



Cerezyme®

(imiglucerase) for injection

CEREZYME® (imiglucerase) FOR INJECTION
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 Cerezyme 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 with public and private payers, to help with access to Cerezyme 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:

Cerezyme[®] (imiglucerase) for injection is indicated for the treatment of non-central nervous system (CNS) manifestations of Type 1 or Type 3 Gaucher disease in adult and pediatric patients.

Important Safety Information

WARNING: 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 CEREZYME 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 CEREZYME immediately, and initiate appropriate medical treatment, including use of epinephrine. Inform patients of the symptoms of life-threatening hypersensitivity reactions, including anaphylaxis, and to seek immediate medical care should symptoms occur.

Warnings and Precautions:

Hypersensitivity Reactions Including Anaphylaxis: See Boxed WARNING.

Patients with antibody to imiglucerase have a higher risk of hypersensitivity reactions. Consider periodic monitoring during the first year of treatment for IgG antibody formation.

Consider risks and benefits of readministering Cerezyme to individual patients following a severe reaction. If a mild or moderate hypersensitivity reaction occurs, consider reducing the rate of infusion, pretreat with antihistamines and/or corticosteroids, and monitor patients for new signs and symptoms of a hypersensitivity reaction.

Infusion-Associated Reactions:

Infusion associated reactions (IARs) have been observed in patients treated with Cerezyme. If a severe IAR occurs, discontinue CEREZYME and immediately initiate appropriate medical treatment. Consider the risks and benefits of re-administering CEREZYME following a severe IAR. If a mild or moderate IAR occurs, consider decreasing the infusion rate, temporarily stopping the infusion, and/or administering antihistamines, antipyretics, and/or corticosteroids.

Adverse Reactions:

- Adverse reactions reported in adults and pediatric patients include back pain, chills, dizziness, fatigue, headache, hypersensitivity reactions, nausea, pyrexia, and vomiting.

Coding Summary

Diagnosis

Codes used to formalize diagnosis come from the *International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM)*, which was originally developed by the World Health Organization. The ICD-10-CM diagnosis code for Gaucher disease, to be used in conjunction with the administration of Cerezyme, is E75.22.¹ This code will be used for both Gaucher disease type 1 and type 3 (GD1 and GD3).

ICD-10-CM Code ¹	
E00-E89	Endocrine, nutritional and metabolic diseases
▶ E75	Disorders of sphingolipid metabolism and other lipid storage disorders
▶ E75.2	Other sphingolipidosis
▶ E75.22	Gaucher disease (The ICD-10-CM diagnosis code is the same for all indicated subtypes of Gaucher disease)

National Drug Code (NDC)

The NDC is a unique 3-segment number that serves as a universal product identifier for human drugs in the US. Cerezyme has a 10-digit NDC displayed on its packaging. In most cases, this should be converted to an 11-digit code for billing purposes.² Dosing/package are the same for both GD1 and GD3 indications, so the Cerezyme NDC code is the same. Payer requirements for NDC use and format may vary. Please contact each payer for specific coding policies.

National Drug Code	
10-digit NDC	58468-4663-1
11-digit NDC	58468-4663-01

CPT® Code

Current Procedural Terminology (CPT) codes are used to describe the procedures performed on a patient and/or how a drug or supply being billed was administered.³ The CPT codes commonly associated with the administration of IV-infused biologic therapies like Cerezyme are listed below. Confirm preferred coding policy with payer prior to administration whenever possible.

Primary Codes ⁴	
96365	IV therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
96366	Each additional hour (list separately in addition to primary procedure code, 96365)*

*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 reporting the actual number of minutes on the claim.

CPT is a registered trademark of the American Medical Association.

CMS, Centers for Medicare & Medicaid Services; IV, intravenous.



HCPCS Procedure Codes

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.⁵ Note that the coding system is not a methodology for making coverage or payment determinations. The existence of a HCPCS code does not imply coverage; it implies only that the product may be reimbursed if covered. Note that the HCPCS code is the same whether Cerezyme is used to treat GD1 or GD3.

HCPCS Code ⁶	
J1786	Cerezyme—injection, imiglucerase, 10 units

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 biologicals.⁷ Refer to each payer’s policy for coding and documentation requirements.

Place of Service Codes

Because Cerezyme 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.⁸

Always verify the preferred POS codes for your patient’s health plan before submitting a claim.

