taliglucerase alfa (Elelyso)

Commercial Medical Benefit Drug Policy

Place of Service

Office Administration
Infusion Center Administration
Home Infusion Administration
Outpatient Facility Infusion Administration

Drug Details

USP Category: GENETIC OR ENZYME OR PROTEIN DISORDER: REPLACEMENT, MODIFIERS, TREATMENT
Mechanism of Action: A recombinant active form of the lysosomal enzyme beta-glucocerebrosidase
HCPCS:
J3060:Injection, taliglucerase alfa, 10 units
How Supplied:
200 units per vial (lyophilized powder)

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

- Gaucher's Disease, Type I

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

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.

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

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

1. **Patient is initiating therapy (allowed for the first infusion) with Elelyso or is being re-initiated on Elelyso 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 Elelyso based on documentation submitted.**
3. **Patient continues to experience moderate to severe adverse events on Elelyso 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.**

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Gaucher's Disease, Type I

Meets medical necessity if all the following are met:

1. Diagnosis of Gaucher's disease Type I
2. Patient has at least ONE of the following (a, b, c, d, or e):
   a. Anemia
   b. Thrombocytopenia
   c. Bone disease (e.g., lesions, fractures, osteopenia, osteonecrosis, osteosclerosis)
   d. Hepatosplenomegaly or splenomegaly
   e. Symptomatic disease (including abdominal or bone pain, fatigue, physical function limitation, growth retardation in children, or malnutrition/cachexia)
3. Not being used in combination with other therapies for Type 1 Gaucher disease [e.g., ERT Cerezyme (imiglucerase), VPRIV (velaglucerase), SRT (Cerdelga (eliglustat), Zavesca (miglustat)],
4. Patient is unable to use Cerezyme (imiglucerase) and Vpriv (velaglucerase alfa)

Covered Doses:
Up to 120 units/kg given intravenously once monthly

Coverage Period:
Yearly, based on continued response to therapy

ICD-10:
E75.22

References

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2. 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.
3. Charrow J, Andersson HC, Kaplan P, et al. Enzyme replacement therapy and monitoring for children with type 1 Gaucher disease: consensus recommendations. J Pediatr 2004;144: 112–120.
4. DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
5. Elelyso (taliglucerase alfa) [prescribing information]. New York, NY: Pfizer Labs; January 2025.
6. Mistry PK, Cappellini MD, Lukina E, et al. A reappraisal of Gaucher disease – Diagnosis and disease management algorithms (Consensus conference) 2010. Am J Hematol 2011; 86(1):110-5.
7. Pastores GM, Weinreb NJ, Aerts H, et al. Therapeutic Goals in the Treatment of Gaucher Disease. Semin Hematol 41 (suppl 5):4-14. 2004.

Review History

Date of Last Annual Review: 3Q2025

Changes from previous policy version:

- No clinical change following annual review.

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee