

Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	August 14, 2024

Lyfgenia (Lovotibeglogene autotemcel)

LENGTH OF AUTHORIZATION: UP TO ONE YEAR FOR ONE INFUSION

REVIEW CRITERIA:

Coverage is provided when **ALL** the following criteria are met:

- Patient is at least 12 years of age; **AND**
- Patient has a confirmed diagnosis of sickle-cell disease with $\beta S/\beta S$ or $\beta S/\beta 0$ or $\beta S/\beta +$ genotypes; **AND**
 - Additional genotypes will be considered on an Individual Consideration (IC) basis based on disease severity.
- Patient does not have a contraindication to the prescribed medication; **AND**
- Patient does not have a clinically suitable, known & available 10/10 human leukocyte antigen matched sibling donor willing to participate in an allogeneic hematopoietic stem cell transplant; **AND**
- Patient has not received other gene therapy or an allogeneic hematopoietic stem cell transplant; **AND**
- Patient is prescribed Lyfgenia (lovotibeglogene autotemcel) by a specialist at a qualified treatment center for Lyfgenia (lovotibeglogene autotemcel); **AND**
- Patient has history of intolerance or failure of hydroxyurea treatment **OR** patient use of hydroxyurea is contraindicated; **AND**
- Prior to treatment, patient must have had at least 4 severe vaso-occlusive crisis (VOC) events in the previous 2 years **OR** is currently receiving chronic red blood cell (RBC) transfusion therapy for the prevention of severe vaso-occlusive episodes; **AND**
 - Severe VOC is defined as an occurrence of at least one of the following events **requiring an evaluation at a medical facility with no medically determined cause other than vaso-occlusion** requiring administration of pain medications such as opioids or intravenous (IV) non-steroidal anti-inflammatory drugs (NSAIDs) or RBC transfusions:
 - Acute pain
 - Acute chest syndrome
 - Acute hepatic sequestration
 - Priapism > 2 hours
 - Splenic sequestration
- Patient has a negative serologic test for HIV infection