CVS Caremark®

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| Reference number(s) |
| 2051-A |

# Specialty Guideline Management Cerezyme

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| Cerezyme | imiglucerase |

## Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

### FDA-approved Indications1

Cerezyme 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, and/or hepatomegaly or splenomegaly.

### Compendial Uses

* Gaucher disease type 26
* Gaucher disease type 32-5

All other indications are considered experimental/investigational and not medically necessary.

## Documentation

Submission of the following information is necessary to initiate the prior authorization review: beta-glucocerebrosidase (glucosidase) enzyme assay or genetic testing results supporting diagnosis.

## Prescriber Specialties

## This medication must be prescribed by or in consultation with physicians knowledgeable in the management of patients with Gaucher disease.

## Coverage ****Criteria****

### Gaucher disease type 11

Authorization of 12 months may be granted for treatment of Gaucher disease type 1 when the diagnosis of Gaucher disease was confirmed by enzyme assay demonstrating a deficiency of beta-glucocerebrosidase (glucosidase) enzyme activity or by genetic testing.

### Gaucher disease type 26

Authorization of 12 months may be granted for treatment of Gaucher disease type 2 when the diagnosis of Gaucher disease was confirmed by enzyme assay demonstrating a deficiency of beta-glucocerebrosidase (glucosidase) enzyme activity or by genetic testing.

### Gaucher disease type 32-5

Authorization of 12 months may be granted for treatment of Gaucher disease type 3 when the diagnosis of Gaucher disease was confirmed by enzyme assay demonstrating a deficiency of beta-glucocerebrosidase (glucosidase) enzyme activity or by genetic testing.

## Continuation of Therapy

Authorization of 12 months may be granted for continued treatment of an indication listed in the coverage criteria section when all of the following criteria are met:

* Member meets the criteria for initial approval.
* Member is not experiencing an inadequate response or any intolerable adverse events from therapy.

## References

1. Cerezyme [package insert]. Cambridge, MA: Genzyme Corporation; July 2024.
2. Altarescu G, Hill S, Wiggs E, et al. The efficacy of enzyme replacement therapy in patients with chronic neuronopathic Gaucher's disease. J Pediatr. 2001;138:539-547.
3. Erikson A, Forsberg H, Nilsson M, Astrom M, Mansson JE. Ten years’ experience of enzyme infusion therapy of Norrbottnian (type 3) Gaucher disease. Acta Paediatr. 2006;95:312-317.
4. Pastores GM, Hughes DA. Gaucher Disease. 2000 July 27 [Updated December 7, 2023]. In: Adam MP, Everman DB, Mirzaa GM, et al, editors. GeneReviews® [Internet]. Seattle, WA: University of Washington, Seattle; 1993-2022.
5. Kaplan P, Baris H, De Meirleir L, et al. Revised recommendations for the management of Gaucher disease in children. *Eur J Pediatr.* 2013;172:447-458.
6. Gaucher Disease. National Organization for Rare Disorders. (2024). NORD guide to rare disorders. Philadelphia: Lippincott Williams & Wilkins.