

Please fax all pages of completed form to your team at 808.650.6487.

To reach your team, call toll-free 808.650.6488.

You can now monitor shipments and chat online if you have questions. Go to [MyAccredoPatients.com](http://MyAccredoPatients.com) to log in or get started.

Prescription & Enrollment Form

# LENMELDY™ (atidarsagene autotemcel)

accredo®

677 Ala Moana Blvd., Suite 404,  
Honolulu, HI 96813-5412

Four simple steps to submit your referral.

## 1 Patient Information



Please provide copies of front and back of all medical and prescription insurance cards.

Orchard COI ID \_\_\_\_\_  
Patient's first name \_\_\_\_\_ Last name \_\_\_\_\_ Middle initial \_\_\_\_\_  
Sex at birth: Male Female Gender identity \_\_\_\_\_ Pronouns \_\_\_\_\_ Last 4 digits of SSN \_\_\_\_\_  
Date of birth \_\_\_\_\_ Street address \_\_\_\_\_ Apt # \_\_\_\_\_  
City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_  
Home phone \_\_\_\_\_ Cell phone \_\_\_\_\_ Email address \_\_\_\_\_  
Parent/guardian \_\_\_\_\_  
Home phone \_\_\_\_\_ Cell phone \_\_\_\_\_ Email address \_\_\_\_\_  
Alternate caregiver/contact \_\_\_\_\_  
Home phone \_\_\_\_\_ Cell phone \_\_\_\_\_ Email address \_\_\_\_\_

OK to leave message with alternate caregiver/contact

Patient's primary language: English Other If other, please specify \_\_\_\_\_

**Provider will read the following statement:** By providing the phone number(s) and email address above, you consent to receiving automated/artificial voice calls, emails and/or text messages from Accredo about your prescription(s), account, and health care. Standard data rates apply. Message frequency varies.

## 2 Prescriber Information

All fields must be completed to expedite prescription fulfillment.

Date \_\_\_\_\_ Estimated Apheresis Date \_\_\_\_\_  
Office/clinic/institution name \_\_\_\_\_  
**Prescriber info:** Prescriber's first name \_\_\_\_\_ Last name \_\_\_\_\_  
Prescriber's title \_\_\_\_\_ If NP or PA, under direction of Dr. \_\_\_\_\_  
Office phone \_\_\_\_\_ Fax \_\_\_\_\_ NPI # \_\_\_\_\_ License # \_\_\_\_\_  
Office contact and title \_\_\_\_\_ Office contact email \_\_\_\_\_  
Office street address \_\_\_\_\_ Suite # \_\_\_\_\_  
City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_

**QTC Info:** QTC site name \_\_\_\_\_  
Delivery address at the QTC for drug product \_\_\_\_\_ Suite # \_\_\_\_\_  
City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_  
QTC site contact \_\_\_\_\_ Phone \_\_\_\_\_ Fax \_\_\_\_\_ Email \_\_\_\_\_

## 3 Clinical Information

**Primary ICD-10 code (REQUIRED):** \_\_\_\_\_ Has the patient been treated previously for this condition? Yes No  
Is patient currently on therapy? Yes No Please list all therapies tried/failed: \_\_\_\_\_

Patient wt \_\_\_\_\_ Date wt obtained \_\_\_\_\_  
NKDA Known drug allergies \_\_\_\_\_  
Concurrent meds \_\_\_\_\_

# 4 Prescribing Information

Medication	Strength/Formulation	Directions	Quantity/Refills		
LENMELDY (atidarsagene autotemcel) suspension	<b>MLD Disease Subtype:</b> Pre-symptomatic late infantile Pre-symptomatic early juvenile Early symptomatic early juvenile Other: _____	Administer as a one time intravenous infusion. Each infusion bag contains approximately 10 to 20mL of LENMELDY and each bag must be infused within 2 hours after thawing. Administer each infusion bag of LENMELDY as an intravenous infusion within 30 minutes.	1 Dose supplied as 1 to 8 infusion bags. Complete number of bags supplied to be determined during the manufacturing process.  No Refills		
	<b>Recommended doses for MLD subtypes:</b>				
	<b>MLD Disease Subtype</b>			<b>Minimum Recommended Dose (CD34+ cells/kg)</b>	<b>Maximum Recommended Dose (CD34+ cells/kg)</b>
	Pre-symptomatic late infantile			4.2 x 10 <sup>6</sup>	30 x 10 <sup>6</sup>
Pre-symptomatic early juvenile	9 x 10 <sup>6</sup>	30 x 10 <sup>6</sup>			
Early symptomatic early juvenile	6.6 x 10 <sup>6</sup>	30 x 10 <sup>6</sup>			

Prescriber's signature required (sign below) (Physician attests this is his/her legal signature. NO STAMPS)

**SIGN HERE**

\_\_\_\_\_ Date Disperse as written \_\_\_\_\_ Date Substitution allowed

The prescriber is to comply with his/her state-specific prescription requirements such as e-prescribing, state-specific prescription form, fax language, etc. Non-compliance with state-specific requirements could result in outreach to the prescriber.

