
**THIS IS A TEMPLATE LETTER
PLEASE CUSTOMIZE FOR YOUR PATIENT**

<<Date>>

<<Contact Name>>
<<Insurance Company>>
<<Address>>
<<Fax>>
<<Email>>

Patient Name: <<Patient Name>>
Subscriber ID#: <<ID Number>>
Group#: <<Group Number>>

Subject: Intent to treat with CEREZYME® (imiglucerase)

Dear <<Contact Name>>:

I am writing on behalf of my patient, <<Patient Name>>, who has been diagnosed with a rare lysosomal storage disorder, Gaucher disease type 1 (GD1). Patients with GD1 have deficient activity of the enzyme acid β -glucosidase, which leads to the accumulation of the enzyme substrate glucosylceramide (GL-1). I plan to treat <<Patient Name>> with CEREZYME® (imiglucerase).

<<Insert paragraph here regarding patient-specific medical information. Provide the patient's clinical history to support the CEREZYME treatment, including relevant documentation.>>

The attached Statement of Medical Necessity contains information pertaining to <<Patient Name>>'s clinical history, including diagnosis of GD1 and clinical features consistent with GD1-symptoms—demonstrating that the use of CEREZYME is medically indicated for treatment of their Gaucher disease type 1. The prescribed dosing regimen will be <<insert value from 2.5 units/kg three times a week to 60 units/kg once every two weeks>> administered by intravenous infusion.

Action Requested

Please send verification of <<Patient Name>>'s coverage and/or approval for CEREZYME as soon as possible. If you have any questions pertaining to <<Patient Name>>'s clinical history and/or my treatment plan, please call me at <<Phone Number>>.

Thank you for your immediate attention to this request.

Indication and Usage

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**.

Sincerely,

<<Physician Name>>

<<Title>>

<<Contact Information>>

cc: <<Patient Name/Legal Guardian>>

Attachments:

- CEREZYME Prescribing Information
- Statement of Medical Necessity

<<Other>>