ARKANSAS DEPARTMENT OF HUMAN SERVICES
Division of Medical Services

Cell-Based Gene Therapy
Lyfgenia® (lovotibeglogene autotemcel)

NOTE: Prior authorization requests must be submitted on a CMS-1450 to the Utilization Review department with the following contact information. https://humanservices.arkansas.gov/wp-content/uploads/DMSUR.docx

Drug Description

Lyfgenia® is a gene addition therapy designed to add genetic material to your cells by adding functional copies of the beta-globin gene to your blood stem cells to help your body make anti-sickling hemoglobin through a viral vector.

FDA Approved Indication(s)

Lyfgenia® is indicated for treatment of patients 12 years of age or older with sickle cell disease (SCD) and a history of vaso-occlusive events.

Prescribing Considerations

- Patient is 12 years of age and older at the expected time of gene therapy administration.
- Patient has a diagnosis of sickle cell disease confirmed by genetic testing with recurrent vaso-occlusive events (VOE) based on provider's attestation and defined as ONE of the following:
    - Currently receiving chronic transfusion therapy for recurrent vaso-occlusive events (VOEs); or
    - Experienced four (4) or more VOEs in previous twenty-four (24) months as determined by the eligible beneficiary's treating clinician with VOE presentation including but not limited to the following:
        - Pain crisis, acute chest syndrome or splenic sequestration that results in a hospital inpatient admission
        - Pain crisis, acute chest syndrome or splenic sequestration that results in an emergency department observation stay lasting more than eight (8) hours
        - Pain crisis that results in hospital outpatient visit, emergency department visit, or emergency department observation stay lasting eight (8) hours or less with administration if intravenous fluids (e.g., pain medication, hydration therapy, or red blood cell transfusions)
- Prescribed by, or in consultation with, a board-certified hematologist with SCD expertise in conjunction with treatment by an Arkansas Medicaid enrolled Sickle Cell treatment

center or out of state treatment center through a single case agreement with prior approval

- Patient is considered clinically stable and fit for transplantation
- Patient of reproductive potential must use adequate contraception for at least 6 months after administration of Lyfgenia®
- Prescriber must document counseling male and female patients of reproductive potential on the potential impact of myeloablative conditioning on fertility and the potential risk of infertility
- Patient must have failure or intolerance to hydroxyurea (defined as being unable to take hydroxyurea per health care professional judgement) at any point in the past.
- Patient should have discontinued hydroxyurea for at least 2 months prior to mobilization and until all cycles of apheresis are completed
- Patient should have discontinued Adakveo® (crizanlizumab-tmca) injection prior to mobilization and remain off this therapy post administration
- Patient should not take prophylactic HIV anti-retroviral medications for at least one month prior to mobilization and until all cycles of apheresis are completed
- Patient should have discontinued iron chelators at least 7 days prior to initiation of mobilization or myeloablative conditioning, and myelosuppressive iron chelators (e.g., deferiprone) should not be restarted for 6 months after Lyfgenia® infusion
- Prior authorization approval will be valid for a time period of 12 months

Monitoring

- Patient must be monitored for hematologic malignancies for lifetime with a complete blood count with differential monitored at least every 6 months for at least 15 years after treatment with Lyfgenia®, and integration site analysis at months 6, 12, and as warranted
- Patient must be monitored for bleeding and have platelets monitored until thrombocytopenia resolves
- Patient must have neutrophils monitored until engraftment has been achieved

Exclusions

- Patient with documented human immunodeficiency virus (HIV)
- Patient had prior treatment with gene therapy for SCD

Renewal / Reauthorization

- Lyfgenia® is a one-time treatment and cannot be renewed/reauthorized

Billing / Coding Information

Applicable Procedure Codes—see the billing guide

- Lyfgenia® J-code is J3394

Literature / References

- https://clinicaltrials.gov/study/NCT02140554?intr=lovotibeglogene%20autotemcel&rank=2&tab=results
- https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=0d1b475e-5781-2bd1-e063-6294a90a7311#S7.4

CHANGE AUTHORIZATION REVIEWS

Any changes/updates to this information must be documented as follows:

Version	Date	Author/Owner	Description of Change
1	11/18/2025	Cindi Pearson	New monograph