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 livery, 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, Drelichman 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