



Lumizyme[®] (alglucosidase alfa)
**BILLING AND CODING GUIDE
FOR REIMBURSEMENT**

USING THIS BILLING AND CODING GUIDE

This document is intended as a general guide for submitting information to payers for reimbursement. Use of this guide does not guarantee that the payer will provide coverage for Lumizyme and is not intended to be a substitute for, or an influence on, the independent medical judgment of the prescriber. Prescribers should follow payer-specific coding requirements and exercise clinical judgment when selecting codes and submitting claims to truthfully and accurately reflect the services and products furnished to a specific patient. Prescribers are solely responsible for ensuring the accuracy of billing submissions to any payer.

The coding information discussed in this guide

- Is provided for informational purposes only
- Is subject to change
- Should not be construed as legal advice

The codes listed herein may not apply to all patients or to all health plans. Conversely, additional codes not listed in this guide may apply to some patients.

Sanofi is committed to working with providers, as well as public and private payers, to help ensure access to Lumizyme as indicated. If you still have questions after reviewing this guide, please contact **CareConnect** at **1-800-745-4447**, Option 3. Sanofi’s **CareConnect Case Managers** have expertise in reimbursement, insurance, case management, and the healthcare delivery system and can provide information to physicians and their patients about the reimbursement process.



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INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

LUMIZYME® (alglucosidase alfa) is a hydrolytic lysosomal glycogen-specific enzyme indicated for patients with Pompe disease (GAA deficiency).

IMPORTANT SAFETY INFORMATION

WARNING: HYPERSENSITIVITY REACTIONS INCLUDING ANAPHYLAXIS, IMMUNE-MEDIATED REACTIONS, AND RISK OF ACUTE CARDIORESPIRATORY FAILURE

Hypersensitivity Reactions Including Anaphylaxis

Patients treated with enzyme replacement therapies have experienced life-threatening hypersensitivity reactions, including anaphylaxis. Anaphylaxis has occurred during the early course of enzyme replacement therapy and after extended duration of therapy. Initiate LUMIZYME in a healthcare setting with appropriate medical monitoring and support measures, including cardiopulmonary resuscitation equipment. If a severe hypersensitivity reaction (e.g. anaphylaxis) occurs, discontinue LUMIZYME immediately and initiate appropriate medical treatment, including the use of epinephrine.

Consider risks and benefits of re-administering LUMIZYME following severe hypersensitivity reactions. If a mild or moderate hypersensitivity reaction occurs, the infusion rate may be slowed or temporarily stopped. Prior to LUMIZYME administration, consider pretreating with antihistamines, antipyretics, and/or corticosteroids.

Immune-Mediated Reactions

Immune-mediated reactions presenting as proteinuria, nephrotic syndrome, and necrotizing skin lesions have occurred in some patients following LUMIZYME treatment. Monitor patients for the development of systemic immune-mediated reactions involving skin and other organs while receiving LUMIZYME.

Risk of Acute Cardiorespiratory Failure

Infantile-onset Pompe disease (IOPD) patients with compromised cardiac or respiratory function may be at risk of serious acute exacerbation of their cardiac or respiratory compromise due to fluid overload and require additional monitoring.

Infusion Associated Reactions (IARs): Infusion Associated Reactions (IARs) have been observed in patients treated with Lumizyme. Discontinue immediately or adjust the infusion rate and provide medical treatment based on the severity of the reaction. Closely monitor patients who have experienced IARs when re-administering LUMIZYME.

Risk of Cardiac Arrhythmia and Sudden Cardiac Death during General Anesthesia for Central Venous Catheter Placement: Caution should be used when administering general anesthesia for the placement of a central venous catheter intended for LUMIZYME infusion.

Risk of Developing Anti-alglucosidase Alfa Antibodies (ADA): Patients with IOPD should have a cross-reactive immunologic material (CRIM) assessment early in their disease course and be managed by a specialist knowledgeable in immune tolerance induction in Pompe disease to optimize treatment. Evidence suggests that patients who develop high and sustained IgG ADA antibody titers may experience reduced clinical efficacy.

IMPORTANT SAFETY INFORMATION (cont'd)

Risk of Developing Anti-alglucosidase Alfa Antibodies: (cont'd)

Patients should be monitored for IgG ADA antibody formation beginning at baseline, then regularly during the first year of treatment with subsequent monitoring as clinically warranted. Patients who experience hypersensitivity reactions, including anaphylaxis, may also be tested for IgE antibodies to LUMIZYME and other mediators of anaphylaxis.

ADVERSE REACTIONS

The most frequently reported adverse reactions ($\geq 5\%$) in clinical trials were hypersensitivity reactions and included: anaphylaxis, rash, pyrexia, flushing/feeling hot, urticaria, headache, hyperhidrosis, nausea, cough, decreased oxygen saturation, tachycardia, tachypnea, chest discomfort, dizziness, muscle twitching, agitation, cyanosis, erythema, hypertension/increased blood pressure, pallor, rigors, tremor, vomiting, fatigue, and myalgia.

Please see the full **Prescribing Information**, including Boxed WARNING.

CODING SUMMARY

Diagnosis Code

Codes used to formalize diagnosis come from the *International Classification of Diseases, Tenth Revision*, which was originally developed by the World Health Organization.¹ The ICD-10-CM diagnosis code for Pompe disease, to be used in conjunction with the administration of Lumizyme, is E74.02.² Lumizyme treats both late-onset Pompe disease (LOPD) and infantile-onset Pompe disease (IOPD), and E74.02 may be used to document either diagnosis.³

ICD-10-CM CODES ²	
E00-E89	Endocrine, nutritional, and metabolic diseases
> E74	Other disorders of carbohydrate metabolism
>> E74.02	Pompe disease

ICD-10-CM, *International Classification of Diseases, Tenth Revision, Clinical Modification*.

National Drug Code (NDC)

National Drug Codes are unique 3-segment numbers that serve as a universal product identifier for human drugs in the US.⁴ Lumizyme has 10-digit NDCs displayed on its packaging. In most cases, these codes should be converted to 11-digit NDCs for billing purposes.⁵ The table below shows the 10-digit and 11-digit NDCs for single-vial and 10-vial cartons of Lumizyme.



NOTE: Payer requirements for NDC use and format may vary. Please contact each payer for specific coding policies.

10-DIGIT NDC	
58468-0160-1	Carton of 1 single-dose vial
58468-0160-2	Carton of 10 single-dose vials
11-DIGIT NDC	
58468-0160-01	Carton of 1 single-dose vial
58468-0160-02	Carton of 10 single-dose vials
How supplied	Lumizyme is supplied as a sterile, nonpyrogenic, white to off-white lyophilized cake or powder, in single-dose vials, for intravenous use after reconstitution and dilution. Each vial contains 10.5 mL reconstituted solution and a total extractable volume of 10 mL at 5 mg/mL alglucosidase alfa. ³

IMPORTANT SAFETY INFORMATION

Infusion Associated Reactions (IARs): Infusion Associated Reactions (IARs) have been observed in patients treated with Lumizyme. Discontinue immediately or adjust the infusion rate and provide medical treatment based on the severity of the reaction. Closely monitor patients who have experienced IARs when re-administering LUMIZYME.

Please see Important Safety Information, including Boxed WARNING, on pages 3-4, and full Prescribing Information.

 **Lumizyme**[®]
(alglucosidase alfa)

CPT® Code

CPT codes are used to describe the procedures performed on a patient and/or how a drug or supply being billed was administered.⁶ The CPT codes most commonly associated with the administration of IV-infused biologic therapies like Lumizyme are listed below. Whenever possible, confirm the preferred coding policy with payers prior to administration of Lumizyme.

PRIMARY CODES ⁷	
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
96366	Each additional hour (list separately in addition to code for primary procedure; report 96366 for infusion intervals of greater than 30 minutes beyond 1-hour increments)*

*Per CMS guidelines, if the incremental amount of infusion time is 30 minutes or less, the time is not to be billed separately. Note that some payers may require including on the claim the actual number of minutes of infusion time.

