

Last review date: 3/26/2024

Applicable Products:
Lyfgenia (lovotibeglogene autotemcel)

Initial Approval Criteria:

Coverage may be approved if all of the following are met:

- Patient has a diagnosis of sickle cell disease and a history of vaso-occlusive events; **AND**
- Patient is at least 12 years of age; **AND**
- For patients with α -thalassemia trait ($-\alpha 3.7/-\alpha 3.7$), both of the following:
 - Patient does not have more than 2 α -globin gene deletions; **AND**
 - Prescriber will monitor for anemia with erythroid dysplasia following treatment as it may require chronic red blood cell transfusions; **AND**
- Must be prescribed by or in consultation with a hematologist; **AND**
- Prescriber attests to monitor for all of the following:
 - Hematologic malignancies by monitoring complete blood count (with differential) at least every 6 months for at least 15 years after treatment with Lygenia, and integration site analysis at months 6, 12, and as warranted; **AND**
 - Thrombocytopenia and bleeding by frequently monitoring platelet counts until platelet engraftment and platelet recovery are achieved; **AND**
 - Neutrophil engraftment failure (defined as failure to achieve three consecutive absolute neutrophil counts (ANC) $\geq 0.5 \times 10^9$ cells/L obtained on different days by Day 43 after treatment) by monitoring neutrophil counts until engraftment has been achieved; **AND**
 - Renal and hepatic function prior to treatment; **AND**
- Patient will not use any of the following:
 - Hydroxyurea for at least 2 months prior to mobilization; **AND**
 - Iron chelators for 6 months post-treatment; **AND**
 - Anti-retroviral medications for at least one month prior to mobilization; **AND**
- If applicable: Trial and failure, intolerance, or a contraindication to the preferred products as listed in the medical drug list

Renewal Criteria:

None

Length of Authorization:

1 dose per lifetime

This policy is designed to address medical guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Each person's unique clinical or other circumstances may warrant individual consideration, based on review of applicable medical records, as well as other regulatory, contractual and/or legal requirements.

Medical policies do not constitute medical advice, nor are they intended to govern the practice of medicine. They are intended to reflect reimbursement and coverage guidelines. Coverage for services may vary for individual members, based on the terms of the benefit contract.