



# BILLING AND CODING GUIDE

## BILLING, CODING, AND OTHER INFORMATION TO SUPPORT REIMBURSEMENT FOR LENMELDY

### INDICATION

LENMELDY is an autologous hematopoietic stem cell-based gene therapy indicated for the treatment of children with pre-symptomatic late infantile (PSLI), pre-symptomatic early juvenile (PSEJ) or early symptomatic early juvenile (ESEJ) metachromatic leukodystrophy (MLD).

Please see [Important Safety Information](#) for LENMELDY on pages 16-17 as well as full [Prescribing Information](#).

The information included in this guide is for informational purposes only and is subject to change. It is not to be used as legal advice or as a substitute for a health professional's judgment. It is important to verify code accuracy when submitting claims. Please contact payers for specific details regarding their coding, coverage, and payment policies. Orchard Therapeutics does not ensure coverage or reimbursement and payer coverage is not guaranteed. This resource should be utilized only after a prescribing decision has been made.

For additional information, contact Orchard Assist at 1-833-ORCHAST (1-833-672-4278) or visit [www.orchardassist.com](http://www.orchardassist.com).



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# INTRODUCTION

## PURPOSE OF THIS GUIDE

The LENMELDY (atidarsagene autotemcel) Billing and Coding Guide is intended to assist Qualified Treatment Centers (QTCs) with billing and coding for LENMELDY. This guide will help educate providers and their staff about LENMELDY reimbursement, Orchard Assist, relevant billing codes for each stage of treatment, and other key considerations.

## DISCLAIMER

The information included in this guide is for informational purposes only and is subject to change. It is not to be used as legal advice or as a substitute for a health professional's judgment. It is important to verify code accuracy when submitting claims. Please contact payers for specific details regarding their coding, coverage, and payment policies. Orchard Therapeutics does not ensure coverage or reimbursement, and payer coverage is not guaranteed.



# TREATMENT OVERVIEW

**LENMELDY** is administered as a one-time infusion prepared from a patient's own hematopoietic stem cells (HSCs). A lentiviral vector introduces functional copies of the *ARSA* gene into the patient's HSCs to correct the genetic cause of early-onset\* metachromatic leukodystrophy (MLD).<sup>1</sup>

1



## Mobilized Peripheral Blood Collection

Following pre-screening, patients travel to and are admitted for an inpatient stay at a QTC for cell collection and then return home.<sup>1</sup>

2



## Shipping and Manufacturing<sup>†</sup>

Cells are shipped to the manufacturing facility where they undergo a series of steps and then are cryopreserved. The cryopreserved cells, which together are the manufactured product, are then shipped to the QTC.<sup>1</sup>

3



## Myeloablative Conditioning

Once the LENMELDY product has been manufactured and shipped to the QTC, the patient returns to undergo conditioning with a chemotherapeutic agent.<sup>1</sup>

4



## Administration

The cells are then delivered to the patient intravenously, and the patient remains in the QTC, thereby allowing time for recovery from the conditioning and for the cells to engraft.<sup>1,‡</sup>

The LENMELDY treatment process is highly specialized with all activities occurring at QTCs.

\*See full indication.

<sup>†</sup>There are no billing codes associated with this step.

<sup>‡</sup>Following recovery from treatment, the patient is discharged from the hospital and monitored as an outpatient.

Please see [Important Safety Information](#) for LENMELDY on pages 16-17 as well as full [Prescribing Information](#).



# MOBILIZED PERIPHERAL BLOOD COLLECTION

1



Following pre-screening, patients travel to a QTC for cell collection and then return home.<sup>1</sup>

The following diagnosis code, procedure codes, and revenue codes may be applicable for billing of the cell mobilization and collection services for patients treated with LENMELDY. CPT codes that describe the cell mobilization and cell collection services are included here for informational purposes and to assist with administrative processes such as requests for prior authorization. Coders should code to the highest level of specificity supported by the documentation.

