

Lyfgenia (Lovotibeglogene autotemcel) Criteria

Revised: 11/01/2024

LYFGENIA (LOVOTIBEGLOGENE AUTOTEMCEL)

Length of Authorization: One treatment course

CRITERIA TO APPROVE

All the following:

- Confirmed diagnosis of sickle cell disease with **one** of the following genotypes:
 - $\beta S/\beta S$
 - $\beta S/\beta 0$
 - $\beta S/\beta +$
 - **Note:** Additional genotypes will be considered on an individual consideration (IC) basis based on disease severity.
- Age 12 years or older
- Prescriber is a specialist at a qualified treatment center for Lyfgenia
- Patient does not have a contraindication to the prescribed medication
- Patient does not have clinically suitable, known and available 10/10 human leukocyte antigen matched sibling donor willing to participate in an allogenic hematopoietic stem cell transplant
- Patient must not have received prior treatment with any gene therapy for sickle cell disease or an allogenic hematopoietic stem cell transplant
- Patient has history of intolerance or failure of hydroxyurea treatment **or** patient use of hydroxyurea is contraindicated
- Prior to treatment, patient must have experienced at least 4 (four) severe vaso-occlusive crises in the past 24 months **or** is currently receiving chronic red blood cell (RBC) transfusion therapy for the prevention of severe vaso-occlusive episodes
 - **Note:** 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

RENEWAL CRITERIA

Not applicable as no further authorizations will be provided

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REVISION HISTORY

Date	Issues/Updates
11/01/2024	<ul style="list-style-type: none">Initial draft creation

Orange Text = Important Information

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