Imiglucerase (Cerezyme®)	Place of Service Office Administration Home Infusion Administration Infusion Center Administration Outpatient Facility Administration* [*Prior authorization required – see section (1)] HCPCS: J1786 per 10 units

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

- Gaucher disease, Type I

AHFS therapeutic class: Enzyme

Mechanism of action: Biosynthetic (recombinant DNA origin) form of human β-glucocerebrosidase

(1) Special Instructions and pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

****CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION ****
AAAAI Guidelines 2011, MCG™ Care Guidelines, 19th edition, 2015

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO/Shared Advantage/HMO (non-direct contract)** 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.

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

1. **Patient is receiving their first infusion of 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.**

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Cerezyme® (imiglucerase) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Gaucher's Type I

1. Patient has at least one of the following:
    a. Anemia, OR
    b. Thrombocytopenia, OR
    c. Bone disease (e.g., lesions, fractures, osteopenia, osteonecrosis, osteosclerosis), OR
    d. Hepatosplenomegaly or splenomegaly, OR
    e. Symptomatic disease (including abdominal or bone pain, fatigue, physical function limitation, growth retardation in children, or malnutrition/cachexia)

    AND

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
Up to 120 Units/kg per month

Coverage Period
Indefinite

ICD-10:
E75.22.

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Cerezyme® (imiglucerase) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:
400-unit (single use vial)

Table 1.

Age and Sex	Reference range (Mean g/dl)[2]	> 2 SD below mean = anemia g/dl for Peds[2]	"High Risk" >2 gm below lower limit of normal for age and sex for children	*Pastores 2004* Definition of Anemia w/ Gaucher Treatment Goals are to increase above these levels in 12-24 mos
0.5-2 years	12.0	<11.0	< 9.0	<9.5
2-6 years	12.5	<11.5	< 9.5	<10.5
6-12 years	13.5	<11.5	< 9.5	<10.5
Female 12-18 years	14.0	<12.0	< 10.0	<11.0
Male 12-18 years	14.5	<13.0	< 11.0	<12.0
Female > 18 years (range)	13.8 (12.3 –15.3)		Refer to Guideline For High risk criteria in adults	<11.0
Male > 18 years (range)	15.7 (14.0 - 17.5)			<12.0

Anemia Thresholds

Reference: Pastores GM, Weinreb NJ, Aerts H, et al. Therapeutic Goals in the Treatment of Gaucher Disease. Semin Hematol 41 (suppl 5):4-14. 2004.

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- 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.
- Cerezyme® (imiglucerase) [Prescribing information]. Cambridge, MA: Genzyme, Inc.; 12/2021.
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com

(7) Policy Update

Date of last review: 2Q2023
Date of next review: 2Q2024
Changes from previous policy version:

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee