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

Casgevy™ (exagamglogene 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

Questions 1–7 are required for all indications.

1. Has prophylactic therapy for seizures prior to myeloablative conditioning been considered for this patient? ☐ Yes ☐ No
2. Has the patient been screened and found negative for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV)? ☐ Yes ☐ No
3. Does the patient have a history of hypersensitivity to dimethyl sulfoxide (DMSO) or dextran 40? ☐ Yes ☐ No
4. Has the patient received any other gene therapy? ☐ Yes ☐ No
5. Will iron chelators and disease-modifying agents be discontinued prior to conditioning and avoided following treatment as recommended? ☐ Yes ☐ No
   - Iron chelators: Avoid for 7 or more days prior and 6 months post-treatment (or 3 months post-treatment for non-myelosuppressive iron chelator).
   - Disease-modifying agents (e.g., hydroxyurea, voxelotor, crizanlizumab): Avoid for 8 or more weeks prior to treatment.

(Form continued on next page.)

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

Review Date: 12/04/2024

Prime THERAPEUTICS™

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PATIENT LAST NAME:

PATIENT FIRST NAME:

SECTION III: CLINICAL HISTORY *(Continued)*

6. Is the patient a candidate for hematopoietic stem cell transplantation (HSCT), has not had HSCT, and does not have a willing, matched donor? ☐ Yes ☐ No
7. Will live vaccines be avoided during immunosuppression? ☐ Yes ☐ No

Sickle Cell Disease (additional questions 8–12)

8. Has the patient been diagnosed with sickle cell disease as determined by one 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

9. Does the patient have symptomatic disease during treatment with hydroxyurea or add-on therapy (e.g., crizanlizumab)? ☐ Yes ☐ No
10. Has the patient experienced 2or more vaso-occlusive events or crises in the last 12 months? ☐ Yes ☐ No
11. Will the patient receive transfusions to target Hb 11 g/dL or less and HbS less than 30% prior to apheresis and myeloablative conditioning? ☐ Yes ☐ No
12. Do you attest that the patient has not received granulocyte-colony stimulating factor for stem cell mobilization? ☐ Yes ☐ No

Transfusion-dependent beta-thalassemia (questions 13–16)

13. Does the patient have a documented diagnosis of beta thalassemia that has been confirmed by the following? (Check all that apply.)

   ☐ Beta-globin gene (HBB) sequence gene analysis showing biallelic pathogenic variants

   ☐ Peripheral blood smear and hemoglobin analysis revealing decreased amounts or complete absence of hemoglobin A and increased amounts of hemoglobin HbA2 with or without increased amounts of hemoglobin F

(Form continued on next page.)

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SECTION III: CLINICAL HISTORY *(Continued)*

14. Does the patient have transfusion-dependent disease as defined by the following criteria? (Check all that apply.)

☐ transfusions of at least 100 mL/kg/year of packed red blood cells (pRBCs)

☐ 10 or more transfusions of pRBCs per year in the two years preceding therapy

15. Will the patient receive transfusions to achieve Hb 11 g/dL or more for 60 days prior to myeloablative conditioning? ☐ Yes ☐ No

16. Do you attest that the patient does not have **any** of the following? ☐ Yes ☐ No

- Severely elevated iron in the heart (cardiac T2* less than 10 msec by magnetic resonance imaging [MRI] or left ventricular systolic function [LVEF] less than 45% by electrocardiogram [ECG])
- Advanced liver disease (aspartate aminotransferase [AST] or alanine transaminase [ALT] more than 3 times upper limit of normal [ULN], direct bilirubin more than 2.5 times ULN, liver biopsy demonstrating bridging fibrosis or cirrhosis)

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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