STATE OF WEST VIRGINIA
DEPARTMENT OF HUMAN SERVICES
BUREAU FOR MEDICAL SERVICES

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Office of Pharmacy Services
Prior Authorization Criteria
Lyfgenia
Effective 2/26/2025

Prior Authorization Request Form

LYFGENIA (lovotibeglogene autotemcel) is an autologous hematopoietic stem cell-based gene therapy indicated for the treatment of patients 12 years of age and older with Sickle Cell Disease (SCD) and a history of vaso-occlusive events (VOEs). Lyfgenia is intended for a one-time administration of human blood stem and progenitor cells that are genetically modified with a replication-incompetent, self-inactivating lentiviral vector (LVV),and a gene delivery vehicle. Lyfgenia works by adding functional copies of a modified β-globin gene into the patient's hematopoietic stem cells (HSCs) through the transduction of autologous CD34+ cells with BB305 LVV leading to reduced erythrocyte sickling.

Limitations of Use: Lyfgenia has not been studied in patients with more than two α-globin gene deletions.

CRITERIA FOR APPROVAL:

1. Prescribed by, or in consultation with, a board-certified hematologist with SCD expertise; **AND**
2. The patient is 12 years of age or older at the expected time of gene therapy administration; **AND**
3. The patient has a Food and Drug Administration (FDA) approved diagnosis with confirmatory genetic testing; **AND**
4. The patient has documented prior use of, including failure or intolerance to, hydroxyurea (defined as being unable to take hydroxyurea per health care professional judgement) at any point in the past; **AND**
5. The patient is clinically stable and fit for transplantation; **AND**
6. The eligible patient's treatment facility has a Sickle Cell Center; **AND**
7. Based on providers' attestation, the patient has one of the following:
    a. Is currently receiving chronic transfusion therapy for recurrent Vaso-Occlusive Events (VOEs); **OR**
    b. Experienced four (4) or more VOEs in the previous 24 months as determined by the patient's treating clinician.

Approval may be authorized for a sufficient duration to allow for a single course of treatment which includes a one-time infusion and will not be reauthorized. Once approved, the prior authorization will be valid for at least 12 months.