FABRAZYME®
(AGALSIDASE BETA)

BILLING AND CODING GUIDE FOR REIMBURSEMENT

Fabrazyme®
agalsidase beta

Using This Billing and Coding Guide

This billing and coding guide for Fabrazyme® (agalsidase beta) is provided for informational purposes only and should be verified, as codes may change. The provision of billing codes does not constitute legal or reimbursement advice. Providers are solely responsible for ensuring the accuracy of billing submissions to any payer. The information in this guide is not intended to substitute for the physician's independent diagnosis or treatment of each patient.

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 Fabrazyme 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 and Important Safety Information

INDICATION AND USAGE

Fabrazyme® is indicated for the treatment of adult and pediatric patients 2 years of age and older with confirmed Fabry disease.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Anaphylaxis and Hypersensitivity Reactions:

In clinical trials and postmarketing safety experience with Fabrazyme, approximately 1% of patients developed anaphylactic or severe hypersensitivity reactions during Fabrazyme infusion. Life-threatening anaphylactic and severe hypersensitivity reactions have been observed in patients during Fabrazyme infusions.

- Reactions have included localized angioedema (including swelling of the face, mouth, and throat), bronchospasm, hypotension, generalized urticaria, dysphagia, rash, dyspnea, flushing, chest discomfort, pruritus, and nasal congestion.
- Interventions have included cardiopulmonary resuscitation, oxygen supplementation, IV fluids, hospitalization, and treatment with inhaled beta-adrenergic agonists, antihistamines, epinephrine, and IV corticosteroids.
- If anaphylactic or severe hypersensitivity reactions occur, immediately discontinue administration of Fabrazyme and provide necessary emergency treatment. Because of the potential for severe hypersensitivity reactions, appropriate medical support measures should be readily available when Fabrazyme is administered.

In clinical trials with Fabrazyme, some patients developed IgE antibodies or skin test reactivity specific to Fabrazyme.

- Higher incidences of hypersensitivity reactions were observed in adult patients with persistent anti-Fabrazyme antibodies and in adult patients with high antibody titer compared to that in antibody negative adult patients.
- Physicians should consider testing for IgE antibodies in patients who experienced suspected hypersensitivity reactions and consider the risks and benefits of continued treatment in patients with anti-Fabrazyme IgE antibodies. Rechallenge of these patients should only occur under the direct supervision of qualified personnel, with appropriate medical support measures readily available.

Indication and Important Safety Information (cont'd)

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Infusion-Associated Reactions

In clinical trials with Fabrazyme, 59% of patients experienced infusion-associated reactions, some of which were severe. Infusion-associated reactions are defined as adverse reactions occurring on the same day as the infusion. The incidence of infusion-associated reactions was higher in patients who were positive for anti-Fabrazyme antibodies than in patients who were negative for anti-Fabrazyme antibodies.

- In patients experiencing infusion-associated reactions, pretreatment with an antipyretic and antihistamine is recommended. Infusion-associated reactions occurred in some patients after receiving pretreatment.
- If an infusion-associated reaction occurs, decreasing the infusion rate, temporarily stopping the infusion, and/or administrating additional antipyretics, antihistamines, and/or steroids may ameliorate the symptoms.
- If severe infusion-associated reactions occur, immediate discontinuation of the administration of Fabrazyme should be considered, and appropriate medical treatment should be initiated. Severe reactions are generally managed with administration of antihistamines, corticosteroids, intravenous fluids, and/or oxygen when clinically indicated. Because of the potential for severe infusion associated reactions, appropriate medical support measures should be readily available when Fabrazyme is administered.
- Patients with advanced Fabry disease may have compromised cardiac function, which may predispose. them to a higher risk of severe complications from infusion-associated reactions. Monitor closely patients with compromised cardiac function if Fabrazyme is administered to these patients.

ADVERSE REACTIONS

- Common adverse reactions reported (≥20% and >2.5% compared to placebo) were upper respiratory tract infection (53% vs 42%), chills (49% vs 13%), pyrexia (39% vs 22%), headache (39% vs 28%), cough (33% vs 25%), paresthesia (31% vs 18%), fatigue (24% vs 17%), peripheral edema (21% vs 7%), dizziness (21% vs 8%), and rash (20% vs 10%).