CMS, Centers for Medicare & Medicaid Services; CPT®, Current Procedural Terminology; IV, intravenous.

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

HCPCS Procedure Code

HCPCS codes are assigned by CMS and are used by Medicare and most private payers to describe products administered in a physician's office or hospital setting.⁸ Note that the coding system is not a methodology for making coverage or payment determinations. The existence of an HCPCS code does not imply coverage; it implies only that the product may be reimbursed if covered.

PERMANENT J CODE ⁹	Description
J0221	Injection, alglucosidase alfa (Lumizyme), 10 mg

HCPCS, Healthcare Common Procedure Coding System.

IMPORTANT SAFETY INFORMATION (cont'd)

Risk of Cardiac Arrhythmia and Sudden Cardiac Death during General Anesthesia for Central Venous Catheter Placement: Caution should be used when administering general anesthesia for the placement of a central venous catheter intended for LUMIZYME infusion.

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JW modifier: Medicare and some commercial payers require providers and suppliers to report the JW modifier on Part B drug claims for discarded drugs and biologics.¹⁰ Refer to each payer's policy for coding and documentation requirements.

Place of Service Codes

Because Lumizyme can be administered in various settings (infusion center, physician office, patient's home if deemed clinically appropriate by the prescribing physician), it is important to populate a claim with the appropriate 2-digit Place of Service (POS) code.¹¹ Always verify the preferred POS codes for your patient's health plan before submitting a claim.

IMPORTANT SAFETY INFORMATION (cont'd)

Risk of Developing Anti-alglucosidase Alfa Antibodies (ADA): Patients with IOPD should have a cross-reactive immunologic material (CRIM) assessment early in their disease course and be managed by a specialist knowledgeable in immune tolerance induction in Pompe disease to optimize treatment. Evidence suggests that patients who develop high and sustained IgG ADA antibody titers may experience reduced clinical efficacy.

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SAMPLE REIMBURSEMENT FORMS

These sample claim forms are intended for reference only. Reimbursement codes are subject to continual change. Please confirm the accuracy of the codes used with each payer.

Annotated claim form CMS-1500¹²

For claims submitted by noninstitutional healthcare providers¹³

A **Field 19:** Provide any required detailed information such as drug name, total dosage and strength, method of administration, 11-digit NDC, and basis of measurement (attach separately if needed)

B **Field 21:** Enter the appropriate ICD-10-CM diagnosis code

C **Field 24A:** Enter the date of service for each procedure. Include the NDC information, if required, in the shaded area above each date

D **Field 24B:** Enter the appropriate Place of Service code (office, infusion center, etc)

E **Field 24D:** Include any payer-required details, such as HCPCS (J code), CPT codes, and modifiers

F **Field 24E:** Enter the diagnosis code reference letter or number from Field 21 that relates to the date of service and the services or procedures performed

HEALTH INSURANCE CLAIM FORM
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

1. MEDICARE MEDICAID TRICARE CHAMPVA GROUP HEALTH PLAN FECA SURVIVING OTHER
(Medicare) (Medicaid) (DMCOP) (Member ID#) (Plan ID#) (Surviving Spouse) (Other)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)
3. PATIENT'S BIRTH DATE
4. INSURED'S NAME (Last Name, First Name, Middle Initial)
5. PATIENT'S ADDRESS (No., Street)
6. PATIENT RELATIONSHIP TO INSURED
7. INSURED'S ADDRESS (No., Street)
8. RESERVED FOR NUCC USE
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)
10. IS PATIENT'S CONDITION RELATED TO:
11. INSURED'S POLICY GROUP OR FECA NUMBER
12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE (I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.)
13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE (I authorize payment of medical benefits to the undersigned physician or supplier for services described below.)
14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (MM/DD/YY)
15. OTHER DATE (MM/DD/YY)
16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION (FROM TO)
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE
18. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)
19. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES (FROM TO)
20. OUTSIDE LAB? (YES/NO)
21. DIAGNOSIS OR NATURE OF ILLNESS (ICD-10-CM)
22. RESUBMISSION CODE
23. PRIOR AUTHORIZATION NUMBER
24. A. DATE(S) OF SERVICE (MM/DD/YY)
B. PLACE OF SERVICE (EMG)
C. PROCEDURES, SERVICES, OR SUPPLIES (CPT/HCPCS)
D. DIAGNOSIS POINTER
E. CHARGES
F. CHARGES
25. FEDERAL TAX ID NUMBER
26. PATIENT'S ACCOUNT NO.
27. ACCEPT ASSIGNMENT? (YES/NO)
28. TOTAL CHARGE
29. AMOUNT PAID
30. Reserved for NUCC Use
31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS
32. SERVICE FACILITY LOCATION INFORMATION
33. BILLING PROVIDER INFO & PH #

