imiglucerase (Cerezyme)

Commercial Medical Benefit Drug Policy

Place of Service
Home Infusion Administration
Infusion Center Administration
Office Administration
Outpatient Facility Administration

Drug Details

USP Category: GENETIC OR ENZYME OR PROTEIN DISORDER: REPLACEMENT, MODIFIERS, TREATMENT

Mechanism of Action: biosynthetic (recombinant DNA origin) form of human β-glucocerebrosidase

HCPCS:
J1786:Injection, imiglucerase, 10 units

How Supplied:
400-unit (single use vial)

Condition(s) listed in policy *(see coverage criteria for details)*

- Gaucher's Type 1

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct)** may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION

MCG Care Guidelines, 19th edition, 2015

ADMINISTRATION OF CEREZYME IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted)*

1. Patient is initiating therapy (allowed for the first two weeks) on Cerezyme or is being re-initiated on Cerezyme after at least 6 months off therapy. *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

OR

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. Patient has experienced a previous severe adverse event on Cerezyme based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on Cerezyme based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
4. Patient is clinically unstable based on documentation submitted.
5. Patient is physically or cognitively unstable based on documentation submitted.

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice.

Gaucher's Type 1

Meets medical necessity if all the following are met:

1. Patient has at least ONE of the following:
   a. Anemia
   b. Thrombocytopenia
   c. Bone disease (e.g., lesions, fractures, osteopenia, osteonecrosis, osteosclerosis)
   d. Hepatosplenomegaly or splenomegaly
   e. Symptomatic disease (including abdominal or bone pain, fatigue, physical function limitation, growth retardation in children, or malnutrition/cachexia)
2. Not being used in combination with other therapies for Type 1 Gaucher disease [i.e., ERT taliglucerase (Elelyso), velaglucerase (VPRIV), SRT eliglustat (Cerdelga), miglustat (Zavesca)]

Covered Doses:

Up to 2.5 units/kg given intravenously 3 times a week to 60 units/kg given intravenously once every two weeks

Coverage Period:

Yearly

ICD-10:

E75.22

References

1. AHFS. Available by subscription at http://www.lexi.com

2. Biegstraaten M, Cox TM, Belmatoug N et al. Management goals for type 1 Gaucher disease: An expert consensus document from the European working group on Gaucher disease. Blood Cell Mol Dis 2018; 68:203–208.
3. Cerezyme (imiglucerase) Prescribing Information. Genzyme Corporation, Cambridge, MA: 12/2024.
4. DrugDex. Available by subscription at http://www.micromedexsolutions.com

Review History

Date of Last Annual Review: 2Q2025
Changes from previous policy version:

- No clinical changes following annual review.

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee