

Pharmacy Drug Policy & Procedure

Policy Name: Zavesca (miglustat)

Policy #: 1065P

Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Zavesca (miglustat).

Statement of the Policy

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

Criteria

1. Coverage Criteria for Treatment of Gaucher Disease

- 1.1 Diagnosis of mild-to-moderate type I Gaucher Disease confirmed by gene testing or enzyme assay
- 1.2 Documented clinically significant manifestations of Gaucher disease such as enlarged spleen, enlarged liver, avascular necrosis (bone blood loss), Erlenmeyer flask deformity (bone enlargement), decrease in bone mineral density, or pathological fracture
- 1.3 Prescribed by a Geneticist (gene doctor), Hematologist (blood doctor), Oncologist (cancer doctor), or physician specializing in the treatment of Gaucher Disease
- 1.4 Age 18 years or older
- 1.5 If a biological female, documented negative pregnancy test

2. Exclusion Criteria

- 2.1 Zavesca will not be approved if used in combination with Cerezyme, Elelyso, or VPRIV or Cerdelga

3. Approval Time

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

CPT Codes

--	--

HCPCS Codes

--	--

References

1. Zavesca [package insert]. Titusville, NJ: Actelion Pharmaceuticals US, Inc.; August 2022.
2. Cox TM, Amato D, Hollak CE, et al. Evaluation of miglustat as maintenance therapy after enzyme therapy in adults with stable type 1 Gaucher disease: a prospective, open-label non-inferiority study. Orphanet J Rare Dis 2012; 7:102

3. Cox TM, Drellichman G, Cravo R, et al. Eliglustat compared with imiglucerase in patients with Gaucher's disease type 1 stabilised on enzyme replacement therapy: a phase 3, randomised, open-label, non-inferiority trial. *Lancet* 2015; 385:2355.
4. Elstein D, Dweck A, Attias D, et al. Oral maintenance clinical trial with miglustat for type I Gaucher disease: switch from or combination with intravenous enzyme replacement. *Blood* 2007; 110:2296.

Created Date: 09/06/04

Effective Date: 09/06/04

Posted to Website: 01/01/22

Revision Date: 10/02/24

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.