Cerezyme® (imiglucerase)
(Intravenous)

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I. Length of Authorization

Coverage will be provided for 12 months and may be renewed.

Coverage and policy application may be contingent on federal or state laws or regulations. In the event of a conflict between this policy and applicable federal or state laws or regulations, state law should apply.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Cerezyme 400 unit powder for injection: 18 vials per 14 days

B. Max Units (per dose and over time) [HCPCS Unit]:

- 720 billable units every 14 days

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 2 years of age; **AND**

Universal Criteria [1]

- Used as a single agent; **AND**

Type 1 Gaucher Disease † Φ [1,6,9,12-15]

- Patient has a documented diagnosis of Type 1 Gaucher Disease confirmed by one of the following:
  - Significantly reduced or absent glucocerebrosidase enzyme activity as measured by a beta-glucosidase leukocyte (BGL) test
  - Detection of mutations in the glucocerebrosidase (*GBA*) gene; **AND**
- Patient's disease results in one or more of the following:

- Anemia-related symptoms [i.e., blood transfusion dependency and/or hemoglobin ≤ 11 g/dL (women and children) or ≤ 12 g/dL (men)]
- Thrombocytopenia (platelet count ≤ 120,000/mm^3)
- Hepatomegaly or splenomegaly
- Skeletal disease (e.g., lesions, remodeling defects and/or deformity of long bones, osteopenia/osteoporosis, etc.)
- Symptomatic disease (e.g., bone pain, fatigue, dyspnea, abdominal distension, diminished quality of life, etc.)

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1,6,9,11,13-15]

Coverage can be renewed based on the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response with treatment as defined by one or more of the following (compared to pre-treatment baseline):
  - Improvement in anemia-related symptoms (i.e., improvement in hemoglobin and/or decrease in blood transfusion dependency)
  - Improvement in platelet counts
  - Reduction in size of liver or spleen
  - Improvement in skeletal disease (e.g., increase in lumbar spine and/or femoral neck BMD, no bone crises or bone fractures, etc.)
  - Improvement in symptoms (e.g., bone pain, fatigue, dyspnea, abdominal distension, quality of life, etc.); **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: hypersensitivity reactions, including anaphylaxis, etc.

V. Dosage/Administration [1]

Indication	Dose
Type 1 Gaucher Disease	– Initial dosages range from 2.5 U/kg of body weight intravenously 3 times a week to 60 U/kg intravenously once every 2 weeks based on disease severity. – Titrate the dosage based on clinical manifestations of disease and therapeutic goals for the patient.

VI. Billing Code/Availability Information

HCPCS Code:

- J1786 – Injection, imiglucerase, 10 units; 1 billable unit = 10 units

NDC:

- Cerezyme 400 unit powder for injection, single-dose vial: 58468-4663-xx

VII. References

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13. Kaplan P, Andersson HC, Kacena KA, Yee JD. The clinical and demographic characteristics of nonneuronopathic Gaucher disease in 887 children at diagnosis. Arch Pediatr Adolesc Med. 2006 Jun;160(6):603-8.
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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
E75.22	Gaucher disease

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Article may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC