Reference number(s)
6292-A

SPECIALTY GUIDELINE MANAGEMENT

LYFGENIA (lovotibeglogene autotemcel)

POLICY

I. 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 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 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.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
A. Molecular or genetic testing results documenting sickle cell disease genotype
B. Chart notes or medical records documenting history of severe vaso-occlusive episodes

III. PRESCRIBER SPECIALTIES

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

IV. 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. Member has a diagnosis of sickle cell disease with one of the following genotypes confirmed by molecular or genetic testing:
   1. β^s/β^s
   2. β^s/β^0
   3. β^s/β^+
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. Member is eligible for a hematopoietic stem cell transplant (HSCT) but is unable to find a human leukocyte antigen (HLA)-matched related 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 α-globin gene deletions.

V. 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

VI. REFERENCES

1. Lyfgenia [package insert]. Somerville, MA: bluebird bio, Inc.; December 2023.
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. Accessed December 13, 2023.