****

THIS IS A SAMPLE LETTER--PLEASE CUSTOMIZE FOR YOUR PATIENT AND RETYPE IT ON YOUR OWN LETTERHEAD

****

[Date**]**
[Contact Name**]**

(address)

Patient Name:
Subscriber ID#:
Group #:
Subject: Intent to Treat with Cerezyme® (imiglucerase for injection)

Dear :

I am writing to inform you that I plan to treat **[patient name]** with Cerezyme enzyme replacement product. Cerezyme is indicated for long-term enzyme replacement therapy for pediatric and adult patients with a confirmed diagnosis of Type 1 Gaucher disease that results in one or more of the following conditions: anemia, thrombocytopenia, bone disease, hepatomegaly or splenomegaly. It is given intravenously and is usually administered on an outpatient basis.

Documentation Enclosed
The attached *Statement of Medical Necessity* contains information pertaining to **[patient name]'s** clinical history and diagnosis, demonstrating that the use of Cerezyme is medically indicated for treatment of **[his/her]** Gaucher disease. Initially, my prescribed dosing regimen will be **[number]** units per kilogram administered **[dosing frequency].**

Action Requested
Please send me verification of **[patient name]'s** coverage for enzyme replacement therapy with 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]**.**

Indication and Usage
Cerezyme® (imiglucerase for injection) is indicated for long-term enzyme replacement therapy for pediatric and adult patients with a confirmed diagnosis of Type 1 Gaucher disease that results in one or more of the following conditions:

a. anemia
b. thrombocytopenia
c. bone disease
d. hepatomegaly or splenomegaly

Important Safety Information
Approximately 15% of patients have developed IgG antibodies to Cerezyme during the first year of therapy. Approximately 46% of patients with detectable IgG antibodies experienced symptoms of hypersensitivity, and these patients have a higher risk of hypersensitivity. It is suggested that patients be monitored periodically for IgG antibody formation during the first year of treatment.

Hypersensitivity has also been observed in patients without detectable IgG antibodies. Symptoms suggestive of hypersensitivity have been noted in approximately 6.6% of all patients, and anaphylactoid

reactions in less than 1%. Treatment with Cerezyme should be approached with caution in patients who have exhibited hypersensitivity symptoms such as pruritus, flushing, urticarial, angioedema, chest discomfort, dyspnea, coughing, cyanosis, and hypotension. Pre-treatment with antihistamines and/or corticosteroids and a reduced rate of infusion may allow continued treatment in most patients.

In less than 1% of patients, pulmonary hypertension and pneumonia have been observed during treatment with Cerezyme. These are known complications of Gaucher disease regardless of treatment. Patients with respiratory symptoms in the absence of fever should be evaluated for the presence of pulmonary hypertension.

Approximately 13.8% of patients have experienced adverse events related to treatment with Cerezyme. Some of these are injection site reactions such as discomfort, pruritus, burning, swelling or sterile abscess at the site at the site of venipuncture. Additional adverse reactions that have been reported include nausea, abdominal pain, vomiting, diarrhea, rash, fatigue, headache, fever, dizziness, chills, backache, and tachycardia. Transient peripheral edema has also been reported for this therapeutic class of drug.

To report suspected adverse reactions, contact Genzyme at 800-745-4447, option 2 or FDA at 800-FDA-1088 or http://www.fda.gov/Safety/MedWatch

Please see Full Prescribing Information (PDF).

Thank you for your immediate attention to this request.

Sincerely,
[Physician Name]

Enclosure
cc **[patient name]**