NUCC Instruction Manual available at: www.nucc.org PLEASE PRINT OR TYPE APPROVED OMB-0938-1197 FORM 1500 (02-12)

Annotated claim form CMS-1450¹⁴

For claims submitted by hospitals, nursing facilities, and other institutional inpatient and outpatient providers¹⁴

A **Field 42:** Enter the 4-digit revenue code that best describes the service provided, in accordance with the hospital billing policy

B **Field 43:** Enter the corresponding description of service (eg, IV therapy)

C **Field 44:** Include any payer-required details, such as relevant HCPCS and CPT codes

D **Field 66:** Enter the appropriate ICD-10-CM diagnosis codes

E **Field 80:** Provide any required detailed information, such as the drug name, total dosage and strength, method of administration, and 11-digit NDC (attach separately if needed)

The image shows a sample CMS-1450 claim form with a large 'SAMPLE' watermark. Callouts A through E point to specific fields:

- A** points to Field 42 (Revenue Code).
- B** points to Field 43 (Description of Service).
- C** points to Field 44 (HCPCS/CPT Codes).
- D** points to Field 66 (ICD-10-CM Diagnosis Codes).
- E** points to Field 80 (Remarks).

The form includes sections for Patient Information, Insurance Information, Treatment Authorization, and Billing Information. The bottom of the form contains the NUBC logo and the text 'THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF'.

ADDITIONAL BILLING AND CODING CONSIDERATIONS

Reimbursement considerations

Lumizyme is designed to be prepared and administered by a healthcare provider, in both outpatient and home settings. Lumizyme may be eligible for reimbursement by commercial payers and Medicare.¹⁵ Please refer to the individual patient's plan to determine any applicable coverage requirements. The specifics of coverage may vary by payer.

When filing a claim

Because there is more than one enzyme replacement therapy (ERT) available to treat LOPD, Lumizyme coverage should be confirmed with payers prior to administration in patients who have been diagnosed with LOPD.

Some payers have policies that may affect coverage for Lumizyme. These include

- **Site of care:** Some payers may have coverage rules that restrict where patients can receive certain types of medical care, such as infusions
- **Network providers:** Some payers have exclusive contracts with in-network or participating providers to administer infusion therapies; these may include contracts for coverage in physician offices and outpatient settings or with specialty pharmacies that provide drugs and biologics to the provider
- **Prior authorization:** Many plans may require providers to obtain prior authorization (eg, statement of medical necessity) to begin a course of treatment; check with the payer to determine their process, requirements, and method for requesting authorization

Documenting medical necessity

Lumizyme is a medication used to treat a rare disease. Therefore, some insurers may not be familiar with Lumizyme and may require additional documentation to process a prior authorization or a claim upon receipt. Documentation requirements might include

- Statement of medical necessity from the attending physician (see next page)
- Lumizyme Prescribing Information
- Details on the patient's case history, previous therapy, and clinical course

IMPORTANT SAFETY INFORMATION (cont'd)

Risk of Developing Anti-alglucosidase Alfa Antibodies: (cont'd)

Patients should be monitored for IgG ADA antibody formation beginning at baseline, then regularly during the first year of treatment with subsequent monitoring as clinically warranted. Patients who experience hypersensitivity reactions, including anaphylaxis, may also be tested for IgE antibodies to LUMIZYME and other mediators of anaphylaxis.

Sample Statement of Medical Necessity

STATEMENT OF MEDICAL NECESSITY FOR THE TREATMENT OF POMPE DISEASE																	
Patient Information	<table border="1"> <tr> <td>Patient Name:</td> <td colspan="3">Address:</td> </tr> <tr> <td>Date of Birth:</td> <td>City:</td> <td>State:</td> <td>Zip:</td> </tr> <tr> <td>Gender: ☐ Male ☐ Female</td> <td colspan="3">Phone No. (Home):</td> </tr> <tr> <td></td> <td colspan="3">Phone No. (Work):</td> </tr> </table>	Patient Name:	Address:			Date of Birth:	City:	State:	Zip:	Gender: ☐ Male ☐ Female	Phone No. (Home):				Phone No. (Work):		
Patient Name:	Address:																
Date of Birth:	City:	State:	Zip:														
Gender: ☐ Male ☐ Female	Phone No. (Home):																
	Phone No. (Work):																
Insurance Information	<table border="1"> <tr> <td>Insurance Co.:</td> <td>Policy Holder Name:</td> </tr> <tr> <td>Subscriber ID No.:</td> <td>Insurance Phone No.:</td> </tr> <tr> <td>Group No.:</td> <td></td> </tr> </table>	Insurance Co.:	Policy Holder Name:	Subscriber ID No.:	Insurance Phone No.:	Group No.:											
Insurance Co.:	Policy Holder Name:																
Subscriber ID No.:	Insurance Phone No.:																
Group No.:																	
Medical Assessment	<table border="1"> <tr> <td>Patient Weight: _____ (kg/lb)</td> <td>Patient Height: _____ (cm/in)</td> </tr> <tr> <td>Respiratory: _____</td> <td>Musculoskeletal: _____</td> </tr> <tr> <td>Cardiac: _____</td> <td>Other: _____</td> </tr> </table> Enclosures <include patient medical history, full Prescribing Information, additional supporting clinical documents> Attach copy of GAA enzyme assay or GAA gene sequencing.	Patient Weight: _____ (kg/lb)	Patient Height: _____ (cm/in)	Respiratory: _____	Musculoskeletal: _____	Cardiac: _____	Other: _____										
Patient Weight: _____ (kg/lb)	Patient Height: _____ (cm/in)																
Respiratory: _____	Musculoskeletal: _____																
Cardiac: _____	Other: _____																
Diagnosis	<table border="1"> <tr> <td colspan="2">Pompe Disease E74.02: Date of Confirmed Diagnosis: _____</td> </tr> <tr> <td colspan="2">Please indicate Pompe disease subtype (if known): ☐ Infantile-onset Pompe disease (IOPD) ☐ Late-onset Pompe disease (LOPD)</td> </tr> <tr> <td colspan="2">How was the diagnosis confirmed? Confirmation REQUIRES the presence of #1 OR #2 below.</td> </tr> <tr> <td> ☐ GAA Enzyme Activity (must be reduced or absent): 1. Value: _____ (units) Date: _____ Normal Reference Range: _____ (for laboratory and sample) ☐ GAA Gene Sequencing: Date: _____ List DNA sequence changes: 1. _____ 2. _____ </td> <td> Sample Type (check all that apply): ☐ Blood ☐ Purified Lymphocytes ☐ Mixed Leukocytes ☐ Muscle Tissue ☐ Cultured Skin Fibroblasts </td> </tr> </table>	Pompe Disease E74.02: Date of Confirmed Diagnosis: _____		Please indicate Pompe disease subtype (if known): ☐ Infantile-onset Pompe disease (IOPD) ☐ Late-onset Pompe disease (LOPD)		How was the diagnosis confirmed? Confirmation REQUIRES the presence of #1 OR #2 below.		☐ GAA Enzyme Activity (must be reduced or absent): 1. Value: _____ (units) Date: _____ Normal Reference Range: _____ (for laboratory and sample) ☐ GAA Gene Sequencing: Date: _____ List DNA sequence changes: 1. _____ 2. _____	Sample Type (check all that apply): ☐ Blood ☐ Purified Lymphocytes ☐ Mixed Leukocytes ☐ Muscle Tissue ☐ Cultured Skin Fibroblasts								
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Treatment Recommendation	<table border="1"> <tr> <td>Lumizyme® (alglucosidase alfa)</td> <td>NDC #: 58468-0160-1 (carton of 1 single-use vial)</td> </tr> <tr> <td>Dose: _____ mg/kg</td> <td>NDC #: 58468-0160-2 (carton of 10 single-use vials)</td> </tr> <tr> <td></td> <td>Frequency: _____</td> </tr> <tr> <td colspan="2">Therapy Start Date: _____</td> </tr> </table>	Lumizyme® (alglucosidase alfa)	NDC #: 58468-0160-1 (carton of 1 single-use vial)	Dose: _____ mg/kg	NDC #: 58468-0160-2 (carton of 10 single-use vials)		Frequency: _____	Therapy Start Date: _____									
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Dose: _____ mg/kg	NDC #: 58468-0160-2 (carton of 10 single-use vials)																
	Frequency: _____																
Therapy Start Date: _____																	
Physician Authorization	<table border="1"> <tr> <td colspan="2">I certify that the above-indicated therapy is medically necessary, and the information provided is accurate to the best of my knowledge.</td> </tr> <tr> <td>Physician Name (printed): _____</td> <td>Date: _____</td> </tr> <tr> <td>Address: _____</td> <td>City: _____ State: _____ Zip: _____</td> </tr> <tr> <td colspan="2">Phone No.: _____</td> </tr> <tr> <td colspan="2">Physician Signature: _____</td> </tr> <tr> <td>Physician's Medical License No.: _____</td> <td>State Issued: _____</td> </tr> </table>	I certify that the above-indicated therapy is medically necessary, and the information provided is accurate to the best of my knowledge.		Physician Name (printed): _____	Date: _____	Address: _____	City: _____ State: _____ Zip: _____	Phone No.: _____		Physician Signature: _____		Physician's Medical License No.: _____	State Issued: _____				
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Physician Name (printed): _____	Date: _____																
Address: _____	City: _____ State: _____ Zip: _____																
Phone No.: _____																	
Physician Signature: _____																	
Physician's Medical License No.: _____	State Issued: _____																

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Note that some payers have their own specific form for medical necessity, which should be used in those cases.

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS

The most frequently reported adverse reactions ($\geq 5\%$) in clinical trials were hypersensitivity reactions and included: anaphylaxis, rash, pyrexia, flushing/feeling hot, urticaria, headache, hyperhidrosis, nausea, cough, decreased oxygen saturation, tachycardia, tachypnea, chest discomfort, dizziness, muscle twitching, agitation, cyanosis, erythema, hypertension/increased blood pressure, pallor, rigors, tremor, vomiting, fatigue, and myalgia.

Please see Important Safety Information,
including Boxed WARNING, on pages 3-4,
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Lumizyme®
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DOSING AND STORAGE INFORMATION³

Dosing

Lumizyme is for intravenous infusion only. The recommended dosage for patients with LOPD or IOPD is 20 mg/kg body weight administered every 2 weeks. The total volume of infusion is determined by the patient's body weight and should be administered over approximately 4 hours. Prior to Lumizyme administration, pretreating with antihistamines, antipyretics, and/or corticosteroids should be considered.

Lumizyme should be administered with an infusion pump at an initial rate of no more than 1 mg/kg/hr. The infusion rate may be increased in a stepwise manner, after patient tolerance to each infusion rate is established, by 2 mg/kg/hr every 30 minutes, until a maximum rate of 7 mg/kg/hr is reached.

