

Policy Name:	Elelyso (taliglucerase alfa)	Policy #:	2475P
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Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Elelyso.

Statement of the Policy

Health Alliance Medical Plans and Health Alliance Northwest will approve the use of Elelyso under the Specialty Medical benefit when the following criteria have been met.

Criteria

1. Coverage Criteria for the Treatment of Gaucher disease

- 1.1 Diagnosis of type 1 Gaucher disease confirmed by genetic testing or enzyme assay
- 1.2 Age 4 years or older
- 1.3 Prescribed by a Geneticist (gene specialist)

2. Exclusion Criteria

- 2.1 Not used in combination with Zavesca, Cerdelga, Cerezyme or VPRIV

3. Approval Period

- 3.1 12 months

CPT Codes

96360 – 96361	Intravenous infusion, hydration
96365 – 96368	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug)
96379	Unlisted therapeutic, prophylactic, or diagnostic intravenous or intra-arterial injection or infusion

HCPCS Codes

J3060 - Injection, taliglucerase alfa, 10 units

References

1. 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(1):112-20.
2. Elelyso [package insert]. New York, NY: Pfizer Labs; May 2023.
3. Pastores GM, Petakov M, Giraldo P, et al. A phase 3, multicenter, open-label, switchover trial to assess the safety and efficacy of taliglucerase alfa, a plant cell-expressed recombinant human glucocerebrosidase, in adult and pediatric patients with Gaucher disease previously treated with imiglucerase. Blood Cells Mol Dis. 2014;53(4):253-260.

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy

and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.