Maryland
DEPARTMENT OF HEALTH

Lyfgenia (lovotibeglogene autotemcel)

Lyfgenia is an autologous hematopoietic stem cell-based gene therapy 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.*

I. Criteria for Initial Approval

Lyfgenia will be considered for coverage when all of the criteria below are met, confirmed with supporting medical documentation.

- For use in patients 12 years of age and older at the expected time of gene therapy administration.
- Prescribed by or in collaboration with a Board Certified Hematologist with SCD expertise.
- Treatment performed in an Authorized Treatment Center (AKA Qualified Treatment Center)
- A VOE including severe VOE (sVOE), examples including but not limited to the following types of 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 requiring a visit to a medical facility (sVOE)
    - Hepatic sequestration
    - Splenic sequestration
- Patients are eligible for treatment if they had;
    - Experienced four (4) or more VOEs in the previous twenty-four (24) months as determined by the treating clinician **OR**
    - Currently receiving chronic transfusion therapy for recurrent Vaso-Occlusive Events (VOEs).
- The patient has had confirmatory Genetic Testing.
- Failure or intolerance to hydroxyurea (defined as being unable to take hydroxyurea per health care professional judgment) at any point in the past.

- The patient is clinically fit and stable for transplantation.
- The prescriber is responsible for confirming that the patient meets the FDA-approved prescribing information clinical parameters for use, including the absence of contraindications and the completion of appropriate screening and monitoring.

II. Dosing/Administration

Lyfgenia must be administered according to the current FDA labeling guidelines for dosage and timing. Please review the current FDA Dosing and Administration recommendations.

III. Length of Authorization For initial therapy

Lyfgenia will be authorized for one-time use only.

Prior authorization approval for Manufacturer CGT Product shall remain valid for a period of at least twelve (12) months.

IV. Billing Code/Information

CPT Code: J3394 Injection, lovotibeglogene autotemcel, per treatment

Prior authorization of benefits is not the practice of medicine nor a substitute for the independent medical judgment of a treating medical provider. The materials provided are a component used to assist in making coverage decisions and administering benefits. Prior authorization does not constitute a contract or guarantee regarding member eligibility or payment. Prior authorization criteria are established through a collaborative effort that incorporates input from the current medical literature and evidence available at the time.