Prior Authorization Criteria

MISSISSIPPI DIVISION OF MEDICAID

LYFGENIA® (*lovotibeglogene autotemcel*) PA CRITERIA for Sickle Cell Disease:

LYFGENIA® (*lovotibeglogene autotemcel*) 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 (SCD) and a history of vaso-occlusive events.

Prior authorization is required for LYFGENIA® (*lovotibeglogene autotemcel*) in sickle cell disease (SCD). Prior authorization approval will be considered when the following criteria are met. Along with the Universal PA Form, please submit any supporting clinical documentation.

Initial Authorization: 12 Months. One single dose per lifetime.

1. Age of the patient is 12 years and older at the expected time of gene therapy administration; **AND**

2. Patient has a diagnosis of sickle cell disease confirmed by genetic testing; **AND**

3. Patient has one of the following based on prescriber attestation:
    a. Experienced 4 or more vaso-occlusive events (VOEs) in the previous 24 months as determined by the treating clinician; **or**
    b. Currently receiving chronic transfusion therapy for recurrent VOEs**; AND**

4. Patient has failure or intolerance to hydroxyurea (defined as being unable to take hydroxyurea per healthcare professional judgement) at any point in the past; **AND**

5. Prescribed by or in consultation with a board-certified hematologist with sickle cell disease expertise; **AND**

6. Patient's treatment center has a Sickle Cell Center**; AND**

7. Prescriber attests that the patient is clinically stable and fit for transplantation.

LYFGENIA® Dosing: Dosing is based on the number of CD34+ cells in the infusion bag(s) per kg of body weight. The minimum recommended dose is 3 x 10^6 CD34+ cells/kg. LYFGENIA® is for autologous use only. Please see the full prescribing information for further details.

Formulation: LYFGENIA® is a cell suspension for intravenous infusion.