ICD-10-CM CODE <sup>2</sup>	DESCRIPTION
E75.25	Metachromatic leukodystrophy

ICD-10-PCS CODE <sup>3</sup>	DESCRIPTION
3E013GC	Introduction of other therapeutic substance into subcutaneous tissue, percutaneous approach
6A550ZV	Pheresis of hematopoietic stem cells, single
6A551ZV	Pheresis of hematopoietic stem cells, multiple

CPT CODE <sup>4</sup>	DESCRIPTION
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

REVENUE CODE <sup>5</sup>	DESCRIPTION
0250	Pharmacy - General
0636	Pharmacy - Drugs requiring detailed coding
0260	IV Therapy - General
0871	Cell/Gene Therapy - Cell Collection
0872	Cell/Gene Therapy - Specialized Biologic Processing and Storage - Prior to Transport
0761	Specialty Services - Treatment Room

**Appropriate codes may vary based on each individual case. Providers are responsible for accurate and correct coding. Please confirm all information with each individual payer.**

CPT, Current Procedural Terminology; ICD-10-CM, *International Classification of Diseases, Tenth Revision, Clinical Modification*; ICD-10-PCS, *International Classification of Diseases, Tenth Revision, Procedure Coding System*; IV, intravenous.

Please see [Important Safety Information](#) for LENMELDY on pages 16-17 as well as full [Prescribing Information](#).



# MYELOABLATIVE CONDITIONING

## Shipping and Manufacturing

2



Cells are shipped to the manufacturing facility where they undergo a series of steps and then are cryopreserved. The cryopreserved cells, which together are the manufactured product, are then shipped to the QTC.<sup>1</sup>

*There are no billing codes associated with this step.*

3



Once the LENMELDY product has been manufactured and shipped to the QTC, the patient returns to undergo conditioning with a chemotherapeutic agent.<sup>1</sup>

The following diagnosis code, procedure codes, and revenue codes may be applicable for billing of the myeloablative conditioning for patients treated with LENMELDY. CPT codes that describe the myeloablative conditioning services are included here for informational purposes and to assist with administrative processes such as requests for prior authorization. Coders should code to the highest level of specificity supported by the documentation.

ICD-10-CM CODE <sup>2</sup>	DESCRIPTION
E75.25	Metachromatic leukodystrophy

ICD-10-PCS CODE <sup>3</sup>	DESCRIPTION
3E03305	Introduction of other antineoplastic into peripheral vein, percutaneous approach
3E04305	Introduction of other antineoplastic into central vein, percutaneous approach

CPT CODE <sup>4</sup>	DESCRIPTION
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
96415	Chemotherapy administration, intravenous infusion technique; each additional hour

REVENUE CODE <sup>5</sup>	DESCRIPTION
0250	Pharmacy - General
0636	Pharmacy - Drugs requiring detailed coding
0335	Radiology/Therapeutic - Chemotherapy IV

**Appropriate codes may vary based on each individual case. Providers are responsible for accurate and correct coding. Please confirm all information with each individual payer.**

Please see [Important Safety Information](#) for LENMELDY on pages 16-17 as well as full [Prescribing Information](#).



# ADMINISTRATION

4



The cells are then delivered to the patient intravenously, and the patient remains in the hospital, thereby allowing time for recovery from the conditioning and for the cells to engraft. Following recovery from treatment, the patient is discharged from the hospital and monitored as an outpatient.<sup>1</sup>

The following diagnosis code, procedure codes, and revenue codes may be applicable for billing of the administration of LENMELDY and the LENMELDY product. Coders should code to the highest level of specificity supported by the documentation.

ICD-10-CM CODE <sup>2</sup>	DESCRIPTION
E75.25	Metachromatic leukodystrophy

ICD-10-PCS CODE <sup>3</sup>	DESCRIPTION
XW133G8	Transfusion of OTL-200 into peripheral vein, percutaneous approach, new technology group 8
XW143G8	Transfusion of OTL-200 into central vein, percutaneous approach, new technology group 8

CPT CODE <sup>4</sup>	DESCRIPTION
38208	Transplant preparation of hematopoietic progenitor cells, thawing of previously frozen harvest, without washing, per donor
38241	Hematopoietic progenitor cell (HPC); autologous transplantation

NDC <sup>1</sup>	DESCRIPTION
83222-0200-1	Atidarsagene autotemcel suspension for intravenous infusion

LENMELDY has not been assigned a unique HCPCS code. Since there is not a specific HCPCS code available, LENMELDY may be billed using one of the following unclassified HCPCS codes.

HCPCS CODE <sup>6</sup>	DESCRIPTION
C9399	Unclassified drug or biological
J3490	Unclassified drugs
J3590	Unclassified biologics

**Appropriate codes may vary based on each individual case. Providers are responsible for accurate and correct coding. Please confirm all information with each individual payer.**

HCPCS, Healthcare Common Procedure Coding System; NDC, National Drug Code.

Please see [Important Safety Information](#) for LENMELDY on pages 16-17 as well as full [Prescribing Information](#).



# ADMINISTRATION (cont)

## REVENUE CODES

Revenue codes are used to track costs associated with the hospital admission and services and items provided. Below is a list of revenue codes that may be associated with the administration of LENMELDY:

REVENUE CODE <sup>5</sup>	DESCRIPTION
0250	Pharmacy: general
0636	Drugs requiring detailed coding
0761	Specialty Services - Treatment Room
0873	Cell/gene therapy - storage and processing after receipt of cells from manufacturer
0874	Cell/gene therapy - infusion of modified cells (Effective 4/1/19)
0892	Special processed drugs - FDA-approved gene therapy (Effective 4/1/20)
0940	Other Therapeutic Services - General

## MS-DRG PAYMENTS

MS-DRG assignment and payments depend on the patient's diagnoses and procedures performed. ICD-10-PCS codes used to describe the administration of LENMELDY map to the MS-DRGs listed below:

PAYMENT GROUP <sup>7</sup>	PAYMENT GROUP #	DESCRIPTION
MS-DRG	016	Autologous bone marrow transplant with CC/MCC
	017	Autologous bone marrow transplant without CC/MCC

## APR-DRG PAYMENTS

APR-DRG classifies hospital inpatients in non-Medicare populations according to their reason for admission, severity of illness, and risk of mortality.

PAYMENT GROUP <sup>7</sup>	DESCRIPTION
APR-DRG	Refer to appropriate state-specific code

**Appropriate codes may vary based on each individual case. Providers are responsible for accurate and correct coding. Please confirm all information with each individual payer.**

APR-DRG, All Patient Refined Diagnosis Related Group; CC, complication or comorbidity; MCC, major complication or comorbidity; MS-DRG, Medicare Severity Diagnosis Related Group.

Please see [Important Safety Information](#) for LENMELDY on pages 16-17 as well as full [Prescribing Information](#).



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# ORDERING AND DISTRIBUTION

Only QTCs can order LENMELDY.

As part of the Site Qualification Process, QTCs are trained on the LENMELDY Product Manual, US Prescribing Information (PI), and order processing and scheduling.

LENMELDY is only available under a limited specialty distribution model. Only Orchard QTCs can order and obtain LENMELDY.

For additional information, please contact [medinfo@orchard-tx.com](mailto:medinfo@orchard-tx.com).

Please see [Important Safety Information](#) for LENMELDY on pages 16-17 as well as full [Prescribing Information](#).

  
**lenmeldy**<sup>™</sup>  
(atidarsagene autotemcel)



## HELPING YOUR PATIENTS WITH GENE THERAPY

Orchard Assist is here to help patients and their families who have received an early-onset\* MLD diagnosis and want to pursue gene therapy from Orchard Therapeutics. If you or your patients and their families have questions about insurance coverage, reimbursement, or billing, Orchard Assist is here to help.

## WHAT YOU AND YOUR PATIENTS CAN EXPECT FROM ORCHARD ASSIST

### Healthcare professionals: Access and coverage assistance

Orchard Assist can help healthcare professionals access information related to their patients' coverage, including:

- Information on prior authorizations and benefit investigations
- Payer medical policies
- Billing and coding

### Patients: Support navigating the treatment journey

There are 3 main steps that an Orchard Assist representative can help you and your patient and their family explore. Orchard Assist can help answer questions along the way.



 Patients' families and healthcare professionals can contact Orchard Assist to speak with a representative. Call 1-833-ORCHAST (1-833-672-4278) or visit [www.orchardassist.com](http://www.orchardassist.com) for more information.

\*See full indication.



# SAMPLE CLAIM FORMS

## SAMPLE CMS 1450 CLAIM FORM

1		2		3a PAT. CNTL. #		4 TYPE OF BILL	
				b. MED. REC. #			
				5 FED. TAX NO.		6 STATEMENT COVERS PERIOD FROM THROUGH	
8 PATIENT NAME a				9 PATIENT ADDRESS a			
b				c			
10 BIRTHDATE		11 SEX		12 DATE		13 HR	
14 TYPE		15 SRC		16 DHR		17 STAT	
18		19		20		21	
22		23		24		25	
26		27		28		29 ACDT STATE	
30		31 OCCURRENCE DATE		32 OCCURRENCE DATE		33 OCCURRENCE DATE	
34 OCCURRENCE DATE		35 OCCURRENCE DATE		36 OCCURRENCE SPAN FROM THROUGH		37 OCCURRENCE SPAN FROM THROUGH	
38		39 CODE		40 VALUE CODES AMOUNT		41 VALUE CODES AMOUNT	
		a		b		c	
		b		c		d	
		c		d		e	
		d		e		f	
42 REV. CD.		43 DESCRIPTION		44 HCPCS / RATE / HIPPS CODE		45 SERV. DATE	
46 SERV. UNITS		47 TOTAL CHARGES		48 NON-COVERED CHARGES		49	
42		43		46			

### 4 TYPE OF BILL

Enter the appropriate type of bill code

Type of bill codes describe the facility and care type and are 4 digits

### 43 DESCRIPTION

Enter appropriate descriptions

Provide revenue code descriptions and any associated drugs

### 42 REVENUE CODES

Enter revenue codes

Revenue codes identify specific accommodations, services, and procedures for patients and are 4 digits

### 46 SERVICE UNITS

Enter the total amount of units of service administered

Be sure to enter the total amount for each line item



# SAMPLE CLAIM FORMS (cont)

## SAMPLE CMS 1450 CLAIM FORM (cont)

58 INSURED'S NAME					59 P REL	60 INSURED'S UNIQUE ID					61 GROUP NAME					62 INSURANCE GROUP NO.																																																																									
63 TREATMENT AUTHORIZATION CODES															64 DOCUMENT CONTROL NUMBER															65 EMPLOYER NAME																																																											
66 DX															67 A															68																																																											
69 ADMIT DX															70 PATIENT REASON DX															71 PPS CODE															72 ECI															73																													
74 PRINCIPAL PROCEDURE CODE															75 OTHER PROCEDURE CODE															76 ATTENDING NPI															77 OPERATING NPI															78 OTHER NPI															79 OTHER NPI														
80 REMARKS															81CCI a															82															83															84															85														

### 63 TREATMENT AUTHORIZATION CODES

Enter the authorization number

If required by the payer, this field is used for the PA number

### 67A-67Q DIAGNOSIS

Enter ICD-10-CM diagnosis codes

List all relevant codes and ensure accuracy and highest level of specificity supported by the documentation

### 74 PRINCIPAL PROCEDURE CODE AND DATE

Enter the primary ICD-10-PCS and date

This field is required on inpatient claims

### 80 REMARKS

Enter any additional information

Provide additional information that may be required by the payer, such as drug name, 11-digit NDC number, and HCPCS codes

PA, prior authorization.

Please see [Important Safety Information](#) for LENMELDY on pages 16-17 as well as full [Prescribing Information](#).



# CODE INDEX

## PRE-SCREENING TESTS

Patients must be screened prior to starting treatment.

The following codes may be relevant for billing and coding for pre-screening tests that are performed prior to LENMELDY administration:

TEST TYPE	CPT CODE <sup>4</sup>	DESCRIPTION
Hepatitis C	86803	Hepatitis C antibody
	86804	Hepatitis C antibody; confirmatory test (eg, immunoblot)
	87522	Hepatitis C, quantification, includes reverse transcription when performed
	87902	Hepatitis C virus
Hepatitis B	86704	Hepatitis B core antibody (HBcAb); total
	86706	Hepatitis B surface antibody (HBsAb)
	87340	Hepatitis B surface antigen (HBsAg)
	87517	Hepatitis B virus, quantification
HIV	87389	HIV-1 antigen(s), with HIV-1 and HIV-1 antibodies, single result
	87806	HIV-1 antigen(s), with HIV-1 and HIV-2 antibodies
	87536	HIV-1 quantification, includes reverse transcription when performed
	87539	HIV-2 quantification, includes reverse transcription when performed
Anti-Treponema Pallidum	86592	Syphilis tests, non-treponemal antibody; qualitative
	86593	Syphilis tests, non-treponemal antibody; quantitative
	86780	Treponema pallidum
Anti-Mycoplasma IgM	86738	Mycoplasma
HTLV	86687	HTLV-I
	86688	HTLV-II
Cytomegalovirus	86644	Cytomegalovirus (CMV)
	86645	Cytomegalovirus (CMV), IgM

