taliglucerase alfa (Elelyso)

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 California Code of Regulations (CCR), Title 22, Section 51303 and 51313 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.

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)

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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: 3Q2026
Changes from previous policy version:

- No clinical changes following annual review.

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