New Hampshire Medicaid Fee-for-Service Program Lyfgenia® (lovotibeglogene autotemcel) Criteria

Approval Date: November 21, 2024

Medications

Brand Names	Generic Names	Indication
Lyfgenia®	lovotibeglogene autotemcel	Treatment of patients 12 years of age and older with sickle cell disease and a history of vaso-occlusive events

Criteria for Approval

1. Patient is 12 years of age or older; **AND**
2. Patient has a confirmed diagnosis of sickle-cell disease (includes genotypes βS/βS or βS/β0 or βS/β+) as determined by one of the following:
   - Identification of significant quantities of sickle cell hemoglobin (HbS) with or without an additional abnormal β-globin chain variant by hemoglobin assay; **OR**
   - Identification of biallelic hemoglobin beta gene (HBB) pathogenic variants where at least one allele is the p.Glu6Val pathogenic variant on molecular genetic testing; **AND**
3. Patient does **not** have disease with more than 2 α-globin gene deletions; **AND**
4. Patient has symptomatic disease despite treatment with hydroxyurea or add-on therapy (e.g., crizanlizumab); **AND**
5. Patient experienced two or more vaso-occlusive events/crises (VOE/VOC)* in the previous year while adhering to the above therapy; **AND**
6. Patient is a candidate for autologous hematopoietic stem cell transplant (HSCT); **AND**
7. Patient does **not** have a history of hypersensitivity to dimethyl sulfoxide (DMSO) or dextran 40; **AND**
8. Patient does **not** have a known 10/10 human leukocyte antigen (HLA) matched related donor willing to participate in an allogeneic HSCT; **AND**
9. Patient will be transfused at least twice (once each month) prior to mobilization to reach a target hemoglobin (Hb) of 8-10 g/dL (less than 12 g/dL) and HbS less than 30%; **AND**
10. Patient is human immunodeficiency virus (HIV) negative as confirmed by a negative HIV test prior to mobilization (**Note:** Patients who have received Lyfgenia are likely to test positive by polymerase chain reaction [PCR] assays for HIV due to integrated BB305 LVV proviral DNA, resulting in a possible false-positive PCR assay test result for HIV. Therefore, patients who have received Lyfgenia should not be screened for HIV infection using a PCR-based assay.); **AND**
11. Provider has considered use of prophylaxis therapy for seizures prior to initiating myeloablative conditioning; **AND**

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12. Patient will be monitored for hematologic malignancies periodically after treatment; **AND**
13. Lyfgenia must **not** be administered concurrently with live vaccines while immunosuppressed; **AND**
14. Patient will **not** receive therapy concomitantly with any of the following:
    - Hydroxyurea for 2 or more months prior to mobilization and until all cycles of apheresis are completed (**Note:** If hydroxyurea is administered between mobilization and conditioning, discontinue 2 days prior to initiation of conditioning); **AND**
    - Myelosuppressive iron chelators (e.g., deferiprone) for 7 days prior to mobilization, conditioning, and 6 months post-treatment; **AND**
    - Disease-modifying agents (e.g., L-glutamine, voxelotor, crizanlizumab) for at least 2 months prior to mobilization; **AND**
    - Prophylactic HIV anti-retroviral therapy (**Note:** Patients receiving prophylactic ART should stop therapy for 1 or more month prior to mobilization and until all cycles of apheresis are completed); **AND**
    - Mobilization of stem cells using granulocyte-colony stimulating factor (G-CSF); **AND**
    - Erythropoietin for 2 or more months prior to mobilization; **AND**
15. Patient has **not** received other gene therapy [e.g., Casgevy™ (exagamglogene autotemcel)]†.

VOE/VOC is defined as an event requiring a visit to a medical facility for evaluation which results in a diagnosis of such being documented due to one (or more) of the following: acute pain, acute chest syndrome, acute splenic sequestration, acute hepatic sequestration, priapism lasting more than 2 hours **and necessitating subsequent interventions such as opioid pain management, non-steroidal anti-inflammatory drugs, RBC transfusion, etc.*

†Requests for subsequent use of lovotibeglogene autotemcel after receipt of exagamglogene autotemcel will be evaluated on a case-by-case basis.

Criteria for Denial

Above criteria are not met.

References

Available upon request.

Revision History

Reviewed by	Reason for Review	Date Approved
DUR Board	New	05/07/2024
Commissioner designee	Approval	06/10/2024
DUR Board	Revision	10/15/2024

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Reviewed by	Reason for Review	Date Approved
Commissioner designee	Approval	11/21/2024

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