**This is not an all-inclusive list of tests and codes. Additional CPT codes may apply. Please refer to the LENMELDY product manual and specific payer coverage to confirm which tests and associated codes are most appropriate for your patient.**

**CPT® is a registered trademark of the American Medical Association.**

HIV, human immunodeficiency virus; HTLV, human T-lymphotropic virus; IgM, immunoglobulin M.

Please see [Important Safety Information](#) for LENMELDY on pages 16-17 as well as full [Prescribing Information](#).



# CODE INDEX (cont)

## CODING SUMMARY

ICD-10-CM CODE <sup>2</sup>	DESCRIPTION
E75.25	Metachromatic leukodystrophy

ICD-10-PCS CODE <sup>3</sup>	DESCRIPTION
3E013GC	Introduction of other therapeutic substance into subcutaneous tissue, percutaneous approach
3E03305	Introduction of other antineoplastic into peripheral vein, percutaneous approach
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38208	Transplant preparation of hematopoietic progenitor cells, thawing of previously frozen harvest, without washing, per donor
38241	Hematopoietic progenitor cell (HPC); autologous transplantation
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug), subcutaneous or intramuscular
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
96415	Chemotherapy administration, intravenous infusion technique; each additional hour

LENMELDY has not been assigned a unique HCPCS code. Since there is not a specific HCPCS code available, LENMELDY may be billed using one of the following unclassified HCPCS codes.

HCPCS CODE <sup>6</sup>	DESCRIPTION
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J3590	Unclassified biologics

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Please see [Important Safety Information](#) for LENMELDY on pages 16-17 as well as full [Prescribing Information](#).



# CODE INDEX (cont)

## CODING SUMMARY (cont)

REVENUE CODES <sup>5</sup>	DESCRIPTION
0250	Pharmacy: general
0260	IV Therapy - General
0335	Radiology/Therapeutic - Chemotherapy IV
0636	Drugs requiring detailed coding
0761	Specialty Services - Treatment Room
0871	Cell/gene therapy - cell collection
0872	Cell/gene therapy - specialized biologic processing and storage - prior to transport
0873	Cell/gene therapy - storage and processing after receipt of cells from manufacturer
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	017	Autologous bone marrow transplant without CC/MCC
APR-DRG	Refer to appropriate state-specific code	

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Please see [Important Safety Information](#) for LENMELDY on pages 16-17 as well as full [Prescribing Information](#).



# CODE INDEX (cont)

## SAMPLE LETTER OF MEDICAL NECESSITY FOR LENMELDY

### Sample Letter of Medical Necessity Template for LENMELDY™ (atidarsagene autotemcel)

[Note: When preparing the actual letter, use professional/physician letterhead.]

This sample letter is for informational purposes only. Use of this information does not constitute medical or legal advice and does not guarantee coverage. It is not intended to be a substitute for, or an influence on, the independent clinical decision of the prescriber. This should be utilized only after a prescribing decision has been made. Please see Important Safety Information on pages 2-4, and full [Prescribing Information](#).

[Date]

[Payer Medical/Pharmacy Director/Contact Name]

[Payer Organization Name]

[Payer Street Address]

[Payer City, State, ZIP Code]

**RE:** [Patient Name]

**Date of Birth:** [Patient Date of Birth]

**Policy ID/Group Number:** [Policy ID/Group Number]

**Policyholder:** [Policyholder's Name]

Dear [Payer Medical/Pharmacy Director/Contact Name]:

I am [Physician Name, Credentials, Specialty, Hospital/Practice]. I am writing on behalf of my patient, [Patient Name], to document the medical necessity for treatment with LENMELDY™ (atidarsagene autotemcel) for the diagnosis of early onset\* metachromatic leukodystrophy (MLD). This letter provides information about [Patient Name]'s medical history, diagnosis, prognosis, and treatment plan with LENMELDY.