Coding Summary

Diagnosis Codes

Codes used to formalize diagnoses come from the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), which was developed by the World Health Organization.[1] The specific diagnostic code for Fabry disease (sometimes called Anderson-Fabry disease) is E75.21.[2]

Please refer to cdc.gov for the most up-to-date code list, as codes may be subject to change.

ICD-10-CM Codes[2]	
E00-E89	Endocrine, nutritional, and metabolic diseases
E70-E88	Metabolic disorders
E75	Disorders of sphingolipid metabolism and other storage disorders
E75.2	Other sphingolipidosis
E75.21	**Fabry disease**

Please see Important Safety Information for Fabrazyme on pages 3-4, and full Prescribing Information.

Coding Summary (cont'd)

National Drug Code (NDC)

NDCs are unique 3-segment numbers that serve as universal product identifiers for human drugs in the US.[3] Fabrazyme is available in 2 vial sizes, 35 mg and 5 mg, and each vial size has its own specific 10-digit NDC displayed on the packaging. In most cases, these codes should be converted to 11-digit NDCs for billing purposes.[4] The table below shows the 10-digit and 11-digit NDC for each vial size of Fabrazyme.

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

Also please refer to the U.S. Food and Drug Administration's National Drug Code Directory website for the most up-to-date NDC information.

NDC Codes[5]	
10-digit NDC	35-mg vial: NDC 58468-0040-1 5-mg vial: NDC 58468-0041-1
11-digit NDC	35-mg vial: NDC 58468-0040-**01** 5-mg vial: NDC 58468-0041-**01**
How supplied	Fabrazyme is supplied as a sterile, nonpyrogenic, white to off-white lyophilized cake or powder in single-dose vials.[5]

CPT® Codes

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.[6] The CPT codes most commonly associated with the administration of IV-infused biologic therapies like Fabrazyme are listed below. Whenever possible, confirm the preferred coding policy with payers prior to administration of Fabrazyme.

Primary Codes[7]	
96365	Intravenous infusion for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour7
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)[7,8]*

*Per Centers for Medicare & Medicaid Services (CMS) guidelines, if the incremental amount of infusion time is 30 minutes or less, the time should not be billed separately.[7] Note that some payers may require reporting the actual number of minutes on the claim.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Anaphylaxis and Hypersensitivity Reactions (cont'd)

- Interventions have included cardiopulmonary resuscitation, oxygen supplementation, IV fluids, hospitalization, and treatment with inhaled beta-adrenergic agonists, antihistamines, epinephrine, and IV corticosteroids.

Please see Important Safety Information for Fabrazyme on pages 3-4, and full Prescribing Information.

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HCPCS Code

Healthcare Common Procedure Coding System (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 a HCPCS code does not imply coverage; it implies only that the product may be reimbursed if covered.

Permanent J Code[9]	**J0180: Agalsidase beta injection, 1 mg**

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.

JZ modifier: Beginning July 1, 2023, providers are required to report the JZ modifier on all claims that bill for drugs from single-dose containers that are separately payable under Medicare Part B when there are no discarded amounts. The JZ modifier is required to attest there were no discarded amounts and no JW modifier amount was reported.[10]

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

Important coding note: Some insurance companies may require the NDC billing method for infused medications, while others may require the HCPCS billing method. Confirm the preferred coding policy with each payer prior to the administration of Fabrazyme.

NDC billing = an individual charge line for each medication vial used during a treatment, plus additional lines for wastage

HCPCS billing = 1 charge line for a medication and 1 charge line for wastage (if applicable), regardless of the number of vials used

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Anaphylaxis and Hypersensitivity Reactions (cont'd)

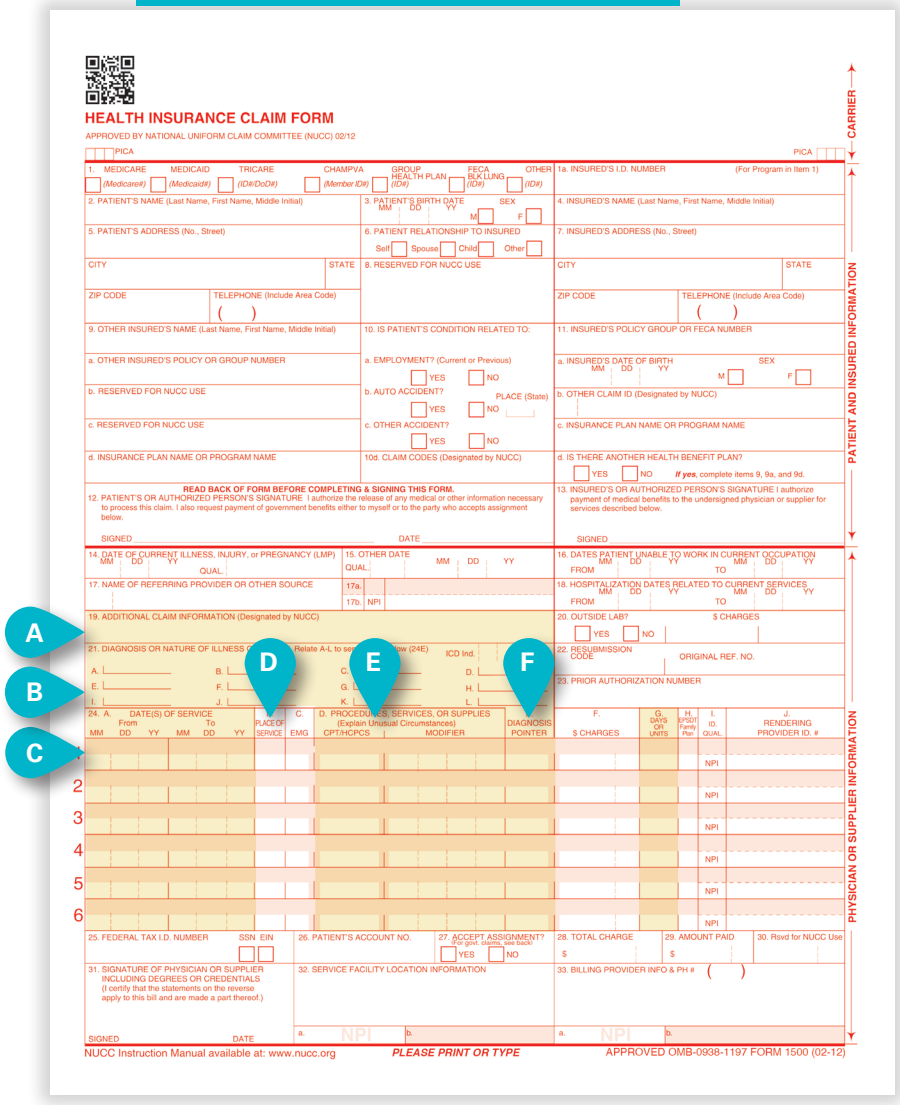
- If anaphylactic or severe hypersensitivity reactions occur, immediately discontinue administration of Fabrazyme and provide necessary emergency treatment. Because of the potential for severe hypersensitivity reactions, appropriate medical support measures should be readily available when Fabrazyme is administered.

Sample Reimbursement Forms

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

For claims submitted by noninstitutional healthcare providers[12]:

Annotated claim form CMS-1500[13]



This sample form is for informational purposes only.

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 POS code (office, infusion center, etc)

E **Field 24D:** Include 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 to the services or procedures performed that are entered on that same line under 24D

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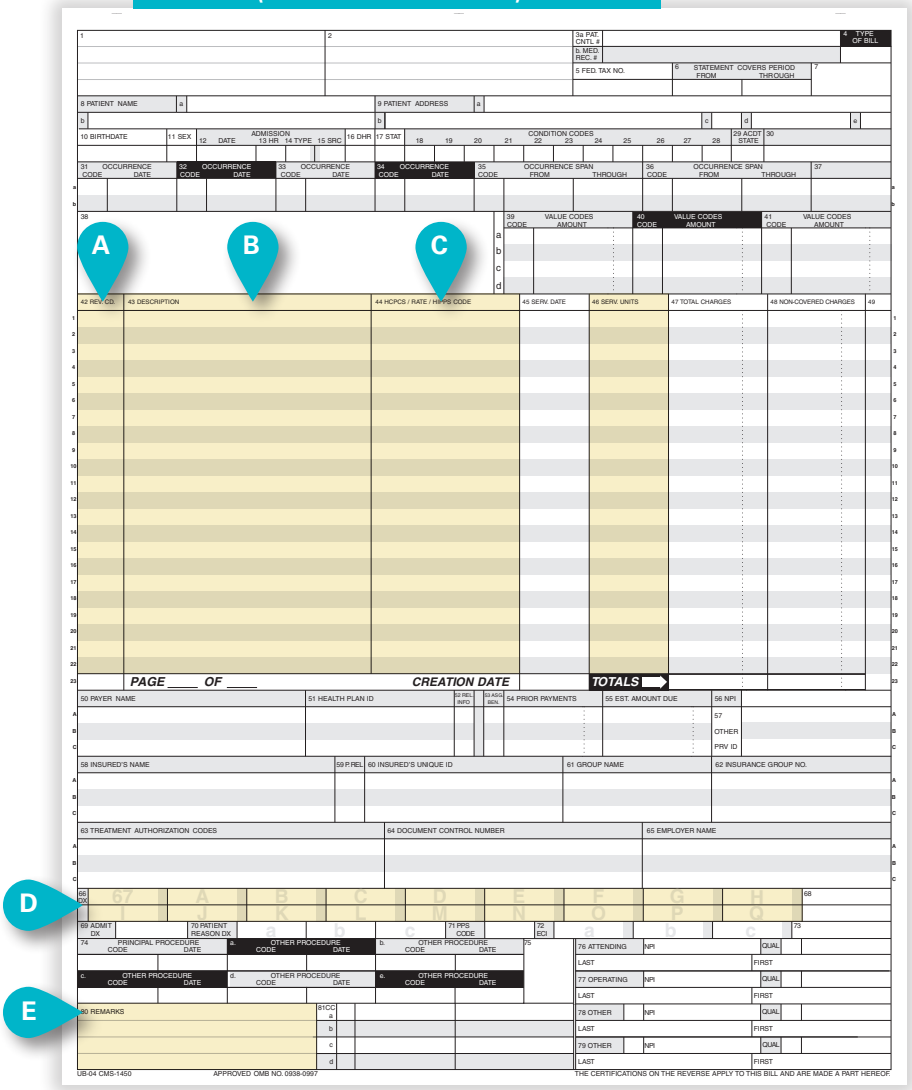
Sample Reimbursement Forms (cont'd)

For claims submitted by hospitals, nursing facilities, and other institutional inpatient and outpatient providers[14]:

Annotated claim form CMS-1450, (also known as UB-04)[15]



This sample form is for informational purposes only.

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 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)

Please see Important Safety Information for Fabrazyme on pages 3-4, and full Prescribing Information.

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Additional Billing and Coding Considerations

Reimbursement Consideration

Fabrazyme is designed to be prepared and administered by a healthcare provider in hospital/outpatient, clinic, and home settings. Fabrazyme may be eligible for reimbursement by commercial payers and Medicare.[16] 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 Fabrazyme coverage be confirmed with payers prior to administration in patients aged 2 and older with confirmed Fabry disease.

Some payers have policies that may affect coverage for Fabrazyme. 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, through documentation of medical necessity) to begin a course of treatment. Check with the payer to determine their process, requirements, and method for requesting authorization

Documenting Necessity

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

Documentation requirements might include:

- Statement of medical necessity/letter of intent to treat from the attending physician
- Fabrazyme Prescribing Information
- Details on the patient's case history, previous therapy, and clinical course

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Anaphylaxis and Hypersensitivity Reactions (cont'd)

In clinical trials with Fabrazyme, some patients developed IgE antibodies or skin test reactivity specific to Fabrazyme.

- Higher incidences of hypersensitivity reactions were observed in adult patients with persistent anti-Fabrazyme antibodies and in adult patients with high antibody titer compared to that in antibody negative adult patients.

Please see Important Safety Information for Fabrazyme on pages 3-4, and full Prescribing Information.

Additional Billing and Coding Considerations (cont'd)

Sample Documentation

Healthcare providers may contact their Sanofi representative for a copy of the sample documents shown below. Note that some payers have a specific form for medical necessity, which should be used in that instance.

Statement of Medical Necessity

STATEMENT OF MEDICAL NECESSITY
FOR THE TREATMENT OF FABRY DISEASE

PATIENT INFORMATION

Patient's Name _____ Social Security No. _____
Address _____
City _____ State _____ Zip Code _____
Gender ☐ Male ☐ Female Phone No. (Home) _____ Phone No. (Work) _____

INSURANCE INFORMATION

Insurance Co _____ Policy Holder's Name _____
Policy Number _____ Group Number _____ Insurance Phone _____

MEDICAL ASSESSMENT

Patient Weight _____ (kg/lbs) Patient Height _____ (cm/in)
Please list signs and symptoms consistent with Fabry disease: _____

DIAGNOSIS

☐ Fabry Disease (Lipidosis) ICD-9-CM 272.7 ☐ Fabry (Anderson) Disease ICD-10-CM* E75.21
Method of diagnosis: ☐ Enzyme Assay ☐ Genetic Testing ☐ Tissue Biopsy
☐ Other (please specify) _____
Diagnostic Results (Values): _____

TREATMENT RECOMMENDATION

☐ Fabrazyme* (agalsidase beta) NDC 58468-0040-1 35mg vial; NDC 58468-0041-1 5mg vial
Dose _____ mg/kg* Frequency* _____ Therapy Start Date _____
**recommended dosage of Fabrazyme is 1 mg/kg body weight infused every 2 weeks*
Please list any additional treatment information, including follow-up evaluations: _____

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 (printed) _____ Date _____
Address _____
City _____ State _____ Zip Code _____
Phone No. (Home) _____ Phone No. (Work) _____
Physician's Signature _____ Medical License # _____
State Issued _____

Letter of Intent to Treat

Sample Letter of Intent to Treat

IMPORTANT INFORMATION:

This letter is a sample that provides background information regarding Fabrazyme® (agalsidase beta) and Fabry Disease, a rare genetic condition. This letter should be modified by the treating physician to address the particular circumstances of the individual patient, as well as the physician's clinical judgment.

Date:

Contact Name:
Insurance Company:
Street Address:
City: State: Zip:

Patient Name:
Subscriber ID#:
Group#:

Subject: Intent to Treat with Fabrazyme® (agalsidase beta)

Dear *contact name*

patient name *patient ID #* has been diagnosed with Fabry disease and I plan to treat *him/her* with Fabrazyme® (agalsidase beta), an enzyme replacement therapy (ERT). Fabrazyme is indicated for the treatment of adult and pediatric patients 2 years of age and older with confirmed Fabry disease. Fabrazyme is administered intravenously and is typically administered on an outpatient basis. Fabrazyme is an FDA-approved ERT for the treatment of this life-threatening, orphan disease.

Fabry disease is an X-linked genetic disorder of glycosphingolipid metabolism. Deficiency of the lysosomal enzyme a-galactosidase A leads to progressive accumulation of glycosphingolipids, predominantly GL-3, in many body tissues, starting early in life and continuing over decades. Clinical manifestations of Fabry disease include renal failure, cardiomyopathy, and cerebrovascular accidents. Accumulation of GL-3 in kidney cells may play a role in renal failure.

Produced by recombinant DNA technology, Fabrazyme has the same amino acid sequence as the native enzyme. Fabrazyme replaces the missing enzyme and works by clearing the fatty substances that accumulate in certain cells and tissues of Fabry patients.

To this end, I feel it is medically necessary to initiate Fabrazyme treatment for *patient name* as soon as possible.

Documentation Enclosed
The attached Statement of Medical Necessity contains information pertaining to *patient name* 's clinical history, diagnosis and signs and symptoms - demonstrating that the use of Fabrazyme is medically indicated and necessary for treatment of *his/her* Fabry disease. Initially, my prescribed dosing regimen will be *dose* mg per kilogram, administered every two weeks.
Also enclosed is full Prescribing Information for Fabrazyme.

Action Requested
Please send verification of *patient name* 's coverage for enzyme replacement therapy with Fabrazyme 's clinical history and/or my treatment plan, please call me at *phone number* .
as soon as possible. If you have any questions pertaining to *patient name*
Thank you for your immediate attention to this request.

Sincerely,

physician name
Full Prescribing Information is enclosed.

cc
patient name

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Anaphylaxis and Hypersensitivity Reactions (cont'd)

- Physicians should consider testing for IgE antibodies in patients who experienced suspected hypersensitivity reactions and consider the risks and benefits of continued treatment in patients with anti-Fabrazyme IgE antibodies. Rechallenge of these patients should only occur under the direct supervision of qualified personnel, with appropriate medical support measures readily available.