# 5 Patient Authorization

## Authorization to Use/Disclose Health Information

I hereby authorize my/my child's treating physicians, health insurance plan(s), pharmacies, or other healthcare providers (collectively "Healthcare Providers") to use and disclose my/my child's protected health information related to my/my child's medical condition relevant to Orchard Therapeutics gene therapy to Orchard Therapeutics North America and its contractors and business partners. This authorization is made for the purpose of enrolling me/my child in Orchard Assist, providing me/my child with patient services, and administering the Orchard Assist Program. I understand that once my/my child's health information has been disclosed, federal privacy laws may no longer protect the information. However, Orchard Therapeutics agrees to protect my/my child's health information by using and disclosing it only for purposes authorized in this Authorization or as required by law or regulations. I understand that I have the right to revoke this Authorization at any time by mailing a letter to Orchard Assist, 101 Seaport Boulevard, 7th Floor Boston, MA 02210 ATTN: Patient Advocacy or visiting [patient.advocacy@orchard-tx.com](mailto:patient.advocacy@orchard-tx.com) I understand that if I revoke this Authorization, I/my child will no longer be able to receive Orchard Assist services.

This Authorization shall remain valid for ten (10) years from the date the Authorization is signed unless earlier revoked by my written request or in accordance with local laws. I understand that I have a right to receive a copy of this consent form. I understand that signing this consent form is voluntary and that my enrollment in any of the services and/or programs described above is entirely voluntary. I further understand that my/my child's treatment, payment for treatment, insurance enrollment, or eligibility for insurance benefits are not conditioned upon my authorization of this disclosure, but if I do not sign this consent form, I/my child will not be able to receive Orchard Assist services.

I understand that certain parties, such as my/my child's pharmacy provider, may receive remuneration (payment) from Orchard Therapeutics North America in connection with the activities described in this consent form.

### Please read the following statement and mark the box:

I hereby authorize the Orchard Assist Program to use my PHI to contact me by mail, email, text, phone, or any communication method I request for the purposes as described herein.

### PATIENT AUTHORIZATION (to be completed by Patient or authorized representative)

By signing this form, I acknowledge that I understand and agree to the terms of this form. My signature certifies that I have read, understood, and agree to the release and use of my and/or my child's personal information, including sensitive personal information, pursuant to the Authorization to Use/Disclose Health Information and as otherwise stated on this form.

\_\_\_\_\_  
Patient Name (Printed)

\_\_\_\_\_  
Patient Signature

\_\_\_\_\_  
Signature of Patient Representative\*

\*If signed by Patient Representative, please explain authority / relation to act on behalf of patient:

\_\_\_\_\_  
Date (MM/DD/YYYY)

# Prior authorization checklist

## LENMELDY™ (atidarsagene autotemcel)

Providing Accredo with the documentation outlined in this checklist may increase the likelihood and speed of obtaining coverage for your patients with MLD. Coverage criteria may vary by payer.

Referral form <sup>1</sup> (not required for electronic prescriptions)	
	Completed LENMELDY referral form (available at <a href="https://www.accredo.com">accredo.com</a> )
	Copies of the front and back of all medical insurance and prescription benefits cards
Clinical documents <sup>2</sup>	
	<p>Provide the following PA information to the form to prevent delay. This would include documenting or attesting to:</p> <ul style="list-style-type: none"> <li>• Arylsulfatase A (ARSA) activity below the normal range</li> <li>• Molecular genetic testing confirming presence of two disease-causing mutations in the ARSA gene</li> <li>• Elevated sulfatide levels in a 24-hour urine collection</li> </ul>
	<p>Attestation to:</p> <p>Patient has not previously received treatment with allogeneic hematopoietic stem cell transplantation (HSCT) or gene therapy for MLD or received allo-HSCT or GT previously or does not have evidence of residual cells of donor origin if the member has received a prior allo-HSCT.</p> <p>Please provide all necessary documentation.</p>

**Fax completed form to 800.330.0756.**

**If you have any questions, please call your Accredo Provider Support Advocate, or call 866.900.8397.**

<sup>1</sup>For referral forms visit [accredo.com](https://www.accredo.com).

<sup>2</sup>Ongoing management and documentation requirements:

- Initial improvement and continued need must be meticulously documented in progress notes
- All weaning must be attempted and documented as either amount or frequency
- Must be a stoppage in IVIG if sustained improvement is noted with weaning or no improvement has taken place at all