HCPCS, Healthcare Common Procedure Code System.



Sample Reimbursement Forms

These sample claim forms are intended for use only as a reference. Reimbursement codes are subject to continual change. Please confirm the accuracy of the codes you use to bill for the prescribed medications with each payer.

Annotated claim form CMS-1500⁹

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

CARRIER (vertical label on right)

PATIENT AND INSURED INFORMATION (vertical label on right)

PHYSICIAN OR SUPPLIER INFORMATION (vertical label on right)

Callout 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)

Callout B: Field 21: Enter the appropriate ICD-10-CM diagnosis codes

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

Callout D: Field 24B: Enter appropriate place of service code (office, infusion center, etc)

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

Callout 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 that are entered

Please see Important Safety Information on page 3 and Full Prescribing Information, including Boxed WARNING.

Sample Reimbursement Forms (cont'd)

The sample claim form shown below is an example of the form used for claims submitted by hospitals, nursing facilities, and other inpatient institutions. Although fields are organized differently than in the CMS 1500, the information captured is essentially the same.

Annotated claim form CMS-1450¹⁰

The image shows a CMS-1450 claim form with several callouts:

- A**: Points to the 42 field (Revenue Code).
- B**: Points to the 43 field (Description of Service).
- C**: Points to the 44 field (HCPCS / Rate / ICD-10).
- D**: Points to the 66 field (ICD-10-CM diagnosis codes).
- E**: Points to the 80 field (Remarks).

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 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 drug name, total dosage and strength, method of administration, and 11-digit NDC (attach separately if needed)

D

E

Additional Billing and Coding Considerations

Reimbursement Considerations

Cerezyme is designed to be prepared and administered by a healthcare provider, in both outpatient and home settings. Cerezyme may be eligible for reimbursement by commercial payers and Medicare. 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

It is recommended that Cerezyme coverage be confirmed with all payers prior to patient administration, as patient benefits vary among payers and by plan.

Some payers also have policies that may affect coverage for Cerezyme. 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, 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

Cerezyme is a medication used to treat a rare disease. Therefore, some insurers may not be familiar with Cerezyme 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
- Cerezyme Prescribing Information
- Details on the patient’s case history, previous therapy, and clinical course

Example of a Statement of Medical Necessity

Note that some payers have their own specific form for medical necessity, which should be used in those cases. Check with the patient’s insurer for details that will be needed in the statement of medical necessity and how the insurer prefers to receive this information.

STATEMENT OF MEDICAL NECESSITY
FOR THE TREATMENT OF NON-CNS MANIFESTATIONS OF GAUCHER DISEASE TYPE 1 AND TYPE 3 IN ADULTS AND PEDIATRIC PATIENTS

Patient Information
 Patient Name: _____ Street Address: _____
 Date of Birth: _____ City: _____ State: _____ ZIP: _____
 Gender: Male Female Phone (Home): _____
 Phone (Work): _____

Insurance Information
 Insurance Co.: _____ Policy Holder Name: _____
 Subscriber ID No.: _____ Insurance Phone No.: _____
 Group No.: _____

Medical Assessment
 Patient Weight: _____ kg/____ lb Patient Height: _____ cm/____ in
 Growth Delay: Yes No Height Percentile: _____
 Hepatomegaly: Yes No Date: _____ Liver Size: _____
 Splenomegaly: Yes No Date: _____ Spleen Size: _____

Hematology
 Anemia: Yes No
 Thrombocytopenia: Yes No
 Bleeding Event: Yes No

Neurological involvement: Yes No
 Cerebellar symptoms Ataxia Cognitive impairment

Bone Disease (check all that apply)
 Lytic lesions Osteopenia/Osteoporosis Marrow infiltration
 Avascular necrosis Pathological fractures Erlenmeyer flask deformity
 Bone pain/bone crisis Intertractions

Diagnosis
 Gaucher disease type 1 E75.22 Date of Confirmed Diagnosis: _____
 Gaucher disease type 3 E75.22 Method of Diagnosis: _____

Treatment Recommendation
 Cerezyme® (imiglucerase) NDC# 58468-4663-1 (400U vial)
 Dose (number of units per kg): _____ Frequency: _____ Therapy Start Date: _____

Physician Authorization
 I certify that the above-indicated therapy is medically necessary, and the information provided is accurate to the best of my knowledge.
 Physician Name: _____ Date: _____
 Street Address: _____ City: _____ State: _____ ZIP: _____
 Phone: _____
 Physician Signature: _____
 Physician's Medical License No.: _____ State Issued: _____

W-01-201002 v4.0 01/2010



Dosing Information¹¹

Dosage and Administration

Cerezyme is administered by IV infusion. The recommended dosage, based upon disease severity, ranges from 2.5 units/kg 3 times a week to 60 units/kg once every 2 weeks. For patients weighing 20 kg and greater, infusions will usually last 1 to 2 hours. For patients weighing less than 20 kg, infusions will usually take 2 hours. Dosage should be titrated based on disease severity and therapeutic goals for the patient.

Cerezyme should be administered under the supervision of a healthcare provider knowledgeable in the management of hypersensitivity reactions including anaphylaxis.

Cerezyme should be initiated in a healthcare setting with appropriate medical monitoring and support measures, including access to cardiopulmonary resuscitation equipment.

Patients who experience hypersensitivity reactions to Cerezyme must be premedicated with antihistamines and/or corticosteroids. Patients should be monitored for the occurrence of new hypersensitivity reactions.

Cerezyme should be stored at 2°C to 8°C (36°F to 46°F). Reconstituted Cerezyme can be stored at room temperature at 20°C to 25°C (68°F to 77°F) or refrigerated at 2°C to 8°C (36°F to 46°F) for up to 12 hours. After dilution, Cerezyme is stable for up to 24 hours when refrigerated.

Please see the Full [Prescribing Information](#) for additional details regarding preparation and administration.



Patient Support Services



Connected Care Throughout Your Patient’s Journey

CareConnect is a free, voluntary, and confidential support program for eligible patients and families living with lysosomal storage disorders, including Gaucher disease types 1 and 3.



Connected Education

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



Connected Team

Dedicated team who connects the dots between specialists, insurance, and appointments for a less fragmented care 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





Ordering Information for Cerezyme

To order Cerezyme, contact one of the specialty distributors listed below:

Specialty Distributors	Phone	Web
Cardinal Health	800-926-3161	cardinalhealth.com
Cardinal Health Specialty Pharmaceutical Distribution	855-855-0708	cardinalhealth.com
McKesson Specialty Health	800-482-6700	mcs.mckesson.com
McKesson Pharmaceutical Distribution	855-625-4677	mckesson.com
McKesson Plasma and Biologics (MPB)	877-625-2566	connect.mckesson.com
Morris & Dickson Specialty Distribution	800-388-3833	mdspecialtydist.com

Use the information below to order Cerezyme directly from Sanofi:

Direct Order Contact	Phone	Email
Rare Disease Product Services	800-745-4447, Option 1	CO@Sanofi.com

Cerezyme is also available through most specialty pharmacies.



References

1. Centers for Disease Control and Prevention. ICD-10-CM tabular list of diseases and injuries. 2022. Accessed October 30, 2025. https://ftp.cdc.gov/pub/Health_Statistics/NCHS/Publications/ICD10CM/2022/icd10cm-tabular-2022-April-1.pdf#:~:text=ICD-10-CM%20TABULAR%20LIST%20of%20DISEASES%20and%20INJURIES%20Table,%28D50-D89%29%204%20Endocrine%2C%20nutritional%20and%20metabolic%20diseases%20%28E00-E89%29
2. Maryland Department of Health. National Drug Code (NDC) conversion table. Accessed October 30, 2025. <https://health.maryland.gov/phpa/OIDEOR/IMMUN/Shared%20Documents/Handout%203%20-%20NDC%20conversion%20to%2011%20digits.pdf>
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5. American Academy of Professional Coders. What is HCPCS? Reviewed October 2019. Accessed October 30, 2025. <https://www.aapc.com/resources/medical-coding/hcpcs.aspx>
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8. Centers for Medicare & Medicaid Services. Place of service codes for professional claims. Updated September 2023. Accessed October 30, 2025. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/Website-POS-database.pdf>
9. Centers for Medicare & Medicaid Services. Sample form CMS-1500. Accessed October 30, 2025. <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf>
10. Centers for Medicare & Medicaid Services. Sample form CMS-1450. Accessed October 30, 2025. <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-1450>
11. Cerezyme. Prescribing Information. Genzyme Corporation.

Please see Important Safety Information on page 3 and Full [Prescribing Information](#), including Boxed WARNING.



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