Clinical Policy Title:	eliglustat
Policy Number:	RxA.062
Drug(s) Applied:	Cerdelga®
Original Policy Date:	02/07/2020
Last Review Date:	08/29/2024
Line of Business Policy Applies to:	All line of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Type 1 Gaucher Disease (GD1) (must meet all):

1. Diagnosis of GD1 confirmed by one of the following (a or b):
   a. Enzyme assay demonstrating a deficiency of beta-glucocerebrosidase (glucosidase) activity;
   b. DNA testing;
2. Member is symptomatic (e.g., anemia, thrombocytopenia, bone disease, hepatomegaly, splenomegaly);
3. Member is a CYP2D6 poor metabolizer, extensive metabolizer, or intermediate metabolizer confirmed by an FDA-cleared test;
4. Cerdelga® is prescribed as monotherapy.

Approval Duration

All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. Type 1 Gaucher Disease (GD1) (must meet all)**:**

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. Hollak, CEM, Weinreb NJ. The attenuated/late onset lysosomal storage disorders: therapeutic goals and indications for enzyme replacement treatment in Gaucher and Fabry disease. Best Pract Res Clin Endocrinol Metab. 2015; 29: 205-218. Available at: https://pubmed.ncbi.nlm.nih.gov/25987174/. Accessed August 29, 2024.
2. Pastores GM, Weinreb NJ, Aerts H, et al. Therapeutic goals in the treatment of Gaucher disease. Semin Hematol. 2004; 41(suppl 5): 4-14. Available at: https://pubmed.ncbi.nlm.nih.gov/15468045/. Accessed August 29, 2024.
3. 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. Molecular Genetics and Metabolism. 2016; 117(2): 95-10. Available at: https://pubmed.ncbi.nlm.nih.gov/26387627/. Accessed August 29, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date

Policy established.	01/2020	02/07/2020
Policy reviewed and updated. 1. Updated references. 2. Updated Criteria II, A, i to: Currently receiving medication that has been authorized by Rxadvance, or documentation supports that member is currently receiving Cabometyx or Cometriq for a covered indication and has received this medication for at least 30 days.	04/29/2020	05/20/2020
Policy reviewed and updated. 1. Clinical policy title and lines of business updated. 2. Commercial approval duration updated. 3. Continued therapy criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance…". 4. References updated.	02/03/2021	03/09/2021
Policy reviewed and updated. 1. Initial Approval Criteria, I.A.2: Updated to include new prescriber criteria Prescribed by or in consultation with a hematologist. 2. References were reviewed and updated.	12/06/2021	01/17/2022
Policy was reviewed: 1. Initial Approval Duration I.A: Approval duration for commercial and medicaid updated to 6 months. 2. References were reviewed and updated.	09/30/2022	01/17/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions.	08/28/2024	09/13/2024

4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 5. Removed other reauthorization requirements including positive response to therapy. 6. Updated approval duration verbiage. 7. References were reviewed and updated.		