

## CAREFIRST: LYFGENIA (lovotibeglogene autotemcel)

**Client Requested:** The intent of the criteria is to ensure that patients follow selection elements as established by CareFirst.

### **COVERAGE CRITERIA**

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 Indication

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  $\alpha$ -thalassemia trait ( $-\alpha 3.7/-\alpha 3.7$ ) 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  $\alpha$ -globin gene deletions.

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

### **I. CRITERIA FOR INITIAL APPROVAL**

#### **Sickle Cell Disease**

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

- A. Member is 12 years of age or older.
- B. Patient has a confirmed diagnosis of sickle-cell disease. Examples of genotypes include, but not limited to,  $\beta S/\beta S$  or  $\beta S/\beta 0$  or  $\beta S/\beta +$
- C. Member has a documented history of at least 2 severe vaso-occlusive episodes per year during the previous two years (see Appendix for examples).
- D. Lack of clinically suitable, willing, and available complete or fully HLA matched sibling donor.
- E. Member has not received a prior hematopoietic stem cell transplant (HSCT).
- F. Member has not received Lyfgenia or any other gene therapy previously.
- G. Member does not have more than two  $\alpha$ -globin gene deletions.
- H. Member 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.

### **APPENDIX**

#### Examples of Severe Vaso-Occlusive Events

1. 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
2. Acute chest syndrome
3. Priapism lasting > 2 hours and requiring a visit to a medical facility
4. Splenic sequestration
5. Hepatic sequestration

### **REFERENCES**

1. Lyfgenia [package insert]. Somerville, MA: bluebird bio, Inc.; December 2023.

Reference number(s)
C28136-A

2. 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](https://www.nhlbi.nih.gov/sites/default/files/media/docs/sickle-cell-disease-report%20020816_0.pdf). Accessed December 13, 2023.