Chiesi TOTAL care

Chiesi Total Care℠ is here to help.
Visit chiesitotalcare.com or call 1-855-282-4883

Lamzede®
velmanase alfa-tycv

Access Resource Guide

Using This Access Resource Guide

This guide is intended for informational purposes only, not to take the place of the provider's diagnosis and treatment decisions. Providers are responsible for the accuracy, legitimacy, and completeness of any claims, invoices, and other documentation supplied to payers. Providers should contact the payer for answers to specific questions about payment or coverage. Specific direction from the payer supersedes the guidance provided in this guide. Using this guide does not guarantee coverage or reimbursement.

Indication and Important Safety Information

Indication

Lamzede® (velmanase alfa-tycv) is indicated for the treatment of non-central nervous system manifestations of alpha-mannosidosis in adult and pediatric patients.

Important Safety Information

WARNING: SEVERE HYPERSENSITIVITY REACTIONS

Hypersensitivity Reactions Including Anaphylaxis

Patients treated with Lamzede have experienced hypersensitivity reactions, including anaphylaxis. Appropriate medical support measures, including cardiopulmonary resuscitation equipment, should be readily available during Lamzede administration. If a severe hypersensitivity reaction (e.g., anaphylaxis) occurs, discontinue Lamzede immediately and initiate appropriate medical treatment. In patients with severe hypersensitivity reaction, a desensitization procedure to Lamzede may be considered.

Please see Important Safety Information on page 2 and Full Prescribing Information, including Boxed Warning on severe hypersensitivity reactions including anaphylaxis.

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Considerations Due to Hypersensitivity Reactions and/or Infusion-Associated Reactions (IARs)

Prior to Lamzede administration, consider pretreating with antihistamines, antipyretics, and/or corticosteroids. Inform patients and caregivers of the signs and symptoms of hypersensitivity reactions and IARs and instruct them to seek medical care immediately if such symptoms occur.

- If a severe hypersensitivity reaction (including anaphylaxis) or severe IAR occurs, immediately discontinue Lamzede administration and initiate appropriate medical treatment.
- In the event of a mild to moderate hypersensitivity reaction or a mild to moderate IAR, consider temporarily holding the infusion for 15 to 30 minutes, slowing the infusion rate to 25% to 50% of the recommended rate, and initiating appropriate medical treatment.

Hypersensitivity Reactions Including Anaphylaxis

Anaphylaxis and severe hypersensitivity signs and symptoms included cyanosis, hypotension, emesis, urticaria, erythema, facial swelling, pyrexia, and tremor.

Infusion-Associated Reactions (IARs)

The most frequent symptoms of IARs that occurred in >10% of the population were pyrexia, chills, erythema, vomiting, cough, urticaria, rash, and conjunctivitis.

Females of Reproductive Potential

Advise females of reproductive potential to use effective contraception during treatment and for 14 days after the last dose if Lamzede is discontinued. For females of reproductive potential, verify that the patient is not pregnant prior to initiating treatment with Lamzede.

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Embryo-Fetal Toxicity

Based on findings from animal reproduction studies, Lamzede may cause embryo-fetal harm when administered to a pregnant female.

Common Adverse Reactions

The most common adverse reactions (incidence >20%) are hypersensitivity reactions including anaphylaxis, nasopharyngitis, pyrexia, headache, and arthralgia.

Patient Support Services

Chiesi TOTAL care℠

A single call to your dedicated Chiesi Total Care Team is all it takes—we will guide you through the process of getting a patient started on Lamzede® (velmanase alfa-tycv) therapy.

Chiesi Total Care assists you and your patients with:

Commercial insurance

If your patients have private insurance through their job or their own business

Government insurance

If your patients have Medicare, Medicaid, Veterans Affairs healthcare, or other government insurance

No insurance

If your patients have no insurance, they may be eligible for financial assistance

Copay Assistance

Chiesi Total Care offers 2 copay programs for eligible patients*:

Prescription copay:

- This covers the medication itself. Patients may pay as little as $0 for their LAMZEDE prescription

Infusion services copay:

- This covers infusion supplies and administration (including home infusion). Patients may pay as little as $0 for their LAMZEDE infusion supplies and administration

*Government-funded plans are not eligible for patient support services that provide financial support through the programs. Patients receiving treatment or residing in MA or RI are not eligible for infusion services copay assistance. To receive home infusion support, patients must be referred to home infusion by their prescribing physician.

Program eligibility:

- Patient must be enrolled in Chiesi Total Care (Enrollment and Authorization Form will be mailed to your patient's home)
- Patient has commercial insurance and a valid prescription for a US Food and Drug Administration (FDA)-approved indication for LAMZEDE
- Patient must be a resident of the United States or one of its territories

Please refer to the accompanying full Terms and Conditions for additional eligibility requirements.

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Lamzede® velmanase alfa-tycv

The dedicated *Chiesi Total Care Team* is made up of:
Pharmacists | Patient Service Coordinators | Reimbursement Support | Nursing Support

Additional *Offerings*

Infusion services*

- Chiesi Total Care clinicians can help patients understand their medication and the infusion process and coordinate a suitable infusion site if needed
- If your patient moves to home infusion, Chiesi Total Care may be able to assist eligible patients with delivery of medication and infusion supplies

*To receive home infusion support, patients must be referred to home infusion by their prescribing physician. Please refer to the full Terms and Conditions for additional eligibility requirements.

Routine testing†

- We provide support for serum oligosaccharide reduction testing and anti-drug antibody (ADA) screenings, with no out-of-pocket costs for patients with commercial insurance.

†Tests must be ordered by prescribing provider for eligible patients. Patients receiving treatment or residing in MA, MI, MN, or RI are not eligible. Please see full Terms and Conditions for additional eligibility.

Chiesi TOTAL care℠

PHONE
1-855-282-4883

FAX
1-855-929-2828

HOURS OF OPERATION
7:00 AM - 7:00 PM (Central Time)

For more information, visit chiesitotalcare.com

Important Safety Information (continued)

Considerations Due to Hypersensitivity Reactions and/or Infusion-Associated Reactions (IARs)

Prior to Lamzede administration, consider pretreating with antihistamines, antipyretics, and/or corticosteroids. Inform patients and caregivers of the signs and symptoms of hypersensitivity reactions and IARs and instruct them to seek medical care immediately if such symptoms occur.

- If a severe hypersensitivity reaction (including anaphylaxis) or severe IAR occurs, immediately discontinue Lamzede administration and initiate appropriate medical treatment.
- In the event of a mild to moderate hypersensitivity reaction or a mild to moderate IAR, consider temporarily holding the infusion for 15 to 30 minutes, slowing the infusion rate to 25% to 50% of the recommended rate, and initiating appropriate medical treatment.

Getting Your Patient Started on LAMZEDE

A step-by-step guide to the coverage process

Step 1

Complete the **Physician Order/Prescription Form for LAMZEDE**, then enroll the patient in the Chiesi Total Care Program by completing the **Patient Enrollment Form**

- Call Chiesi Total Care Program: 1-855-282-4883

or

- **Download the Prescription Order Form**
- **Download the Patient Enrollment Form**
- Visit the Chiesi Total Care website

Step 2

Chiesi Total Care will determine patient insurance eligibility for LAMZEDE coverage

Step 3

You may need to prepare and submit a **prior authorization (PA)** or **formulary exception** (or tiering exception) and include a **letter of medical necessity**

- **If approved,** work with the patient to set up delivery of LAMZEDE through the preferred specialty pharmacy, or order product for buy and bill through Eversana
- **If denied,** a letter of appeal using the resource provided in this guide may be submitted

Chiesi Total Care can help healthcare providers with benefit investigations, PAs, and the appeal process.

Important Safety Information (continued)

Hypersensitivity Reactions Including Anaphylaxis

Anaphylaxis and severe hypersensitivity signs and symptoms included cyanosis, hypotension, emesis, urticaria, erythema, facial swelling, pyrexia, and tremor.

Coverage Considerations

LAMZEDE may be covered under the pharmacy benefit or medical benefit, depending on the patient's health plan[1]

Approval criteria will be defined by[1,2]:

FORMULARIES → PHARMACY BENEFIT

COVERAGE POLICIES → MEDICAL BENEFIT

Health plans typically do not make formulary decisions or establish coverage policies immediately after FDA approval of specialty drugs.[3]

- Conducting a thorough benefit investigation will uncover if there are any specific health plan restrictions or utilization requirements, such as step therapy or PAs[1]
- If you have determined that a patient receiving a different treatment for alpha-mannosidosis should be treated with LAMZEDE, there may be additional requirements or approval processes for the premedication required before treatment

Important Safety Information (continued)

Infusion-Associated Reactions (IARs)

The most frequent symptoms of IARs that occurred in >10% of the population were pyrexia, chills, erythema, vomiting, cough, urticaria, rash, and conjunctivitis.

Females of Reproductive Potential

Advise females of reproductive potential to use effective contraception during treatment and for 14 days after the last dose if Lamzede is discontinued. For females of reproductive potential, verify that the patient is not pregnant prior to initiating treatment with Lamzede.

For most patients, their health plan will require a PA for treatment with LAMZEDE

In some cases, it may be appropriate to submit a letter of medical necessity with a PA[4]

Considerations for submitting PAs:

- Requirements for PAs will vary by health plan[4]
- Check to see if the health plan has a plan-specific PA form and process for submission[4]
  – This information can generally be found on a plan's website or by contacting their customer service department

Information generally required on a PA:

Patient information

- Name
- Address
- Date of birth
- Name of policyholder
- Policy ID and group numbers

Provider information

- Name
- NPI number
- Plan provider number
- Address
- Phone/fax numbers

Patient clinical information

- Diagnosis/ICD-10-CM code
- Description of treatment or procedure being requested
- Previous treatment history
- Treatment start date

If approved, it is important to understand the length of time the authorization is valid. This can vary by health plan, and in some cases, reauthorization may be required annually.

Important Safety Information (continued)

Embryo-Fetal Toxicity

Based on findings from animal reproduction studies, Lamzede may cause embryo-fetal harm when administered to a pregnant female.

Common Adverse Reactions

The most common adverse reactions (incidence >20%) are hypersensitivity reactions including anaphylaxis, nasopharyngitis, pyrexia, headache, and arthralgia.

Please see Important Safety Information on page 2 and Full Prescribing Information, including Boxed Warning on severe hypersensitivity reactions including anaphylaxis.

Pharmacy Benefits Formulary Exceptions

A formulary exception under the pharmacy benefit is a request for coverage of a drug that is not included on a plan's formulary, or it may be a request to have a utilization requirement waived[5]

Formulary exceptions may include requests for[5]:

- A drug that is not on the plan's list of covered drugs
- A drug that was previously included on the plan's list of covered drugs but was or is being removed from this list during the plan year
- PA for the prescribed drug
- Forgoing the requirement to use another drug before receiving the prescribed drug (step therapy)
- An exception to the plan's requirement of a quantity limit

Tiering exceptions may include situations when[5]:

- A health plan charges a higher copay for the prescribed drug than it charges for another drug that treats the condition, and the lower copayment is preferred
- A patient has been using a drug that was previously included on a lower copayment tier, but was or is being moved to a higher copayment tier
- A health plan charged a higher copay for a drug than it should have
- A patient wants to be reimbursed for a covered prescription drug that was paid for out-of-pocket

Medicare Part D Prescription Drug Plans (PDPs) include Medicare Advantage plans that offer prescription drug coverage (MA-PD), and Medicare/Medicaid plans (for dually eligible individuals) that vary in their requirements for making exception requests. Centers for Medicare and Medicaid Services (CMS) provides some guidance for coverage determination requests.[2,5,6]

A model coverage determination request form and instructions can be downloaded from the CMS website.

It may be appropriate to submit a letter of medical necessity with a formulary exception request.

Important Safety Information

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Hypersensitivity Reactions Including Anaphylaxis

Patients treated with Lamzede have experienced hypersensitivity reactions, including anaphylaxis. Appropriate medical support measures, including cardiopulmonary resuscitation equipment, should be readily available during Lamzede administration. If a severe hypersensitivity reaction (e.g., anaphylaxis) occurs, discontinue Lamzede immediately and initiate appropriate medical treatment. In patients with severe hypersensitivity reaction, a desensitization procedure to Lamzede may be considered.

Medical Necessity

A letter of medical necessity is used to help explain the clinical rationale behind prescribing a specific treatment[7]

May be required if a medication:

- Is subject to step therapy or PA
- Is recently FDA-approved
- Is not preferred or not available on the plan's formulary and a formulary exception request is necessary
- Has unfavorable coverage or no established coverage policy with the plan

Considerations for preparing a letter of medical necessity:

- Understand and adhere to the health plan–specific process and deadlines for PAs and exception request

Recommended information to include in a letter of medical necessity:

Patient information

- Name
- Address
- Date of birth
- Name of policyholder
- Policy ID and group numbers

Provider information

- Name
- NPI number
- Plan provider number
- Address
- Phone/fax numbers

Patient clinical information

- Diagnosis/ICD-10-CM code
- Description of treatment or procedure being requested
- Previous treatment history, including duration and reason for discontinuation
- Severity of the patient's condition

Clinical rationale for treatment with LAMZEDE

- Include clinical trial outcomes that supported FDA approval
- In the case of a formulary exception request, explain the rationale for not treating with the health plan's preferred alternative

Summary of recommendations based on provider clinical expertise

Enclosures that support the rationale for treatment with LAMZEDE

- Peer-reviewed literature
- Patient medical records/notes
- Relevant lab or diagnostic test results

Important Safety Information (continued)

Considerations Due to Hypersensitivity Reactions and/or Infusion-Associated Reactions (IARs)

Prior to Lamzede administration, consider pretreating with antihistamines, antipyretics, and/or corticosteroids. Inform patients and caregivers of the signs and symptoms of hypersensitivity reactions and IARs and instruct them to seek medical care immediately if such symptoms occur.

Please see Important Safety Information on page 2 and Full Prescribing Information, including Boxed Warning on severe hypersensitivity reactions including anaphylaxis.

Lamzede® velmanase alfa-tycv

Sample Letter of Medical Necessity

[Insurance Company]
[Address]
[City, State, Zip]

Re: **[Patient Name]**
[Policy #]
[DOB]
[Address]
[City, State, Zip]

To Whom It May Concern:

I am writing this letter of medical necessity on behalf of **[Patient Name, ID#, Group #]** to request coverage for **[Product name (generic name)].** Included in this letter of medical necessity is information on the treatment rationale, medical records, medical necessity data, and medical studies confirming currently prescribed product as an effective treatment for the diagnosis associated with **[ICD10 Code]**.

Treatment Rationale:
[Provide information on patient response and history to past treatments and anticipated prognosis and rationale for the currently prescribed product].

Outline of Medical Studies:
[Outline a brief overview of the studies evaluating the use of the currently prescribed product in this condition and/or patient population. Remember to include the FDA-approved indications and usage].

Medical Record Information:
[Highlight key dates and entries of the medical record how the currently prescribed product is used].

Per the included medical information, it is my professional opinion that the currently prescribed product is medically necessary in treating the patient and the denials for the patient's use of the drug should be reversed. Please call my office at **[Office Phone Number]** if I can provide further information.

Sincerely,
[Physician Name and Signature]
[Phone Number]
Enclosure: [As required]

This is a sample letter. Use of this template does not guarantee coverage of LAMZEDE.

Important Safety Information (continued)

Considerations Due to Hypersensitivity Reactions and/or Infusion-Associated Reactions (IARs) (continued)

- If a severe hypersensitivity reaction (including anaphylaxis) or severe IAR occurs, immediately discontinue Lamzede administration and initiate appropriate medical treatment.
- In the event of a mild to moderate hypersensitivity reaction or a mild to moderate IAR, consider temporarily holding the infusion for 15 to 30 minutes, slowing the infusion rate to 25% to 50% of the recommended rate, and initiating appropriate medical treatment.

Navigating Denials and Appeals

In the case of a denied coverage request, patients and providers have the right to submit an appeal to the health plan[8]

Common reasons for denials[9]:

- New drug that has not been reviewed by the health plan yet for formulary inclusion or medical policy development
- The drug is non-preferred or not on formulary
- Step therapy is required and a different drug must be used first
- PA is required and was not submitted (or PA has expired)
- Missing information on the PA form or coverage determination request

Considerations for navigating denials and appeals:

- Identify the reason for the denial by reviewing the explanation of benefits (EOB) and the denial letter
- Understand and adhere to the health plan–specific appeals process and deadlines
- Prepare a detailed letter of appeal to submit to the plan

Recommended information to include with a letter of appeal:

Patient information

- Name
- Address
- Date of birth
- Name of policyholder
- Policy ID and group numbers

Provider information

- Name
- NPI number
- Plan provider number
- Address
- Phone/fax numbers

Medical records and treatment rationale

- Date and reason for denial
- Patient diagnosis (ICD-10-CM code), description of treatment being requested, previous treatment history, including duration and reason for discontinuation, if applicable
- Explanation for why an alternative formulary treatment is not appropriate for the patient
- Clinical rationale for treatment with LAMZEDE
  – Include clinical trial outcomes that supported FDA approval
- Summary of recommendations based on provider clinical expertise

Enclosures that support the rationale for treatment with LAMZEDE

- Peer-reviewed literature
- Patient medical records/notes
- Relevant lab or diagnostic test results
- Prescribing Information

Chiesi Total Care can help with denials and appeals.

If your PA submission was denied, please send a copy of the denial letter and call Chiesi Total Care at 1-855-282-4883.

Important Safety Information (continued)

Hypersensitivity Reactions Including Anaphylaxis

Anaphylaxis and severe hypersensitivity signs and symptoms included cyanosis, hypotension, emesis, urticaria, erythema, facial swelling, pyrexia, and tremor.

Sample Letter of Appeal

[Insurance Company]
[Address]
[City, State, Zip]

Re: **[Patient Name]**
[Policy #]
[DOB]
[Address]
[City, State, Zip]

To Whom It May Concern:

I am writing to appeal the denial of benefits for the use of **[Product name (generic name)]** for services requested for **[Patient Name, ID#, Group #]**. Included in this letter of appeal are information on the treatment rationale, medical records, medical necessity data, and medical studies confirming currently prescribed product as an effective treatment for the diagnosis associated with **[ICD10 Code]**.

Treatment Rationale:
[Provide information on patient response and history to past treatments and anticipated prognosis and rationale for the currently prescribed product].

Outline of Medical Studies:
[Outline a brief overview of the studies evaluating the use of the currently prescribed product in this condition and/or patient population. Remember to include the FDA-approved indications and usage].

Medical Record Information:
[Highlight key dates and entries of the medical record how the currently prescribed product is used].

Per the included medical information, it is my professional opinion that the currently prescribed product is medically necessary in treating the patient and the denials for the patient's use of the drug should be reversed. Please call my office at **[Office Phone Number]** if I can provide further information or speak with a review board to appeal the denial of coverage decision. I look forward to reaching resolution of overturning the denied status of the currently prescribed product for this patient.

