Taliglucerase alfa (Elelyso®)	Place of Service Office Administration Infusion Center Administration Home Infusion Administration Outpatient Facility Infusion Administration HCPCS: J3060 per 10 units

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

- Gaucher's disease, Type 1

AHFS therapeutic class: Enzymes
Mechanism of action: A recombinant active form of the lysosomal enzyme beta-glucocerebrosidase

(1) Special Instructions and Pertinent Information

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

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

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

Gaucher's disease, Type I

1. Diagnosis of Gaucher's disease Type I, **AND**
2. 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
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)],

    AND
4. Either of the following:
    a. ***Effective through 4/28/2024***: Patient is unable to use Cerezyme (imiglucerase), OR
    b. ***Effective 4/29/2024 and after***: Patient is unable to use Cerezyme (imiglucerase) and VPRIV (velaglucerase alfa)

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 Elelyso® (taliglucerase) 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:
200 units per vial (lyophilized powder)

Anemia Thresholds. Table 1.

Age and Sex	Reference range (Mean g/dl)	> 2 SD below mean = anemia g/dl for Peds	"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

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

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- 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.
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- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Elelyso® (taliglucerase alfa) [Prescribing Information]. New York, NY: Pfizer, Inc.; 2023.
- 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.
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(7) Policy Update

Date of last revision: 1Q2024
Date of next review: 3Q2024
Changes from previous policy version:

- Section (2): Gaucher's disease: Effective 4/29/2024, VPRIV will be added as a step therapy in addition to Cerezyme

  Rationale: Cost effective therapeutic alternative

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