Not Applicable to BlueCare

Lovotibeglogene Autotemcel (Lyfgenia®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Lyfgenia is indicated for the treatment of patients 12 years of age or older with sickle cell disease and a history of vaso-occlusive events.

Limitations of Use:
Following treatment with Lyfgenia, patients with α-thalassemia trait (-α3.7/-α3.7) may experience anemia with erythroid dysplasia that may require chronic red blood cell transfusions. Lyfgenia has not been studied in patients with more than two α-globin gene deletions.

All other indications are considered experimental/investigational and not medically necessary.

DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

- Molecular or genetic testing results documenting sickle cell disease genotype
- Chart notes or medical records documenting history of severe vaso-occlusive episodes

PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a hematologist.

COVERAGE CRITERIA

Sickle Cell Disease

Authorization of 3 months for one dose total may be granted for sickle cell disease when all of the following criteria are met:

- Member is 12 years of age or older.

- Member has a diagnosis of sickle cell disease with one of the following genotypes confirmed by molecular or genetic testing:
  - β^s/β^s
  - β^s/β^0
  - β^s/β^+
- Member has a documented history of at least 2 severe vaso-occlusive episodes per year during the previous two years (see Appendix for examples).
- Member is eligible for a hematopoietic stem cell transplant (HSCT) but is unable to find a matched (10/10) human leukocyte antigen (HLA) related donor.
- Member has not received a prior hematopoietic stem cell transplant (HSCT).
- Member has not received Lyfgenia or any other gene therapy previously.
- Member does not have more than two α-globin gene deletions.
- Member meets one of the following:
  - Has experienced, at any time in the past, an inadequate response or intolerance to a trial of hydroxyurea
  - Has a contraindication to hydroxyurea
- Member does not have any of the following conditions:
  - Positive for the presence of human immunodeficiency virus type 1 or 2 (HIV-1 and HIV-2), hepatitis B virus (HBV), or hepatitis C (HCV).
  - Any prior or current malignancy.
  - Clinically significant active infection.
  - Advanced liver disease (e.g., bridging fibrosis, cirrhosis, active hepatitis).
  - Uncorrected bleeding disorder.
  - Immunodeficiency disorder.
  - Severe cerebral vasculopathy.
  - Clinically significant pulmonary hypertension.
  - Inadequate pulmonary or cardiac function.
  - Uncontrolled seizure disorder.
  - Renal impairment (e.g., estimated glomerular filtration rate < 70 mL/min/1.73 m^2).

APPENDIX

Examples of Severe Vaso-Occlusive Events

- Acute pain event requiring a visit to a medical facility and administration of pain medications (opioids or intravenous [IV] non-steroidal anti-inflammatory drugs [NSAIDs]) or RBC transfusions.
- Acute chest syndrome.
- Priapism lasting > 2 hours and requiring a visit to a medical facility.
- Splenic sequestration.
- Hepatic sequestration.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Lyfgenia [package insert]. Somerville, MA: bluebird bio, Inc.; December 2023.
2. Kanter J, Walters JK, Krishnamurti L, Mapara MY, et al. Biologic and clinical efficacy of LentiGlobin for sickle cell disease. NEJM. 2022;386(7):617-628.
3. Evidence-Based Management of Sickle Cell Disease: Expert Panel Report, 2014. National Institutes of Health. Available at https://www.nhlbi.nih.gov/sites/default/files/media/docs/sickle-cell-disease-report%20020816_0.pdf. Accessed July 16, 2024.

EFFECTIVE DATE 4/2/2026

ID_CHS_2025