Fax completed form to designated gene therapy fax (833) 910-1625
For Urgent requests please outreach to Cigna Gene Therapy Program at (855) 678-0051 or email to GeneTherapyProgram@Cignahealthcare.com

Gene Therapy Lenmeldy™

(atidarsagene autotemcel intravenous infusion)

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 under physician and patient information are completed.		
Specialty:	* DEA, NPI or TIN:				
Office Contact Person:			* Patient Name:		
Office Phone:			* Cigna ID:	* Date of Birth:	
Office Fax:			* Patient Street Address:		
Office Street Address:			City:	State:	Zip:
City:	State:	Zip:	Patient Phone:		

FACILITY BILLING INFORMATION FOR PAYMENT SUPPORT		
Billing Office Contact Name:	Billing Office Phone:	Billing Office Email:
Billing Adress:		
Billing TIN:	Billing NPI:	

CLINICAL DETAILS

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)

Medication Request Detail:

ICD10: HCPCS Code

NDC: Additional Comment:

New Start: Continuation:

Where will this medication be obtained?

☐ Accredo

☐ Other (please specify):

☐ Physician's office stock (billing on a medical claim form)

Facility and/or doctor administering medication:

Facility Name: State: Tax ID#:

Address (City, State, Zip Code):

Where will this drug be administered?

☐ Hospital Outpatient

☐ Other (please specify):

☐ Hospital Inpatient

What is the indication or diagnosis?

☐ Metachromatic Leukodystrophy (MLD)

☐ other

Clinical Information. **Documentation is required for use of this gene therapy. Documentation may include, but is not limited to, chart notes, laboratory results, medical test results, claims records, prescription receipts, and/or other information. All documentation must include patient-specific identifying information.**

Check all that apply:

	Patient meets ONE of the following (**i, ii, or iii**):
☐ i.	i. Patient has presymptomatic late infantile (PSLI) metachromatic leukodystrophy (MLD) and meets ALL of the following (a, b, and c):
☐ i.a.	a) Patient has an arylsulfatase A (ARSA) genotype consistent with presymptomatic late infantile MLD **[documentation required]**
☐ i.b.	b) The disease onset was at ≤30 months of age
☐ i.c.	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.	ii. Patient has presymptomatic early juvenile (PSEJ) metachromatic leukodystrophy (MLD) and meets ALL of the following (a, b, and c):
☐ ii.a.	a) Patient has an arylsulfatase A (ARSA) genotype consistent with presymptomatic early juvenile MLD **[documentation required]**
☐ ii.b.	b) The disease onset was between > 30 months and < 7 years of age
☐ ii.c.	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.	iii. Patient has early symptomatic early juvenile (ESEJ) metachromatic leukodystrophy (MLD) and meets ALL of the following (a, b, and c):
☐ iii.a.	a) Patient has an arylsulfatase A (ARSA) genotype consistent with early symptomatic early juvenile MLD **[documentation required]**
☐ iii.b.	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)]:
☐ iii.c.1.	(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
☐ iii.c.2.	(2) Patient has an intelligence quotient ≥ 85
☐	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.	i. Patient will undergo mobilization, apheresis, and myeloablative conditioning
☐ ii.	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.	i. Human immunodeficiency virus (HIV)-1 and HIV-2 **[documentation required]**
☐ ii.	ii. Hepatitis B virus **[documentation required]**
☐ iii.	iii. Hepatitis C virus **[documentation required]**
☐ iv.	iv. Human T-lymphotrophic virus (HTLV)-1 and HTLV-2 **[documentation required]**
☐ v.	v. Cytomegalovirus **[documentation required]**
☐ vi.	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]** Date Obtained:
☐	Late Juvenile Form of Metachromatic Leukodystrophy
☐	Adult Form of Metachromatic Leukodystrophy
☐	Gross Motor Function Classification for Metachromatic Leukodystrophy (GMFC-MLD) > Level 1
☐	Prior Allogeneic Hematopoietic Stem Cell Transplantation in the Past 6 Months or Evidence of Residual Donor Cells.
☐	Prior Receipt of Gene Therapy

If any of the requirements listed above are not met and you feel administration of the requested gene therapy is medically necessary, please provide clinical support and rationale for the use of this gene therapy.

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)

Additional CPT and/or Administration Codes for Billing.

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

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:**_____

Our standard response time for prescription drug coverage requests is 5 business days. If your request is urgent, it is important that you call us to expedite the request. View our Coverage Policies online at cigna.com.

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