\*See full indication.

#### 1. Summary of Patient's Medical History

[You may be required to include the following:

- Patient's date of MLD diagnosis including:
  - Patient subtype of pre-symptomatic late infantile (PSLI), pre-symptomatic early juvenile (PSEJ), or early-symptomatic early juvenile (ESEJ).
  - Appropriate ICD-10-CM code, dates of lab testing, such as genetic test, arylsulfatase A (ARSA) deficiency, and sulfatides urine test, etc.
- Patient and family medical history:
  - Sibling diagnosis, if applicable, and age/date of onset
- Patient's current condition]

#### 2. Patient-Specific Rationale for Treatment

[Insert summary statement for treatment rationale, as well as a summary of your professional opinion of the patient's anticipated prognosis or disease progression without treatment with LENMELDY and the importance of a quick treatment decision. You may include supporting clinical studies, peer-reviewed literature, and any relevant information from the LENMELDY Prescribing Information.]

[Prescriber may choose to include the specific criteria for coverage that the patient meets based

1



Download Sample Letter of Medical Necessity

Please see [Important Safety Information](#) for LENMELDY on pages 16-17 as well as full [Prescribing Information](#).

  
**lenmeldy™**  
 (atidarsagene autotemcel)



## INDICATION

LENMELDY™ (atidarsagene autotemcel) is an autologous hematopoietic stem cell-based gene therapy indicated for the treatment of children with pre-symptomatic late infantile (PSLI), pre-symptomatic early juvenile (PSEJ), or early symptomatic early juvenile (ESEJ) metachromatic leukodystrophy (MLD).

## IMPORTANT SAFETY INFORMATION

### WARNINGS AND PRECAUTIONS

#### • **Thrombosis and Thromboembolic Events:**

Treatment with LENMELDY may increase the risk of thrombosis and thromboembolic events. A child with PSEJ MLD died after experiencing a left hemisphere cerebral infarction secondary to a thrombotic event in a large blood vessel approximately 1 year after treatment with LENMELDY. Evaluate the risk factors for thrombosis prior to and after LENMELDY infusion according to best clinical practice.

#### • **Encephalitis:**

Treatment with LENMELDY may increase the risk of encephalitis. A child with ESEJ developed a serious event of encephalitis after treatment with LENMELDY. The etiology of this event is unclear but attribution to LENMELDY cannot be ruled out. Treatment with LENMELDY may trigger a relapsing-remitting pattern of disease progression. No other events related to encephalitis have been reported during the clinical development of LENMELDY. Monitor children for signs or symptoms of encephalitis after LENMELDY treatment.

#### • **Serious Infection:**

In the period between start of conditioning and within 1 year after LENMELDY treatment, severe Grade 3 infections occurred in 39% of all children (21% bacterial, 5% viral, 5% bacterial and viral or bacterial and fungal, and 8% unspecified). Grade 3 febrile neutropenia developed within 1 month after LENMELDY infusion in 82% of children. In the event of febrile neutropenia, monitor for signs and symptoms of infection and manage with broad-spectrum antibiotics, fluids, and other supportive care as medically indicated. Monitor children for signs and symptoms of infection after myeloablative conditioning and LENMELDY infusion and treat appropriately. Administer prophylactic antimicrobials according to best clinical practice.

#### • **Veno-Occlusive Disease:**

Three children (8%) treated in clinical trials of LENMELDY developed veno-occlusive disease (VOD) with one Grade 4 SAE and two Grade 3 AEs. None of these three events met Hy's Law criteria. Monitor children for signs and symptoms of VOD including liver function tests in all children during the first month after LENMELDY infusion. Consider prophylaxis for VOD with anti-thrombotic agents based on risk factors for VOD and best clinical practice.

