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

Lenmeldy™ (atidarsagene 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. Is the patient under18 years of age? ☐ Yes ☐ No
2. Does the patient have a documented diagnosis of metachromatic leukodystrophy (MLD) that has been confirmed by one of the following? (Check all that apply.)
   - ☐ Arylsulfatase A (ARSA) enzyme activity below normal range in peripheral mononuclear cells
   - ☐ Increased urinary excretion of sulfatides and presence of biallelic ARSA pathogenic mutation of known polymorphisms
3. Does the patient have pre-symptomatic late infantile (PSLI), presymptomatic early juvenile (PSEJ), or early symptomatic early juvenile (ESEJ) disease? ☐ Yes ☐ No

(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: 07/01/2024

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SECTION III: CLINICAL HISTORY *(Continued)*

4. Has the patient received prior allogeneic stem cell transplant? ☐ Yes ☐ No
   If yes, go to question 5. If no, go to question 6.
5. Are residual donor cells present? ☐ Yes ☐ No
6. Is the patient eligible to undergo hematopoietic stem cell transplant (HSCT)? ☐ Yes ☐ No
7. Does the patient have a willing, eligible 10/10 matched donor? ☐ Yes ☐ No
8. Has the patient received other gene therapy for MLD? ☐ Yes ☐ No
9. Has the patient has been screened for the following conditions? ☐ Yes ☐ No
   - hepatitis B virus (HBV)
   - hepatitis C virus (HCV)
   - human T-lymphotrophic virus 1 and 2 (HTLV-1/HTLV-2)
   - human immunodeficiency virus 1 and 2 (HIV-1/HIV-2)
   - cytomegalovirus (CMV) and mycoplasma infection
10. Will the patient have mobilization of stem cells using granulocyte-colony stimulating factors with or without plerixafor? ☐ Yes ☐ No
11. Will myeloablative conditioning occur at least 24 hours prior to the Lenmeldy™ infusion? ☐ Yes ☐ No
12. Will the patient be evaluated for risk factors for thrombosis and veno-occlusive disease prior to administration? ☐ Yes ☐ No
13. Will the patient receive prophylaxis for infection according to the institutional guidelines? ☐ Yes ☐ No
14. Will vaccines be avoided 6 weeks prior to ablative conditioning until hematological recovery post-treatment? ☐ Yes ☐ No
15. Will prophylactic human immunodeficiency viruses (HIV) anti-retroviral therapy be avoided for at least one month prior to mobilization? ☐ Yes ☐ No
16. Has pregnancy been ruled out prior to starting mobilization and will lack of pregnancy be re-confirmed prior to conditioning procedures and again before administration of Lenmeldy™? ☐ Yes ☐ No
17. Will Lenmeldy™ be used as a single-agent therapy? ☐ Yes ☐ No
18. Do you attest that the patient will receive periodic monitoring for hematological malignancies? ☐ Yes ☐ No

(Form continued on next page.)

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SECTION III: CLINICAL HISTORY *(Continued)*

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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