Protocol for Lyfgenia™ (lovotibeglogene autotemcel)

Approved January 2025

Background:

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Lyfgenia™ is an autologous hematopoietic stem cell-based gene therapy indicated for the treatment of patients 12 years of age or older with sickle cell disease and a history of vaso-occlusive events (VOEs).

Criteria for approval:

1. Diagnosis has been confirmed by genetic testing.
2. Patient has had a failure or intolerance to hydroxyurea (defined as being unable to take hydroxyurea per health care professional judgement) at any point in the past.
3. Patient is ≥ twelve (12) years of age at the expected time of gene therapy administration.
4. Patient is clinically stable for transplantation.
5. Medication is prescribed by or in consultation with a board-certified hematologist with SCD expertise.
6. Member's treatment center is a Qualified Treatment Center for the product
7. Either a or b (based on provider attestation):
    a. Is currently receiving chronic transfusion therapy for recurrent VOEs
    b. Has experienced four (4) or more VOEs in previous twenty-four (24) months as determined by the member's treating clinician.
8. Any prior authorization, once approved, will be valid for at least twelve (12) months

    NOTE: Black box warnings exist for hematologic malignancy. Patients should be monitored closely for evidence of malignancy through complete blood counts.

Approval Duration: Approve, once per lifetime (one single dose intravenously)

References:

1. Lyfgenia™ [package insert]. Somerville, MA: bluebird bio, Inc.; December 2023