Cigna Healthcare Lenmeldy Gene Therapy Prior Auth
This therapy requires supportive documentation (chart notes, genetic test results, etc.).

Gene Therapy Prior Authorization

To allow more efficient and accurate processing of your medication request, please complete this form and fax it back along with copies of all supporting clinical documentation. Fax completed form to Fax# 833-910-1625.

Notice: Failure to complete this form in its entirety may result in delayed processing or an adverse determination for insufficient information.

Gene Therapy Product Name: **Lenmeldy**

Cigna has designated the above product to be a gene therapy product, which is included in the Cigna Gene Therapy Provider Network.

Questions pertaining to gene therapy may be directed to the dedicated Gene Therapy Program team at 855.678.0051 or email to GeneTherapyProgram@Cigna.com

PHYSICIAN INFORMATION			PATIENT INFORMATION		
***Physician Name:**			Due to privacy regulations, we will not be able to respond via fax with the outcome of our review unless all asterisked (*) items on this form are completed.		
Specialty:	***DEA, NPI or TIN:**				
Office Contact Person:			***Customer Name:**		
Office Phone:			***Cigna ID:**	***Customer Date of Birth:**	
Office Fax: *Is your fax machine kept in a secure location: ☐ Yes ☐ No *May we fax our response to your office? ☐ Yes ☐ No			***Customer / Patient Street Address:**		
Office Street Address:			**City:**	**State:**	**Zip:**
City:	**State:**	**Zip:**	**Patient Phone:**		

Urgency:
☐ Standard
☐ Urgent (in checking this box, I attest to the fact that applying the standard review time frame may seriously jeopardize the customer's life, health, or ability to regain maximum function)

Where will this medication be obtained?
☐ Accredo
☐ Buy and Bill / Office Stock
☐ Other

What location will this medication be administered?
☐ Outpatient Hospital ☐ Inpatient Hospital ☐ MD Office / Clinic
☐ Home ☐ Other

Facility Name:
Address: State:

Tax ID#:

ICD 10 Associated with the Indication of this request:

Lenmldy is considered medically necessary when the following criteria are met, check all that apply:

Documentation is required for use of Lenmeldy as noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, laboratory results, medical test results, claims records, prescription receipts, and/or other information.

☐ Patient meets ONE of the following (i, ii, or iii):

☐ i. Patient has presymptomatic late infantile (PSLI) metachromatic leukodystrophy (MLD) and meets ALL of the following (a, b, and c):

☐ a) Patient has an arylsulfatase A (ARSA) genotype consistent with presymptomatic late infantile MLD **[documentation required]**

☐ b) The disease onset was at ≤ 30 months of age

☐ c) According to the prescribing physician, the patient is presymptomatic; **OR**

Note: Presymptomatic status is defined as the absence of neurological signs and symptoms of MLD. However, presymptomatic children are allowed to have abnormal reflexes or abnormalities on brain magnetic resonance imaging and/or nerve conduction tests not associated with functional impairment (e.g., no tremor, no peripheral ataxia).

☐ ii. Patient has presymptomatic early juvenile (PSEJ) metachromatic leukodystrophy (MLD) and meets ALL of the following (a, b, and c):

☐ a) Patient has an arylsulfatase A (ARSA) genotype consistent with presymptomatic early juvenile MLD **[documentation required]**

☐ b) The disease onset was between > 30 months and < 7 years of age

☐ c) According to the prescribing physician, the patient is presymptomatic; **OR**

Note: Presymptomatic status is defined as the absence of neurological signs and symptoms of MLD or physical examination findings limited to abnormal reflexes and/or clonus. However, presymptomatic children were allowed to have abnormal reflexes or abnormalities on brain magnetic resonance imaging and/or nerve conduction tests not associated with functional impairment (e.g., no tremor, no peripheral ataxia).

