

Policy Name:	Cerdelga (Eliglustat Tartrate)	Policy #:	2435P
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Purpose of the Policy

The purpose of this policy is to define the criteria for coverage of Cerdelga.

Statement of the Policy

Health Alliance Medical Plans will approve the use of Cerdelga under the Specialty Pharmacy benefit when the following criteria have been met.

Criteria

1. Coverage Criteria

- 1.1 Diagnosis of non-neuropathic (type 1) Gaucher's disease confirmed by enzyme assay or gene testing
- 1.2 CYP2D6 phenotype determination testing
- 1.3 Age 18 years or older
- 1.4 Ordered by a Geneticist or physician who is specialized in the treatment of Gaucher Disease

2. Exclusion Criteria

- 2.1 Not used in combination with Zavesca, Elelyso, Cerezyme or VPRIV
- 2.2 Patients whose CYP2D6 genotype cannot be determined or those who are ultra-rapid metabolizers (ultra-rapid metabolizers may not be able to achieve adequate concentrations of eliglustat to achieve a therapeutic effect)

3. Approval Period

- 3.1 Initial: 12 months
- 3.2 Reauthorization: 12 months with documented clinical benefit from therapy

CPT Codes

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HCPCS Codes

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References

1. Cerdelga (eliglustat) [prescribing information]. Waterford, Ireland: Genzyme Ireland Ltd; August 2024.
2. Lukina E, Watman N, Arreguin EA, et al. Improvement in hematological, visceral, and skeletal manifestations of Gaucher disease type 1 with oral eliglustat tartrate (Genz-112638) treatment: 2-year results of a phase 2 study. *Blood* 2010; 116:4095.
3. Mistry PK, Lukina E, Turkia HB, et al. Effect of oral eliglustat on splenomegaly in patients with Gaucher disease type 1: the ENGAGE randomized clinical trial. *JAMA* 2015; 313:695.

4. Balwani M, Burrow TA, Charrow J, et al. Recommendations for the use of eliglustat in the treatment of adults with Gaucher disease type 1 in the United States. *Mol Genet Metab.* 2016;117(2):95-103.

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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.