



State of New Jersey
Department of Human Services
Division of Medical Assistance & Health Services
New Jersey Drug Utilization Review Board

Protocol for Lyfgenia™ (lovotibeglogene autotemcel)
Approved January 2025

Background:

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 \geq 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.

References:

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