☐ iii. Patient has early symptomatic early juvenile (ESEJ) metachromatic leukodystrophy (MLD) and meets ALL of the following (a, b, and c):

☐ a) Patient has an arylsulfatase A (ARSA) genotype consistent with early symptomatic early juvenile MLD **[documentation required]**

☐ b) The disease onset was between > 30 months and < 7 years of age

☐ c) The patient has early symptomatic status by meeting BOTH of the following [(1) and (2)]:

☐ (1) Patient is walking independently as defined as being at gross motor function classification for metachromatic leukodystrophy [GMFC-MLD] Level 0 (with or without ataxia) or GMFC-MLD Level 1

☐ (2) Patient has an intelligence quotient ≥ 85; AND

☐ Patient has not received Lenmeldy in the past

☐ Patient has low arylsulfatase A (ARSA) activity indicative of metachromatic leukodystrophy (MLD) **[documentation required]**. *Note: Normal laboratory reference range for ARSA activity in the peripheral blood mononuclear cells is 31 to 198 nmol/mg/hour. In patients with MLD, ARSA activity is 0% to less than or equal to 13%.*

☐ Patient has elevated sulfatide levels above the normal laboratory reference range as evaluated by 24-hour urine collection **[documentation required]**

☐ According to the prescribing physician, a hematopoietic stem cell transplantation is appropriate for the patient

☐ According to the prescribing physician, patient will have discontinued from anti-retrovirals (prophylactic for human immunodeficiency virus) for at least 1 month prior to mobilization. *Note: Examples of anti-retrovirals include abacavir, emtricitabine, lamivudine, and zidovudine.*

☐ According to the prescribing physician, patient meets ALL of the following (i, ii, and iii):
- ☐ i. Patient will undergo mobilization, apheresis, and myeloablative conditioning
- ☐ ii. A granulocyte-colony stimulating factor product with or without a hematopoietic stem cell mobilizer will be utilized for mobilization. *Note: Filgrastim products are examples of a granulocyte-colony stimulating factor therapy and Mozobil (plerixafor subcutaneous injection) is an example of a hematopoietic stem cell mobilizer.*
- ☐ iii. Busulfan will be used for myeloablative conditioning

☐ Patient screening is negative for ALL of the following (i, ii, iii, iv, v, and vi):
- ☐ i. Human immunodeficiency virus (HIV)-1 and HIV-2 **[documentation required]**
- ☐ ii. Hepatitis B virus **[documentation required]**
- ☐ iii. Hepatitis C virus **[documentation required]**
- ☐ iv. Human T-lymphotrophic virus (HTLV)-1 and HTLV-2 **[documentation required]**
- ☐ v. Cytomegalovirus **[documentation required]**
- ☐ vi. Mycoplasma **[documentation required]**

☐ The medication is prescribed by a hematologist, a neurologist, a medical geneticist physician, or a stem cell transplant specialist physician

☐ Current patient body weight has been obtained within the past 30 days **[documentation required]**

If any of the requirements listed above are not met and provider feels administration of Lenmeldy is medically necessary, please provide clinical support and rationale for the use of Lenmeldy.

Additional pertinent information: (including recent history and physical, recent lab work, disease stage, prior therapy, performance status, and names/doses/admin schedule of any agents to be used concurrently)

If any of below apply to your patient, please provide clinical support and rationale for the use of this gene therapy.

☐ **Late Juvenile Form of Metachromatic Leukodystrophy.** The safety and efficacy have not yet been established in children with the late juvenile form of the disease.[1]

☐ **Adult Form of Metachromatic Leukodystrophy.** The safety and efficacy have not yet been established in patients with the adult form of the disease.

☐ **Gross Motor Function Classification for Metachromatic Leukodystrophy (GMFC-MLD) > Level 1.** These patients were not included in the clinical studies.

☐ **Prior Allogeneic Hematopoietic Stem Cell Transplantation in the Past 6 Months or Evidence of Residual Donor Cells.**

Note: Prescribing physician must confirm that the patient has not received a prior allogeneic hematopoietic stem cell transplantation in the past 6 months.
Prior allogeneic hematopoietic stem cell transplant within the past 6 months prevented participation, as well as evidence of residual donor cells in those who had underdone allogeneic hematopoietic stem cell transplantation.

☐ **Prior Receipt of Gene Therapy.** Lenmeldy has not been studied in a patient who has received prior gene therapy.

Additional CPT and Administration Codes for Consideration Following Medical Necessity Determination:

Please indicate any other CPT codes that will be billed for administration.
☐ Other

Agreement and Attestation

Do you and your patient agree to share any required plan specific outcome measures?
☐ Yes
☐ No

I attest the information provided is true and accurate to the best of my knowledge. I understand that the Health Plan or insurer its designees may perform a routine audit and request the medical information necessary to verify the accuracy of the information reported on this form.

Prescriber Signature: _____

Date: _____

[redacted]

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