



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.

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 **CareConnectPSS[®]** at **1-800-745-4447**, Option 3. Sanofi's **CareConnectPSS 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 treatment of adults and pediatric patients 2 years of age and older with Type 1 Gaucher disease that results in one or more of the following conditions:

- anemia
- thrombocytopenia
- bone disease
- hepatomegaly or splenomegaly

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 access to cardiopulmonary resuscitation equipment. If a severe hypersensitivity reaction (e.g., anaphylaxis) occurs, discontinue CEREZYME and immediately 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. Consider reducing the rate of infusion, pretreat with antihistamines and/or corticosteroids, and monitor patients for new signs and symptoms of a severe hypersensitivity reaction.

Infusion-Associated Reactions:

Infusion associated reactions (IARs) have been observed in patients treated with Cerezyme. If an IAR occurs, decreasing the infusion rate, temporarily stopping the infusion and/or administering antihistamines and/or antipyretics may ameliorate the symptoms. Closely monitor patients who have experienced IARs when re-administering Cerezyme.

Adverse Reactions:

- Adverse reactions reported in adults include back pain, chills, dizziness, fatigue, headache, hypersensitivity reactions, nausea, pyrexia, and vomiting.
- Adverse reactions reported in pediatric patients 2 years of age and older are similar to adults.

Please see accompanying Full [Prescribing Information](#), including Boxed WARNING.



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

| 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 |

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 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.

| 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

- 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 codes
- C** Field 24A: Enter the date of service for each procedure. Include NDC information, if required, in the shaded areas above each date
- D** Field 24B: Enter appropriate place of service code (office, infusion center, etc)
- E** Field 24D: Include payer-required details such as HCPCS code (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 that are entered

- A**
- B**
- C**

- D**
- E**
- F**

The image shows a sample CMS-1500 Health Insurance Claim Form with several callouts (A-F) pointing to specific fields. Callout A points to Field 19 (Diagnosis), callout B to Field 21 (ICD-10-CM diagnosis codes), callout C to Field 24A (Date of service), callout D to Field 24B (Place of service), callout E to Field 24D (HCPCS code, CPT codes, and modifiers), and callout F to Field 24E (Diagnosis code reference letter or number).

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)

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 GAUCHER DISEASE TYPE 1

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

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

Medical Assessment: Patient Weight (kg/lb), Patient Height (cm/in), Splenectomy (No/Yes, Date, Select Type: Partial/Total), Organomegaly (No/Yes, Date, Spleen, Liver Size), Hematology (Anemia, Thrombocytopenia, Bleeding Event), Bone Disease (Lytic Lesions, Avascular Necrosis, Bone Pain, Erlenmeyer flask deformity), Joint replacement(s), Osteopenia, Pathological fracture(s), Marrow infiltration, Infection(s).

Diagnosis: Gaucher Disease Type 1 E75.22, Method of Diagnosis, Date of Confirmed Diagnosis.

Treatment Recommendation: Cerezyme® (imiglucerase), NDC: 09468-4663-1 (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.

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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 18 kg and greater, infusions will usually last 1 to 2 hours. For patients weighing less than 18 kg, infusions will usually take more than 2 hours. Dosage should be titrated based on clinical manifestations of disease and therapeutic goals for the patient.

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 can be premedicated with antihistamines and/or corticosteroids. Patients should be monitored for the occurrence of new hypersensitivity reactions.

Cerezyme should be stored at 36°F to 46°F (2°C to 8°C). Reconstituted Cerezyme can be stored at room temperature at 68°F to 77°F (20°C to 25°C) or refrigerated at 36°F to 46°F (2°C to 8°C) 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



CareConnectPSS®

CareConnectPSS, personalized support services for patients, represents Sanofi's more than 35-year commitment to supporting the rare disease community. CareConnectPSS is designed to support each patient's unique journey.

Our range of support to help patients manage living with a rare disease

- Programs and other offerings on a range of disease, treatment, and support topics
- Dedicated CareConnectPSS Case Managers and Patient Education Liaisons
- Disease-specific information, including genetic education and other resources
- Care coordination for moves, vacations, and more
- Assistance with understanding new or changing insurance, as well as resources to help with out-of-pocket costs

Access to these and other services is voluntary, and your patients are not obligated to begin treatment if they contact us. You and your patients make all treatment-related decisions, and most importantly the privacy and security of their personal information are always protected.

CareConnectPSS Co-Pay Program

Helps eligible patients in the United States who are prescribed Cerezyme pay for eligible out-of-pocket drug costs and specified infusion-related charges, including co-pays, coinsurance, and deductibles, up to the program maximum.*

CareConnectPSS Patient Assistance Program

Provides Cerezyme at no cost to eligible patients who do not have health insurance or cannot access Cerezyme under the terms of their insurance plan(s), until insurance coverage for Cerezyme is secured.†

To find out more, contact a Case Manager at
 1-800-745-4447 (Option 3)
 or visit www.CareConnectPSS.com

* Patients must be eligible under applicable state law(s). Patients whose medication or infusion-related costs are covered by a state or federal health care program, including but not limited to Medicare, Medicare Part D, Medigap, Medicaid, Veterans Affairs (VA), Department of Defense (DoD), or TRICARE®, are not eligible. Patient must live in the US or a US territory. Other terms and conditions of the Program apply.

Co-Pay Program does not cover or provide support for MD office visits/evaluations, nursing services/observation periods, blood work, x-rays or other testing, pre-medications/other medications, transportation or other related services associated with treatment. In accordance with state law, infusion-related costs are not covered for commercially insured patients residing in MA or RI. Sanofi reserves the right to modify or discontinue the program at any time without notice. Savings may vary depending on patients' out-of-pocket costs.

† Patient Assistance Program eligibility criteria include the following:

- Patient must not have insurance coverage or not have access to CERZYME under the terms of the patient's insurance plan(s)
- Patient must live in the US or a US territory
- Patient must have a valid prescription from a health care provider licensed in the US or a US territory
- Other terms and conditions of the Program apply

TRICARE is a registered trademark of the Department of Defense, Defense Health Agency.



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

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10. Centers for Medicare & Medicaid Services. Sample form CMS-1450. Accessed March 25, 2024. <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](#).



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