Please see Important Safety Information for Fabrazyme on pages 3-4, and full Prescribing Information.

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Dosing and Storage[5]

Dosing

Fabrazyme is for intravenous infusion only. The recommended dosage for patients ages 2 and older with confirmed Fabry disease is 1 mg/kg body weight infused every 2 weeks.

Sample billing calculation based on body weight:

Patient weight: 75 kg

Patient dose: 75 mg

Calculated billing units: 75

Please see the full Prescribing Information for complete details regarding infusion rates, as well as the required steps for preparation and administration of Fabrazyme.

Storage

Refrigerate vials of Fabrazyme at 2°C to 8°C (36°F to 46°F). Do not use Fabrazyme after the expiration date on the vial. Reconstituted and diluted solutions of Fabrazyme should be used immediately. If immediate use is not possible, the reconstituted and diluted solution may be stored for up to 24 hours at 2°C to 8°C (36°F to 46°F).

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Infusion-Associated Reactions

In clinical trials with Fabrazyme, 59% of patients experienced infusion-associated reactions, some of which were severe. Infusion-associated reactions are defined as adverse reactions occurring on the same day as the infusion. The incidence of infusion-associated reactions was higher in patients who were positive for anti-Fabrazyme antibodies than in patients who were negative for anti-Fabrazyme antibodies.

Please see Important Safety Information for Fabrazyme on pages 3-4, and full Prescribing Information.

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Patient Support Services

careconnect PSS®
Personalized Support Services

CareConnectPSS® provides personalized support services designed to support each patient's unique journey. Support includes:

- Dedicated CareConnectPSS Case Managers and Patient Education Liaisons
- Disease-specific content and resources, including information about how rare diseases may run in families
- Information regarding genetic testing options and diagnostics
- Care coordination for treatment
- Help with handling insurance issues

CareConnectPSS Co-pay Program*

Helps eligible patients in the US who are prescribed Fabrazyme 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 Fabrazyme at no cost to eligible patients who do not have health insurance or cannot access Fabrazyme under the terms of their insurance plan(s), until insurance coverage for Fabrazyme 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, epinephrine injection pens, 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 programs at any time. Savings may vary depending on patients' out-of-pocket costs. All program details provide upon registration.

†Patient Assistance Program and eligibility criteria include the following:
- Patient must not have insurance coverage or not have access to Fabrazyme 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. All rights reserved.

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Please see Important Safety Information for Fabrazyme on pages 3-4, and full Prescribing Information.

Ordering Information

To order Fabrazyme, please contact one of these authorized distributors:

Authorized Distributor	Phone	Web
Cardinal Health	800-926-3161	www.cardinalhealth.com
Cardinal Health Specialty Pharmaceutical Distribution	855-855-0708	www.cardinalhealth.com
McKesson Pharmaceutical Distribution	855-625-4677	www.mckesson.com
McKesson Plasma and Biologics	877-625-2566	connect.mckesson.com
McKesson Specialty Health	800-482-6700	mscs.mckesson.com
M&D Specialty Distribution	800-388-3833	www.mdspecialtydist.com

To order Fabrazyme directly from Sanofi:

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

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Infusion-Associated Reactions (cont'd)

- In patients experiencing infusion-associated reactions, pretreatment with an antipyretic and antihistamine is recommended. Infusion-associated reactions occurred in some patients after receiving pretreatment.
- If an infusion-associated reaction occurs, decreasing the infusion rate, temporarily stopping the infusion, and/or administrating additional antipyretics, antihistamines, and/or steroids may ameliorate the symptoms.
- If severe infusion-associated reactions occur, immediate discontinuation of the administration of Fabrazyme should be considered, and appropriate medical treatment should be initiated. Severe reactions are generally managed with administration of antihistamines, corticosteroids, intravenous fluids, and/or oxygen when clinically indicated. Because of the potential for severe infusion-associated reactions, appropriate medical support measures should be readily available when Fabrazyme is administered.

Please see Important Safety Information for Fabrazyme on pages 3-4, and full Prescribing Information.

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Please see Important Safety Information for Fabrazyme on pages 3-4, and full Prescribing Information.