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CENTRAL HEALTH MEDICARE PLAN

Medical Policy

Cerezyme® - imiglucerase	
MEDICAL POLICY NUMBER	MED_Clin_Ops_045
CURRENT VERSION EFFECTIVE DATE	January 1. 2024
APPLICABLE PRODUCT AND MARKET	*Individual Family Plan:* All Plans *Small Group*: All Plans *Medicare Advantage:* All Plans

Brand New Day/Central Health Medicare Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/ Central Health Medicare Plan policy may contact the Health Plan. Brand New Day/Central Health Medicare Plan policies and practices are compliant with federal and state requirements, including mental health parity laws.

If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at http://www.cms.gov for additional information.

Brand New Day/Central Health Medicare Plan medical policies address technology assessment of new and emerging treatments, devices, drugs, etc. They are developed to assist in administering plan benefits and do not constitute an offer of coverage nor medical advice. Brand New Day/Central Health Medicare Plan medical policies contain only a partial, general description of plan or program benefits and do not constitute a contract. Brand New Day/Central Health Medicare Plan does not provide health care services and, therefore, cannot guarantee any results or outcomes. Treating providers are solely responsible for medical advice and treatment of members. Our medical policies are updated based on changes in the evidence and healthcare coding and therefore are subject to change without notice. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). MCG™ and Care Guidelines® are trademarks of MCG Health, LLC (MCG).

PURPOSE

To promote consistency between reviewers in clinical coverage decision-making by providing the criteria that generally determine the medical necessity of Cerezyme® (imiglucerase) therapy.

POLICY/CRITERIA

Prior Authorization and Medical Review is required.

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

1. Patient has a diagnosis of Gaucher Disease, Type 1 confirmed by one of the following:
    a. Demonstration of deficient β-glucocerebrosidase activity in leukocytes or fibroblasts; **OR**
    b. Molecular genetic testing documenting glucocerebrosidase gene mutation; **AND**
    c. Patient's disease has resulted in one of the following:
        i. Anemia
        ii. Thrombocytopenia

iii. Bone disease

iv. Hepatomegaly or splenectomy; **AND**

d. Cerezyme is prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders.

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value

BACKGROUND

Cerezyme (imiglucerase) is indicated for the long-term enzyme replacement therapy for pediatric and adult patients with a confirmed diagnosis of Type 1 Gaucher disease that results in at least one of the following: anemia, thrombocytopenia, bone disease, hepatomegaly, or splenomegaly.

Cerezyme is an analogue of β-glucocerebrosidase produced via recombinant DNA technology in Chinese hamster ovary cells. Cerezyme differs from human placental glucocerebrosidase by one amino acid at position 495. Cerezyme catalyzes the breakdown of glucocerebroside to glucose and ceramide.

DEFINITIONS

1. CEREZYME (imiglucerase for injection). US Approval: May 1994
   a. CEREZYME (imiglucerase for injection) is supplied as a sterile, non-pyrogenic, lyophilized product.

CODING

Applicable NDC Codes	
58468-4663-01	Cerezyme (imiglucerase) 400 unit injection per vial

Applicable Procedure Code	
J1786	Injection, imiglucerase, 10 units

Applicable ICD-10 Codes	
E75.22	Lipidosis (Gaucher Disease)

EVIDENCE BASED REFERENCES

1. Cerezyme® for injection [prescribing information]. Cambridge, MA: Genzyme Corporation; April 2018.

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POLICY HISTORY

Original Effective Date	May 24, 2021
Revised Date	November 1, 2021 – no changes made. February 22, 2022 – Annual review – no changes made February 28, 2023 – Annual Review and approval (no policy revisions made) March 1, 2023 – Adopted by MA UM Committee (no policy revisions made) January 1, 2024 - Updated to Brand New Day/Central Health Medicare Plan (no policy revisions made)

Approved by Pharmacy and Therapeutics Committee on February 28, 2023