Medical Policy:

Elelyso® (taliglucerase) intravenous infusion

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.226	April 3, 2025	2019

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Elelyso, an analogue of β-glucocerebrosidase, is indicated for the treatment of patients 4 years and older with a confirmed diagnosis of Type 1 Gaucher disease

Length of Authorization

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

Dosing Limits [Medical Benefit]

Each individual dose must not exceed 60 Units/kg administered intravenously no more frequently than once every 2 weeks.

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

700 billable units every 14 days

Guideline

I. INITIAL CRITERIA

1. **Gaucher Disease – Type 1** Approve for 1 year if the patient meets the following criteria (A, B, C, **AND** D):

Note: Type 1 Gaucher disease is also known as non-neuronopathic Gaucher disease.

A. Patient has Type 1 Gaucher disease; **AND**
B. Patient is ≥ 4 years of age; **AND**
C. The diagnosis is established by ONE of the following (i **OR** ii):
    i. Demonstration of deficient β-glucocerebrosidase activity in leukocytes or fibroblasts; **OR**
    ii. Molecular genetic testing documenting biallelic pathogenic variants in the glucocerebrosidase (GBA) gene; **AND**
D. Elelyso 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.

II. RENEWAL CRITERIA

1. Patient continues to meet Initial Criteria; **AND**
2. Disease response with treatment; **AND**
3. Absence of unacceptable toxicity from the drug. *Examples of unacceptable toxicity include: severe hypersensitivity reactions, etc.*

Applicable Procedure Codes

Code	Description
J3060	Injection, taliglucerase alfa, 10 units

Applicable NDCs

Code	Description
00069-0106-01	Elelyso 200 Unit Solution Reconstituted

ICD-10 Diagnoses

Code	Description
E75.22	Gaucher Disease

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	4/3/2025	Annual Review: Gaucher Disease – Type 1: Added qualifier "Type 1" to the condition name and Note to indicate Type 1 disease is also referred to as non-neuronopathic disease. For diagnosis established by genetic testing, genetic testing demonstrating a mutation in the glucocerebrosidase (*GBA*) gene was further specified to state a genetic test documenting biallelic pathogenic variants in the *GBA* gene.
EmblemHealth & ConnectiCare	3/19/2024	Annual Review: Updated dosing limits, added renewal criteria, updated ICD 10 code from E75.2 to E75.22
EmblemHealth & ConnectiCare	04/10/2023	Transfer from CCUM Template to CoBranded Medical template Retired MG.MM.PH.77

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EmblemHealth & ConnectiCare	03/16/2022	Annual Revision: no criteria changes
EmblemHealth & ConnectiCare	03/17/2021	Annual Revision: Gaucher Disease: Moved the designation of "Type 1" disease from the indication to the criteria. A criterion was added that requires the patient to be ≥ 4 years of age.

References

1. Elelyso® intravenous infusion [prescribing information]. New York, NY: Pfizer; May 2023.

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