Sincerely,
[Physician Name and Signature]
[Phone Number]
Enclosure: [Original denial notification copy]

This is a sample letter. Use of this template does not guarantee coverage of LAMZEDE.

Important Safety Information (continued)

Infusion-Associated Reactions (IARs)

The most frequent symptoms of IARs that occurred in >10% of the population were pyrexia, chills, erythema, vomiting, cough, urticaria, rash, and conjunctivitis.

Females of Reproductive Potential

Advise females of reproductive potential to use effective contraception during treatment and for 14 days after the last dose if Lamzede is discontinued. For females of reproductive potential, verify that the patient is not pregnant prior to initiating treatment with Lamzede.

Payer Landscape

Commercial, Medicare Advantage, and Medicare Part D (PDP) coverage for LAMZEDE will vary by plan and by patient. A thorough benefit investigation will determine coverage, including requirements for PAs or step therapy.[1]

Medicare Part B covers LAMZEDE. Infusions would have to be delivered in a setting where buy and bill is available for LAMZEDE directly versus the provider acquiring it through a specialty pharmacy.[1,10,11]

Eligibility and benefit plans through state Medicaid programs (administered by the state) and **Managed Medicaid** (administered by commercial payers) vary from state to state.[2,12] Usually, treatment with LAMZEDE will need to be considered medically necessary to be covered under the Medicaid program. Depending on the state, initial treatment with LAMZEDE may require PA by the state Medicaid program.

Tips on engaging with health plans

- **Follow the individual health plan's guidelines** and processes for submitting any type of coverage determination, including PAs, exception requests, and letters of medical necessity and appeal
- **Review and thoroughly understand** the health plan's formulary criteria or coverage policy when preparing communications
- **Thoroughly consider the reason(s) for denial** and address those reason(s) specifically when preparing an appeal letter
- **Provide a clear and concise description** of the patient's medical history and the clinical rationale for the treatment request
- **Clearly state the provider's credentials** and relevant affiliations in communications, including experience in treating the disease state
- **Submit all requested forms,** medical records, and any additional supporting clinical documentation through the health plan's preferred or recommended method
- **Document and keep record** of all communication with the health plan, including phone calls and written communication
- **Adhere to any specific deadlines** for coverage determinations and appeals, including requests from the health plan for additional information

Important Safety Information (continued)

Embryo-Fetal Toxicity

Based on findings from animal reproduction studies, Lamzede may cause embryo-fetal harm when administered to a pregnant female.

Common Adverse Reactions

The most common adverse reactions (incidence >20%) are hypersensitivity reactions including anaphylaxis, nasopharyngitis, pyrexia, headache, and arthralgia.

How to Acquire LAMZEDE

Chiesi Total Care offers product acquisition support based on an inventory approach that fits your business needs and your patient's insurance coverage.

Specialty Pharmacy

(White bagging if LAMZEDE is covered under the pharmacy benefit or available through assignment of benefit under the medical plan)

An arrangement between payers and specialty pharmacies to ship LAMZEDE directly to the physician's office.

1. Call Chiesi Total Care Program: 1-855-282-4883
2. Download, complete, and submit **Physician Order/Prescription Form** and **Enrollment and Authorization Form** to Chiesi Total Care by fax.
3. Eversana™ Life Sciences Specialty Pharmacy will ship LAMZEDE based on acquisition preference.

Buy and Bill

(If LAMZEDE is covered under the medical benefit)

Your practice places an order for LAMZEDE to stock on-site so it is available when needed.

1. Ensure LAMZEDE is covered on your institution's formulary.
2. Submit a purchase request to CTCPurchasing@eversana.com that includes product requested, quantity of product, and approved dollar amount for the purchase order.

Chiesi Total Care | EVERSANA®

Chiesi Total Care is offered through EVERSANA® Life Science Services Specialty Pharmacy.

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Lamzede® velmanase alfa-tycv

Coding and Billing

The codes provided here are commonly associated with the administration of LAMZEDE; however, providers should contact the patient's health plan for specific guidance on coding and site of care requirements before administration.

Healthcare Common Procedure Coding System (HCPCS) Codes

Provider-administered drugs are typically reported with HCPCS Level II J-codes and assigned by CMS.[13]

Code	Description
J0217	Injection, velmanase alfa-tycv, 1 mg

National Drug Codes (NDCs)

NDCs are unique numbers that identify a drug's labeler, product, and trade package size. The FDA uses a 10-digit format when registering NDCs; however, payer requirements regarding use of a 10-digit or 11-digit NDC on claim forms varies. CMS requires an 11-digit NDC format. It is important to check with individual health plans before billing.[14,15]

10-Digit Code[15] (5-3-2 format)	**11-Digit Code** (5-4-2 format)	**Description**[15]
10122-180-02	10122-0180-02	Single-dose 10-mg vial

International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Codes

ICD-10-CM is the diagnosis code set used for all healthcare settings for medical claims reporting.[16]

Code[17]	Description
E77.1	Defects in glycoprotein degradation

Important Safety Information (continued)

Considerations Due to Hypersensitivity Reactions and/or Infusion-Associated Reactions (IARs)

Prior to Lamzede administration, consider pretreating with antihistamines, antipyretics, and/or corticosteroids. Inform patients and caregivers of the signs and symptoms of hypersensitivity reactions and IARs and instruct them to seek medical care immediately if such symptoms occur.

- If a severe hypersensitivity reaction (including anaphylaxis) or severe IAR occurs, immediately discontinue Lamzede administration and initiate appropriate medical treatment.
- In the event of a mild to moderate hypersensitivity reaction or a mild to moderate IAR, consider temporarily holding the infusion for 15 to 30 minutes, slowing the infusion rate to 25% to 50% of the recommended rate, and initiating appropriate medical treatment.

Current Procedural Terminology (CPT®) Codes

CPT is the code set used to describe procedures and services performed by healthcare providers. Evaluation and management codes, or E/M codes, are CPT codes that allow providers to bill for the total time and level of service spent treating the patient.[18]

Code[17]	Description
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 primary procedure code, 96365)

Modifiers

Modifiers are 2-digit codes that are added to a CPT or HCPCS code and used to provide additional information about an item or service provided.[19]

Code[20,21]	Description
59	Distinct Procedural Service: Under certain circumstances, it may be necessary to indicate that a procedure or service was distinct or independent from other non-E/M services performed on the same day
JW	Discarded drug not administered
JZ	Zero drug wasted. IOD Medicare plans require the JZ Modifier to attest that there was no discarded amount from a single vial. Requirements vary by plan

Place of Service (POS) Codes

POS codes are 2-digit numeric codes used to indicate the setting in which a healthcare service was provided and are only used on professional claims.[22]

Code[22]	Description
11	Office
12	Home
19	Off-Campus Outpatient Hospital
22	On-Campus Outpatient Hospital

Revenue Codes

Revenue codes are 4-digit numeric codes used only by hospital-based facilities to indicate what department and where a procedure was performed within the facility or to identify supplies used in the procedure. Revenue codes are only used on institutional claims.[23]

Code[24]	Description
0258	Pharmacy, IV solutions
0260	IV Therapy, general IV
0261	IV Therapy, infusion pump
0636	Pharmacy, drugs requiring detailed coding

Important Safety Information (continued)

Hypersensitivity Reactions Including Anaphylaxis

Anaphylaxis and severe hypersensitivity signs and symptoms included cyanosis, hypotension, emesis, urticaria, erythema, facial swelling, pyrexia, and tremor.

Please see Important Safety Information on page 2 and Full Prescribing Information, including Boxed Warning on severe hypersensitivity reactions including anaphylaxis.

Sample CMS-1500 Claim Form for a Provider Office

Billing for reimbursement or administration of LAMZEDE in the provider office setting should be submitted on the CMS-1500 manual claim form, or its electronic equivalent 837P (Professional).[25]

Use HCPCS code J0217 for LAMZEDE.

Additional Claim Information: Some payers may require additional detail about the drug administered. — **Item 19**

Diagnosis/Nature of Illness or Injury: Enter the clinically appropriate ICD-10-CM code. — **Item 21**

PA: Enter the PA number if one was issued. — **Item 23**

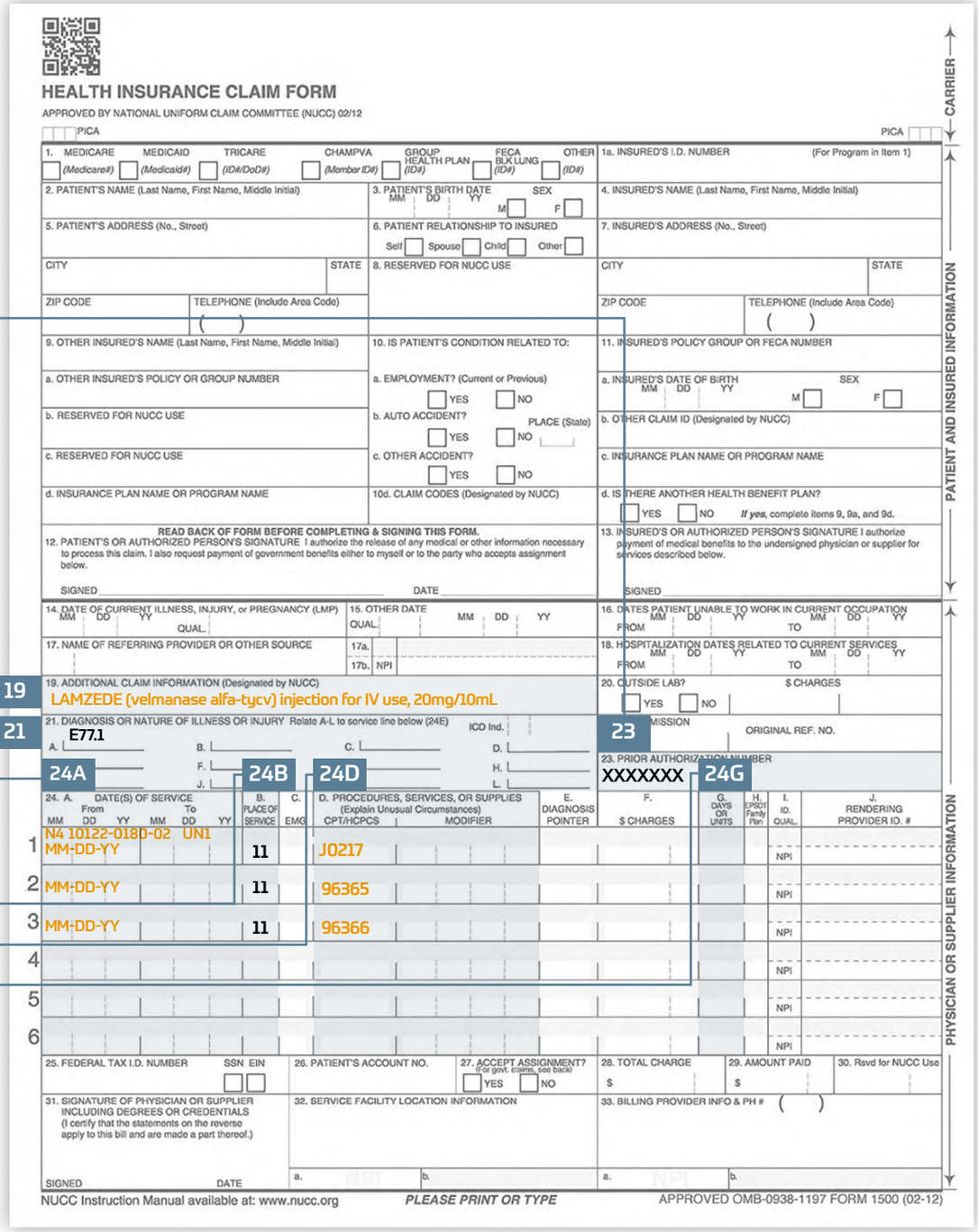
Date of Service: Enter the appropriate date for each procedure, service, or supply. Some payers require that the shaded area of 24A includes the NDC, and the appropriate qualifier (N4) and NDC units (UN, ML). — **Item 24A**

Place of Service: Enter the appropriate site of care code indicating where the medical service was rendered. — **Item 24B**

Procedures, Services, or Supplies: Enter the appropriate CPT and HCPCS codes and modifiers, if required. — **Item 24D**

Days or Units: Enter the number of units that were administered. — **Item 24G**

TIP: Some payers may require you to include the 11-digit NDC.



Providers should contact the health plan for questions about coverage, coding, and payment. Specific direction from the plan supersedes the codes included here.

Important Safety Information (continued)

Infusion-Associated Reactions (IARs)

The most frequent symptoms of IARs that occurred in >10% of the population were pyrexia, chills, erythema, vomiting, cough, urticaria, rash, and conjunctivitis.

Females of Reproductive Potential

Advise females of reproductive potential to use effective contraception during treatment and for 14 days after the last dose if Lamzede is discontinued. For females of reproductive potential, verify that the patient is not pregnant prior to initiating treatment with Lamzede.

Please see Important Safety Information on page 2 and Full Prescribing Information, including Boxed Warning on severe hypersensitivity reactions including anaphylaxis.

Lamzede® velmanase alfa-tycv

Sample CMS-1450 (UB-04) Claim Form for the Institutional or Hospital Outpatient Setting

Billing for reimbursement or administration of LAMZEDE in the institutional or hospital outpatient setting should be submitted on the CMS-1450 (UB-04) manual claim form, or its electronic equivalent 837I (Institutional).[26]

Use HCPCS code J0217 (in the hospital outpatient setting) for LAMZEDE.

Revenue Code: Enter the appropriate revenue code based on the cost center and service provided. — **FL 42**

Revenue Description: Enter a narrative description or standard abbreviation for each corresponding revenue code. — **FL 43**

HCPCS & Procedure Codes: Enter the appropriate HCPCS and CPT codes. — **FL 44**

Service Units: Enter the number of times a single procedure or item was performed or provided for the date of service. — **FL 46**