The infusion rate may be slowed or temporarily stopped in the event of mild-to-moderate hypersensitivity reactions. In the event of anaphylaxis or severe hypersensitivity reaction, administration of Lumizyme should be discontinued and appropriate medical treatment should be initiated.

Please see the full **Prescribing Information** for complete details regarding infusion rates, as well as additional details regarding preparation and administration.

Storage

Lumizyme should be stored under refrigeration between 2°C and 8°C (36°F and 46°F). Once reconstituted and diluted, Lumizyme should be administered without delay. If immediate use is not possible, the reconstituted and diluted solution is stable for up to 24 hours when stored at 2°C to 8°C (36°F to 46°F). The reconstituted and diluted alglucosidase alfa solution should be protected from light. Storage of the solution at room temperature is not recommended.

Do not use Lumizyme after the expiration date on the vial.

IMPORTANT SAFETY INFORMATION (cont'd)

Infusion Associated Reactions (IARs): Infusion Associated Reactions (IARs) have been observed in patients treated with Lumizyme. Discontinue immediately or adjust the infusion rate and provide medical treatment based on the severity of the reaction. Closely monitor patients who have experienced IARs when re-administering LUMIZYME.

PATIENT SUPPORT SERVICES



Connected Care Throughout Your Patient's Journey

CareConnect is a free, voluntary, and confidential support program for eligible patients living with Pompe disease.



Connected Education

Comprehensive disease education from diagnosis and beyond for individuals, families, and communities.



Connected Team

Dedicated team that connects the dots between specialists, insurance, and appointments for a less fragmented case experience.



Connected Experience

Programs designed to support patients by connecting them with experts and the community to navigate life transitions and disease management.

Your patient's team is made up of two dynamic professionals.



Case Managers assist with reimbursement matters, provide financial assistance resources, and help patients navigate access hurdles throughout treatment.



Patient Education Liaisons have a clinical background and provide patients with disease and treatment education throughout their journey.

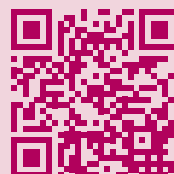
If affording treatment is an issue, CareConnect may be able to help eligible patients access financial assistance.

CONNECT WITH US

www.careconnectpss.com

1-800-745-4447 (Option 3)

info@careconnectpss.com



Please see Important Safety Information,
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 **Lumizyme®**
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ORDERING INFORMATION FOR LUMIZYME

To order Lumizyme, contact one of the authorized distributors listed below:

SPECIALTY DISTRIBUTOR	Phone	Web
Cardinal Health Pharmaceutical Distribution	800-926-3161	cardinalhealth.com/en/login.html
Cardinal Health Specialty Distribution	800-926-3161	cardinalhealth.com/en/login.html
McKesson Plasma and Biologics	877-625-2566	connect.mckesson.com
McKesson Pharmaceutical Distribution	855-625-4677	connect.mckesson.com
McKesson Specialty Health	800-482-6700	mcs.mckesson.com
Morris & Dickson Specialty Distribution	800-388-3833	mdspecialtydist.com

To order Lumizyme directly from Sanofi

DIRECT ORDER CONTACT	Phone	Email
Rare Disease Product Services	800-745-4447, Option 1	CO@Sanofi.com

Lumizyme is also available through most specialty pharmacies.

IMPORTANT SAFETY INFORMATION (cont'd)

Risk of Cardiac Arrhythmia and Sudden Cardiac Death during General Anesthesia for Central Venous Catheter Placement: Caution should be used when administering general anesthesia for the placement of a central venous catheter intended for LUMIZYME infusion.

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REFERENCES

1. Techtarget. *ICD-10-CM* (clinical modification). Updated June 2024. Accessed May 8, 2026. <https://www.techtarget.com/searchhealthit/definition/ICD-10-CM>
2. Centers for Disease Control and Prevention. *ICD-10-CM* tabular list of diseases and injuries. January 22, 2026. Accessed May 8, 2026. https://ftp.cdc.gov/pub/Health_Statistics/NCHS/Publications/ICD10CM/2026-update/
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