

Cerezyme® (imiglucerase for injection)



When requesting Cerezyme® (imiglucerase for injection), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved indication¹

- Cerezyme® (imiglucerase) is indicated for the treatment of individuals with Type 1 Gaucher disease.

Approved Off-label Compendial use²

- No off-label uses meet evidence standards

Coverage Guidelines

Type 1 Gaucher Disease

The individual must meet **all** of the following criteria for approval:

- Has a diagnosis of Type 1 Gaucher disease confirmed by enzyme assay demonstrating a deficiency of glucocerebrosidase enzyme activity or by genetic testing^{1,3}
- Has one or more of the following conditions^{1,3}:
 - o Anemia
 - o Thrombocytopenia
 - o Bone disease
 - o Hepatomegaly
 - o Splenomegaly

Approval duration: 12 months

Additional Information for Prescribers¹

Our prescribers are alerted to the following safety concern as educational points/reminders:

- Individuals with antibody to Cerezyme® (imiglucerase) have a higher risk of hypersensitivity reaction. Individuals should be monitored periodically for IgG antibody formation during the first year of treatment.

References

1. Cerezyme® prescribing information. Cambridge, MA: Genzyme Corporation: Revised May 2011. <https://cerezyme.com/>. Accessed February 15, 2017.
2. Klasco RK (Ed): DRUGDEX® system. Thomson Micromedex, Greenwood Village, CO. Accessed February 15, 2017. <https://www.micromedexsolutions.com>
3. Thomas AS, Mehta AB, Hughes DA. Diagnosing gaucher disease: an on-going need for increased awareness among haematologists. *Blood Cells Mol Dis*. 2013;50(3):212-217.