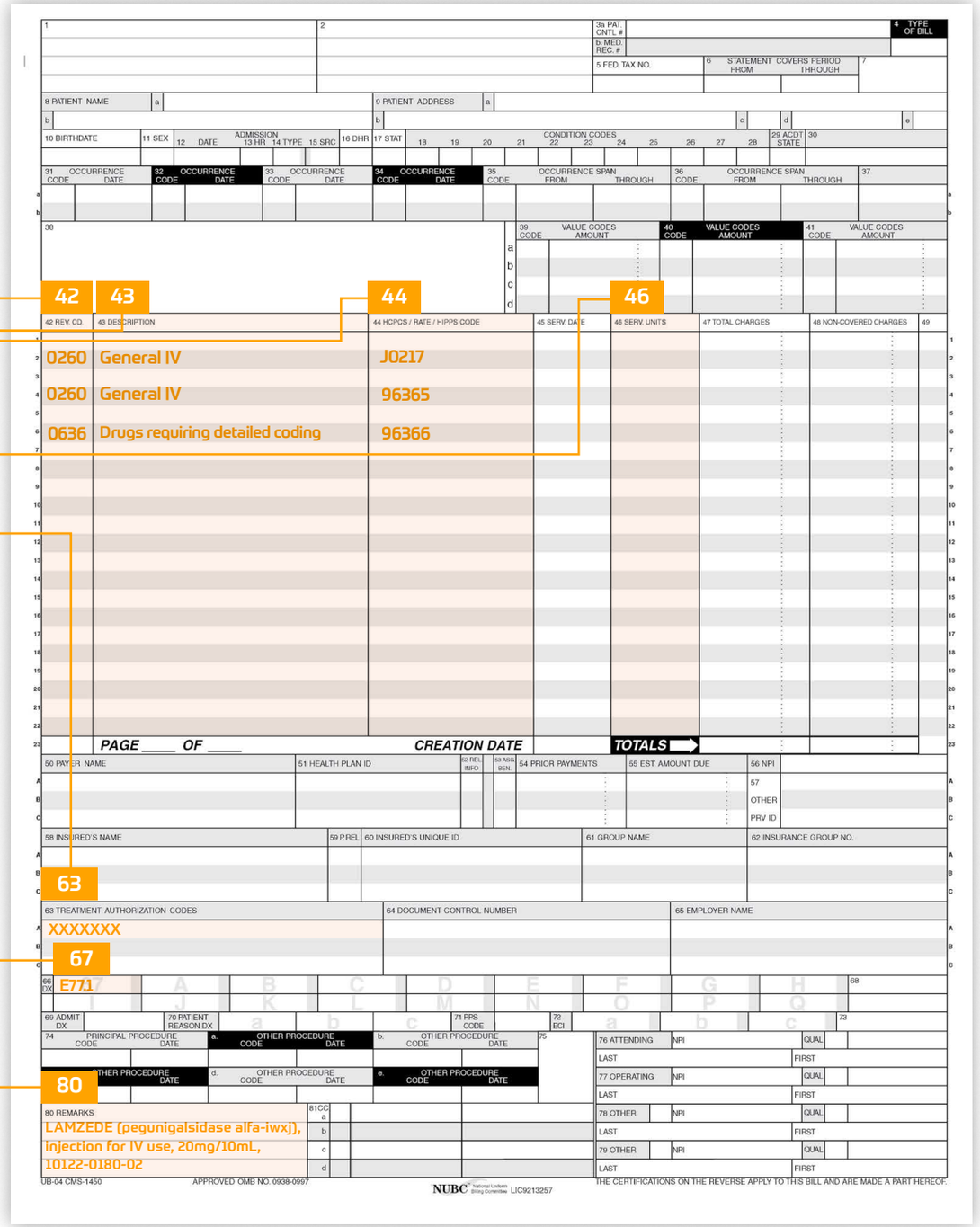
PA: Enter the PA number if one was issued. — **FL 63**

Diagnosis (DX) Code: Enter the clinically appropriate ICD-10-CM code. — **FL 67**

Remarks: Some payers may require additional information about the drug administered. — **FL 80**

TIP: Some payer may require you to include the 11-digit NDC.

Providers should contact the health plan for questions about coverage, coding, and payment. Specific direction from the plan supersedes the codes included here.



Important Safety Information (continued)

Embryo-Fetal Toxicity

Based on findings from animal reproduction studies, Lamzede may cause embryo-fetal harm when administered to a pregnant female.

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Enroll Your Patient in Chiesi Total Care Today

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Chiesi TOTAL care℠

PHONE
1-855-282-4883

FAX
1-855-929-2828

HOURS OF OPERATION
7:00 AM - 7:00 PM (Central Time)

For more information, visit chiesitotalcare.com

Important Safety Information (continued)

Common Adverse Reactions

The most common adverse reactions (incidence >20%) are hypersensitivity reactions including anaphylaxis, nasopharyngitis, pyrexia, headache, and arthralgia.

Please see accompanying Full Prescribing Information for LAMZEDE and full Terms and Conditions for additional Chiesi Total Care eligibility requirements.

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Chiesi

Chiesi is a specialty pharmaceutical company with a long history of bringing innovative products to the healthcare marketplace. We are deeply committed to developing products for rare diseases.

For more information, visit https://www.lamzede.com/hcp/.

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