

Cerezyme® (imiglucerase) (Intravenous)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 12 months (365 days).
- Renewal: Prior authorization validity may be renewed every 12 months (365 days).

II. Dosing Limits

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

- 720 billable units every 14 days

III. Initial Approval Criteria ¹

Prior authorization validity is provided in the following conditions:

Universal Criteria ¹

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

Gaucher Disease (Type 1 or Type 3) † Φ ^{1,6,9,12-15}

- Patient has a documented diagnosis of Type 1 or Type 3 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 has non-central nervous system (CNS) manifestations of Type 1 or Type 3 Gaucher disease defined as 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/mm³)

- 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); Ⓢ Orphan Drug

IV. Renewal Criteria ^{1,6,9,11,13-15}

Prior authorization validity 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**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe hypersensitivity reactions, including anaphylaxis, severe infusion-associated reactions (e.g., angioedema, pruritus, rash, urticaria, chest discomfort, chills, fatigue, infusion-site burning, infusion-site discomfort, infusion-site swelling, pyrexia, hypertension, etc.), etc.; **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.)

V. Dosage/Administration ¹

| Indication | Dose |
|----------------------------------|---|
| Type 1 or Type 3 Gaucher Disease | <ul style="list-style-type: none"> – 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. – Titrate the dosage based on disease severity and therapeutic goals for the patient. |

NOTE:

- *If a severe hypersensitivity reaction (e.g., anaphylaxis) or a severe infusion-associated reaction (IAR) occurs, discontinue CEREZYME and immediately initiate appropriate medical treatment.*
- *If a mild or moderate hypersensitivity reaction or a mild or moderate IAR occurs, consider decreasing the infusion rate, temporarily stopping the infusion, and/or administering antihistamines, antipyretics, and/or corticosteroids.*

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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Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime’s assessment led to for each.

| Factor | Conclusion |
|----------------------------|-----------------------|
| Indication | Yes: Consider for PA |
| Safety and efficacy | Yes: Consider for PA |
| Potential for misuse/abuse | No: PA not a priority |
| Cost of drug | Yes: Consider for PA |

Appendix 1 – Covered Diagnosis Codes

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

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

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied 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 |
| M (11) | NC, SC, WV, VA (excluding below) | Palmetto GBA |
| 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 |