

**SOUTH DAKOTA MEDICAID  
PRIOR AUTHORIZATION CRITERIA**

*Physician Administered Drugs, Vaccines, and Immunizations*

**Lovotibeglogene autotemcel (Lyfgenia) – PA Criteria**

HCPC: J3394

Lovotibeglogene autotemcel (Lyfgenia) is a gene therapy indicated for the treatment of sickle cell disease (SCD) in adults and pediatric patients ≥12 years of age who have a history of vaso-occlusive events (VOEs). It is covered by South Dakota Medicaid following prior authorization when the patient meets the following criteria:

\*\* All requests under this policy require SD medical director review in addition to meeting specified criteria below \*\*

• **Initial Therapy (must meet all):**

- Therapy is prescribed by a hematologist
- Individual has a diagnosis of SCD with a  $\beta^S/\beta^S$  genotype
- Documentation is provided that the individual has had ≥4 \*severe VOEs (as defined below), while receiving appropriate supportive care, for the previous 24 months prior to therapy request
- Individual has a documented failure (or contraindication) of ≥6 months with hydroxyurea within the last 24 months
- Attestation from provider that member is clinically stable and able to undergo gene therapy
- Individual does not have a known, human leukocyte antigen (HLA)-matched donor
- Screening has been done within the last 6 months and documentation is provided indicating that the individual is negative for the following active diseases: HIV, Hepatitis B, and Hepatitis C
- Individual has not previously received a hematopoietic stem cell transplant or prior gene therapy
- Individual does not have advanced liver disease (defined as aspartate transaminase, alanine transaminase or direct bilirubin >3x the upper limit of normal or baseline prothrombin time or partial thromboplastin time >1.5x upper limit of normal, or MRI of the liver demonstrating evidence of cirrhosis or active hepatitis or fibrosis)
- Individual does not have ≥2  $\alpha$ -globin gene deletions (i.e., alpha-thalassemia trait)
- If female, documentation of negative pregnancy test must be submitted prior to therapy
- Male and female members of reproductive potential must use an effective method of contraception at start of treatment and at least 6 months following Lyfgenia administration
- Individual is 12-50 years of age
- Approval duration: one dose

• **Continuation of Therapy: not authorized**

\*Severe VOE defined as one of the following that required a hospitalization or multiple visits to an emergency department/urgent care over 72 hours and required IV medications at each visit:

- Acute pain episode with no medically determined cause other than a VOE
- Acute chest syndrome (ACS), defined by an acute event with pneumonia-like symptoms and the presence of a new pulmonary infiltrate consistent with ACS, and requiring oxygen treatment and/or blood transfusion
- Acute hepatic sequestration, defined by a sudden increase in liver size associated with pain the right upper quadrant, abnormal results of liver function test not due to biliary tract disease, and reduction in Hb concentration by ≥2g/dL below the baseline value
- Acute Splenic sequestration, defined by a sudden enlargement of the spleen and reduction in Hb concentration ≥2g/dL below the baseline value
- Acute priapism: defined as sustained, unwanted painful erection lasting more than 2 hours and requiring care at a medical facility (with or without hospitalization)