



Prior Authorization Approval Criteria

Cerezyme (imiglucerase)

Generic name:	Imiglucerase
Brand name:	Cerezyme
Medication class:	Enzyme
FDA-approved use:	Type 1 Gaucher disease (non-neuropathic Gaucher disease)
Available dosage forms:	Intravenous powder for solution: 200 U, 400 U.
Usual dose range:	60 units/kg IV over 1-2 hours every 2 weeks; may range from 2.5 units/kg 3 times weekly to 60 units/kg once every 2 weeks.
Duration of therapy:	Indefinite
Approximate cost: (based on AWP 2006)	200 U (20 CC vial, NDC 58468-1983-01) = \$ 925 Biweekly cost = \$ 19,425 Annual cost = \$ 505,050

Criteria for use (*bullet points below are all inclusive unless otherwise noted*):

Patient must have a diagnosis of Type 1 Gaucher disease with at least one of the following:

- Anemia
- Thrombocytopenia
- Bone disease
- Hepatomegaly
- Splenomegaly

Criteria for continuation of therapy:

- Clinical evidence of efficacy and tolerability

Cautions:

- Presence of IgG antibodies
- Pregnancy
- Breastfeeding
- Pulmonary hypertension

Monitoring: Therapeutic efficacy (i.e. improvement in hemoglobin, hematocrit, and platelet counts, and a decrease in hepatomegaly and splenomegaly)

Contraindications: None reported.

Not approved if: Above-stated criteria are not met

Special considerations: Imiglucerase (Cerezyme) was developed to overcome supply constraints of placenta-derived alglucerase (Ceredase), which was previously the only effective treatment for Type I Gaucher disease. The manufacturer (Genzyme) is planning to phase out production of alglucerase, replacing it with imiglucerase.

Unlike alglucerase, which is extracted from pooled human placenta tissue, imiglucerase is produced by recombinant DNA technology using mammalian cell culture (Chinese hamster ovary); therefore, the risk of viral contamination and subsequent infection is reduced.

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 04/13/05