#### • **Delayed Platelet Engraftment (DPE):**

DPE has been observed with LENMELDY treatment. Bleeding risk is increased prior to platelet engraftment and may continue after engraftment in children with prolonged thrombocytopenia. In clinical trials of LENMELDY, 4 (10%) children had delayed platelet engraftment after day 60 (range day 67-109), with 3 children requiring platelet transfusions until engraftment occurred. Inform children of the risk of bleeding until platelet recovery has been achieved. Monitor children for thrombocytopenia and bleeding.

#### • **Neutrophil Engraftment Failure:**

There is a potential risk of neutrophil engraftment failure after treatment with LENMELDY. Monitor neutrophil counts until engraftment has been achieved. If neutrophil engraftment failure occurs in a child treated with LENMELDY, provide rescue treatment with the unmanipulated back-up collection of CD34+ cells.

**WARNINGS AND PRECAUTIONS (cont)****• Insertional Oncogenesis:**

There is a potential risk of LVV-mediated insertional oncogenesis after treatment with LENMELDY. Children treated with LENMELDY may develop hematologic malignancies and should be monitored lifelong. Monitor for hematologic malignancies with a complete blood count (with differential) annually and integration site analysis as warranted for at least 15 years after treatment with LENMELDY. In the event that a malignancy occurs, contact Orchard Therapeutics at 1-888-878-0185 for reporting and to obtain instructions on collection of samples for testing.

**• Hypersensitivity Reactions:**

The dimethyl sulfoxide (DMSO) in LENMELDY may cause hypersensitivity reactions, including anaphylaxis which is potentially life-threatening and requires immediate intervention. Hypersensitivity including anaphylaxis can occur in children with and without prior exposure to DMSO. Monitor for hypersensitivity reactions during infusion and after infusion.

**• Anti-Retroviral Use:**

Children should not take prophylactic HIV anti-retroviral medications for at least one month prior to mobilization, or for the expected duration of time needed for the elimination of the medications. Anti-retroviral medications may interfere with the manufacturing of LENMELDY. If a child requires antiretrovirals for HIV prophylaxis, initiation of LENMELDY treatment should be delayed until confirmation of a negative test for HIV.

**• Interference With Serology Testing:**

Due to the likelihood of a false-positive test for HIV, children who have received LENMELDY should not be screened for HIV infection using a PCR-based assay.

**USE IN SPECIFIC POPULATIONS**

Females and Males of Reproductive Potential

Pregnancy Testing

As a precautionary measure, a negative serum pregnancy test must be confirmed prior to the start of mobilization, and reconfirmed prior to conditioning procedures, and before administration of LENMELDY in females of childbearing potential.

Contraception

Consult the Prescribing Information of the mobilization and conditioning agents for information on the need for effective contraception. Males capable of fathering a child and females of childbearing age should use an effective method of contraception from start of mobilization through at least 6 months after administration of LENMELDY.

Infertility

There are no data on the effects of LENMELDY on fertility.

Data are available on the risk of infertility with myeloablative conditioning. In clinical trials of LENMELDY, seven children (50% of females) developed ovarian failure. Advise children of the option to cryopreserve semen or ova before treatment, if appropriate.

For additional safety information, please see the full [Prescribing Information](#) for LENMELDY.

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References

Please visit [www.LENMELDY.com](http://www.LENMELDY.com) for more information.

**References:** **1.** LENMELDY (atidarsagene autotemcel). Prescribing Information. Orchard Therapeutics; 2024. **2.** American Medical Association. *ICD-10-CM 2024: The Complete Official Codebook*. Optum 360 LLC; 2023. **3.** American Medical Association. *ICD-10-PCS 2024: The Complete Official Codebook*. Optum 360 LLC; 2023. **4.** American Medical Association. *CPT 2024: Professional Edition*. American Medical Association; 2023. **5.** Noridian Healthcare Solutions. Revenue Codes. Accessed November 22, 2024. <https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes> **6.** Centers for Medicare & Medicaid Services. HCPCS quarterly update. Published November 4, 2024. Accessed November 22, 2024. **7.** Centers for Medicare & Medicaid Services. FY 2024 IPPS Final Rule Home Page. Table 5 (ZIP). Accessed November 22, 2024. <https://www.cms.gov/files/zip/fy2024-ippss-fr-table-5.zip>

Please see [Important Safety Information](#) for LENMELDY on pages 16-17 as well as full [Prescribing Information](#).



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