Reference number(s)
6292-A

Standard Medicare Part B Management
Lyfgenia

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Lyfgenia	lovotibeglogene autotemcel

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

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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:
    - βs/βs
    - βs/β0
    - βs/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 human leukocyte antigen (HLA)-matched 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

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

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 July 16, 2024.