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New Hampshire Medicaid Fee-for-Service Program Prior Authorization Drug Approval Form

Lyfgenia™ (lovotibeglogene autotemcel)

DATE OF MEDICATION REQUEST: / /

SECTION I: PATIENT INFORMATION AND MEDICATION REQUESTED

LAST NAME:

FIRST NAME:

MEDICAID ID NUMBER:

DATE OF BIRTH: – –

GENDER: ☐ Male ☐ Female

Drug Name:

Strength:

Dosing Directions:

Length of Therapy:

SECTION II: PRESCRIBER INFORMATION

LAST NAME:

FIRST NAME:

SPECIALTY:

NPI NUMBER:

PHONE NUMBER: – –

FAX NUMBER: – –

SECTION III: CLINICAL HISTORY

1. Has the patient been diagnosed with sickle cell disease as determined by 1 of the following? (Check all that apply.)
   - ☐ Significant quantities of HbS with or without abnormal β-globin chain variant by hemoglobin assay
   - ☐ Biallelic HBB pathogenic variants where 1 or more allele is p.Glu6Val by molecular genetic testing
2. Does the patient have disease with more than 2 α – globin gene deletions? ☐ Yes ☐ No
3. Does the patient have symptomatic disease during treatment with hydroxyurea or add-on therapy (e.g., crizanlizumab)? ☐ Yes ☐ No
4. Has the patient experienced 2 or more vaso-occlusive events or crises in the last 12 months? ☐ Yes ☐ No
5. Has the patient received any other gene therapy? ☐ Yes ☐ No
6. Will the patient receive transfusions to target Hb of 8–10 g/dL and HbS less than 30% prior to apheresis and myeloablative conditioning? ☐ Yes ☐ No

Fax to DHHS; medication is administered in inpatient setting:
Phone: 1-603-271-9384
Fax: 1-603-314-8101

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Review Date: 12/04/2024

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PATIENT LAST NAME:

PATIENT FIRST NAME:

SECTION III: CLINICAL HISTORY *(Continued)*

7. Is the patient a candidate for hematopoietic stem cell transplant (HSCT), has not had HSCT, and does not have a willing, matched donor? ☐ Yes ☐ No
8. Will live vaccines be avoided during immunosuppression? ☐ Yes ☐ No
9. Does the patient have a history of hypersensitivity to dimethyl sulfoxide (DMSO) or dextran 40? ☐ Yes ☐ No
10. Has prophylactic therapy for seizures prior to myeloablative conditioning been considered for this patient? ☐ Yes ☐ No
11. Has the patient been screened and found negative for human immunodeficiency virus (HIV)? ☐ Yes ☐ No
12. Do you attest that the patient will be monitored periodically for hematologic malignancies? ☐ Yes ☐ No
13. Will the patient receive any of the following? ☐ Yes ☐ No
    - 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.)
    - Myelosuppressive iron chelators (e.g., deferiprone) for 7 days prior to mobilization, conditioning, and 6 months post-treatment
    - Disease-modifying agents (e.g., L-glutamine, voxelotor, crizanlizumab) for at least 2 months prior to mobilization
    - Prophylactic HIV anti-retroviral therapy (ART) (**Note:** Patients receiving prophylactic ART should stop therapy for 1 or more months prior to mobilization and until all cycles of apheresis are completed.)
    - Mobilization of stem cells using granulocyte-colony stimulating factor (G-CSF)
    - Erythropoietin for 2 or more months prior to mobilization

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SECTION III: CLINICAL HISTORY *(Continued)*

Please provide any additional information that would help in the decision-making process. If additional space is needed, please use a separate sheet.

I certify that the information provided is accurate and complete to the best of my knowledge and I understand that any falsification, omission, or concealment of material fact may subject me to civil or criminal liability.

PRESCRIBER'S SIGNATURE: _____ **DATE**: _____

Facility where infusion to be provided: _____

Medicaid Provider Number of Facility: _____

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