OKLAHOMA Health Care Authority

State of Oklahoma
SoonerCare
Lenmeldy™ (atidarsagene autotemcel) Prior Authorization Form

Member Name: _____ ***Date of Birth:*** _____ ***Member ID#:*** _____

Drug Information

Physician billing (HCPCS code: _____***)*** ***Start Date:*** _____

Dose: _____ ***Regimen:*** _____

Billing Provider Information

Provider NPI: _____ ***Provider Name:*** _____

Provider Phone: _____ ***Provider Fax:*** _____

Prescriber Information

Prescriber NPI: _____ ***Prescriber Name:*** _____

Prescriber Phone: _____ ***Prescriber Fax:*** _____ ***Specialty:*** _____

Criteria

For Authorization: *(approvals will be for 1 dose per lifetime)*

1. Please indicate the diagnosis and information:
   - ☐ Metachromatic Leukodystrophy (MLD)
   - ☐ Other _____
2. How was the diagnosis confirmed? *(select one)*
   - ☐ Arylsulfatase A (ARSA) enzyme activity below the normal range in peripheral blood mononuclear cells or fibroblasts ***(Please submit results of assay)***
   - ☐ Molecular genetic testing confirming biallelic pathogenic variants in the ARSA gene of known polymorphisms ***(Please submit results of genetic testing)***
     a. Were novel ARSA variants identified? Yes☐ No☐
        i. If yes, did a 24-hour urine collection demonstrate increased urinary excretion of sulfatides? Yes☐ No☐ ***(Please submit results)***
3. Does the member have 1 of the following forms of MLD? ***(Please submit clinical documentation)***
   - ☐ Pre-symptomatic late infantile (PSLI) MLD with expected disease onset ≤30 months of age
   - ☐ Pre-symptomatic early juvenile (PSEJ) MLD with expected disease onset >30 months and <7 years of age
   - ☐ Early symptomatic early juvenile (ESEJ) MLD with disease onset >30 months and <7 years of age
4. Is Lenmeldy™ prescribed by a geneticist, hematologist/oncologist, neurologist, or other specialist with expertise in the treatment of MLD and the administration of Lenmeldy™? Yes☐ No☐
5. Does member have a history of prior hematopoietic stem cell transplantation (HSCT)? Yes☐ No☐
   a. If yes, is there evidence of residual cells of donor origin? Yes☐ No☐
6. Is member clinically stable and eligible to undergo HSCT? Yes☐ No☐

PLEASE PROVIDE THE INFORMATION REQUESTED AND RETURN TO:	CONFIDENTIALITY NOTICE
University of Oklahoma College of Pharmacy Pharmacy Management Consultants Product Based Prior Authorization Unit Fax: 1-800-224-4014 Phone: 1-800-522-0114 Option 4	*This document, including any attachments, contains information which is confidential or privileged. If you are not the intended recipient, be aware that any disclosure, copying, distribution, or use of the contents of this information is prohibited. If you have received this document in error, please notify the sender immediately by telephone to arrange for the return of the transmitted documents or to verify their destruction.*

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Criteria

For Authorization *(continued)**:***

7. Does the member have a negative serology test for human immunodeficiency virus 1 & 2 (HIV-1/HIV-2), hepatitis B virus (HBV), hepatitis C virus (HCV), human T-lymphotrophic virus 1 & 2 (HTLV-1/HTLV-2), cytomegalovirus (CMV), and mycoplasma prior to apheresis? Yes☐ No☐
8. For female members of reproductive potential, please answer the following:
   a. Is the member pregnant? Yes☐ No☐
   b. Does the member have a negative pregnancy test prior to the start of mobilization, prior to conditioning procedures, and prior to Lenmeldy™ administration? Yes☐ No☐
9. For all members of reproductive potential, please answer the following:
   a. Does member agree to use an effective method of contraception from the start of mobilization through at least 6 months after administration of Lenmeldy™? Yes☐ No☐
   b. Has member been counseled on the potential effects of myeloblative conditioning on fertility? Yes☐ No☐
   c. Is the potential risk of infertility acceptable to the member or member's caregiver? Yes☐ No☐
10. Has the member been evaluated for and counseled on all warnings and precautions related to Lenmeldy™, including the risk of thrombosis and thromboembolic events, serious infections, and veno-occlusive disease? Yes☐ No☐
11. Will member be monitored for hematologic malignancies lifelong, with a complete blood count (with differential) performed annually and integration site analysis as warranted for at least 15 years after treatment with Lenmeldy™? Yes☐ No☐
12. Will Lenmeldy™ be administered at a Lenmeldy™ qualified treatment center? Yes☐ No☐
    a. Name of facility: _____
    b. Does the receiving facility have a mechanism in place to track the patient-specific Lenmeldy™ dose from receipt to storage to administration? Yes☐ No☐

Additional Information: _____

_____

_____

_____

Prescriber Signature: _____ **Date:** _____

I certify that the indicated treatment is medically necessary and all information is true and correct to the best of my knowledge. Failure to complete all pages will result in processing delays.

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