imiglucerase (Cerezyme)

Medicare Part B Drug Policy

- Medicare coverage is limited to items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury (and within the scope of a Medicare benefit category).
- Medicare Benefit Policy Manual - Pub. 100-02, Chapter 15, Section 50, describes national policy regarding Medicare guidelines for coverage of drugs and biologicals.
- Blue Shield of California (BSC) follows Medicare statutes, regulations, National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and policy articles for determining coverage for Part B drug requests when applicable.
- BSC Medicare Part B Drug Policies will be used when coverage criteria are not fully established or there is an absence of any applicable Medicare statutes, regulations, NCDs or LCDs.

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 request for a condition not listed in policy must meet the definition of a medically accepted indication. Section 1861(t)(2)(B) of the Act defines "medically-accepted indication," as any use of a prescription drug or biological product which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included (or approved for inclusion) in one or more of the CMS approved compendia.

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.

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 [ERT taliglucerase (Elelyso), velaglucerase (VPRIV), SRT eliglustat (Cerdelga), miglustat (Zavesca)]

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

Coverage Period:
indefinite

ICD-10:
E75.22

Additional Information

Summary of Evidence

The contents of this policy were created after examining the following resources:

1. The prescribing information for Cerezyme
2. Management goals for type 1 Gaucher disease: An expert consensus document from the European working group on Gaucher disease (2018)
3. Consensus Conference: A reappraisal of Gaucher disease - diagnosis and disease management algorithms (2011)
4. Enzyme replacement therapy and monitoring for children with type 1 Gaucher disease: consensus recommendations (2004)

Explanation of Rationale:

- Support for FDA-approved indications can be found in the manufacturer's prescribing information.

References

1. CMS Benefit Policy Manual. Chapter 15; § 50 Drugs and Biologicals
2. Medicare Coverage Database. Available at https://www.cms.gov/Medicare-Coverage-Database/search.aspx
3. Social Security Act (Title XVIII) Standard References, Sections: 1862(a)(1)(A) Medically Reasonable & Necessary; 1862(a)(1)(D) Investigational or Experimental; 1833(e) Incomplete Claim; 1861(t) (1) Drugs and Biologicals
4. AHFS®. Available by subscription at http://www.lexi.com
5. 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.
6. Cerezyme® (imiglucerase) [Prescribing information]. Cambridge, MA: Genzyme, Inc.; 12/2022.
7. Charrow J, Andersson HC, Kaplan P, et al. Enzyme replacement therapy and monitoring for children with type 1 Gaucher disease: consensus recommendations. J Pediatr 2004;144: 112–120.
8. DrugDex®. Available by subscription at http://www.micromedexsolutions.com
9. Mistry PK, Cappellini MD, Lukina E, et al. A reappraisal of Gaucher disease – Diagnosis and disease management algorithms (Consensus conference) 2010. Am J Hematol 2011; 86(1):110-5.
10. Pastores GM, Weinreb NJ, Aerts H, et al. Therapeutic Goals in the Treatment of Gaucher Disease. Semin Hematol 41 (suppl 5):4-14. 2004.

Review History

Date of Last Annual Review: 2Q2024
Changes from previous policy version:

- New Part B policy

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

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