e.g., liver cirrhosis, active hepatitis, significant fibrosis, liver iron concentration of ≥15 mg/g), AND
13. Patient does not have evidence of chronic kidney disease, AND
14. Patient does not have history of iron overload (e.g., serum ferritin levels >1000 ng/mL, cardiac T2 <10 ms on MRI), AND
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), AND
16. Patient does not have any of the following viruses:
    a. HIV-1 or HIV-2, and
    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), or
        ii. Patient has previous HBV exposure (e.g., positive for hepatitis B core antibody or hepatitis B e antibody) AND negative for HBV DNA, and
    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

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]. Somerville, MA: bluebird bio, Inc.; 12/2023.

Review History

Date of Last Annual Review: 1Q2024
Date of last revision: 02/28/2024
Changes from previous policy version:

- New policy

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