Cigna Healthcare Gene Therapy Prior Auth Request Form

This therapy requires supportive documentation (chart notes, genetic test results, etc.).

****Due to privacy regulations we will not be able to respond via fax with the outcome of our review unless all asterisked (*) fields on this form are completed****

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?
☐ Other (please specify):

ICD10:

Name of Facility administering medication:
Facility Name: State: Tax ID#:
Address (City, State, Zip Code):

Clinical Information

Diagnosis related to use (please specify):

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

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

a. Patient has and arylsulfatase A (ARSA) genotype consistent with presymptomatic late infantile MLD AND
b. The disease onset was </= 30 months of age, AND
c. According to the prescribing physician, the patient is presymptomatic (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 the following [documentation required],:

a. Patient has and arylsulfatase A (ARSA) genotype consistent with presymptomatic early juvenile MLD AND
b. The disease onset was </= 30 months of age, AND
c. According to the prescribing physician, the patient is presymptomatic. 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 the following (a, b, and c) [documentation required],:

a. Patient has arylsulfatase A (ARDS) genotype consistent with early symptomatic early juvenile MLD AND
b. The disease onset was between >30 months and <7 Years of age, AND
c. The patient is early symptomatic status by meaning 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; AND
(2) Patient has intelligence quotient >/= 85

Patient has not received Lenmeldy in the past?

☐ Yes
☐ No

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%).

☐ Yes
☐ No

Patient has elevated sulfatide levels above the normal laboratory reference range as evaluated by 24-hour urine collection? [Documentation Required]

☐ Yes
☐ No

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

☐ Yes
☐ No

According to prescribing physician, patient meets ALL the following (i, ii, and iii) – check all that apply

☐ 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

Prior to collection of cells for manufacturing cellular screening is negative for ALLof the following (i, ii, iii, iv, v and vi) – check all that apply [Documentation Required for i through vi]:

☐ i. Human immunodeficiency virus (HIV) 1 and HIV-2, AND
☐ ii. Hepatitis B, AND
☐ iii. Hepatitis C, AND
☐ iv. Human T-lymphotropic virus (HTLV) 1 and HTLV-2, AND
☐ v. Cytomegalovirus, AND
☐ vi. Mycoplasma

This medication is prescribed by a hematologist, neurologist, a medical geneticist, or a stem cell specialist.
☐ Yes
☐ No

Current patient body weight been obtained within the last 30 days? [Documentation Required]
☐ Yes
☐ No
Date obtained: ____/___/___

Has your patient received prior Allogeneic Hematopoietic Stem Cell Transplantation in the past 6 months or evidence of residual donor cells?
☐ Yes
☐ No

Has your patient had prior receipt of gene therapy?
☐ Yes
☐ No

Has your patient ever received any other therapies for this diagnosis?
☐ Yes
☐ No
If yes, please provide the following details: date(s) taken and for how long, what the documented results were of taking this treatment, including any intolerances or adverse reactions your patient experienced.

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.

Lenmeldy is one dose given by intravenous infusion to provide a one-time (per lifetime) single dose within the following dosing ranges according to ONE of the following metachromatic leukodystrophy (MLD) disease types (A, B, or C):
☐ A) Presymptomatic late infantile MLD, the minimum recommended dose is 4.2 x 106 CD34+ cells/kg up to a maximum recommended dose of 30 x 106 CD34+ cells/kg [verification required]; **OR**
☐ B) Presymptomatic early juvenile MLD, the minimum recommended dose is 9 x 106 CD34+ cells/kg up to a maximum recommended dose of 30 x 106 CD34+ cells/kg [verification required]; **OR**
☐ C) Early symptomatic early juvenile MLD, the minimum recommended dose is 6.6 x 106 CD34+ cells/kg up to a maximum recommended dose of 30 x 106 CD34+ cells/kg [verification required].

Additional CPT and Administration Codes for Consideration Following Medical Necessity Determination
Cell Collection
☐96372 Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
☐38206 Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; autologous
☐Other
Select applicable G-CSF (Cigna preferencing may apply). Include dose, quantity, duration
☐J2562 Injection, plerixafor, 1mg (Mozobil) Plus
☐J1442 Injection, filgrastim (G-CSF), excludes biosimilar, 1 mcg
☐J1447 Injection, tbo-filgrastim, 1 mcg
☐Q5101 Injection, filgrastim-sndz, biosimilar (Zarxio), 1 mcg
☐Q5110 Injection, filgrastim-aafi, biosimilar (Nivestym), 1 mcg
☐Other

Conditioning Regimen
☐J0594 Injection, bulsulfan, 1 mg
☐Other

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

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).*

Agreement and Attestation

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

Attestation: 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:_____

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 Address: Cigna Pharmacy Services, PO Box 42005, Phoenix AZ 85080-2005