Clinical Policy Title:	velaglucerase alfa
Policy Number:	RxA.560
Drug(s) Applied:	Vpriv®
Original Policy Date:	03/06/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Gaucher Disease (must meet all):

1. Diagnosis of Type 1 (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. Age ≥ 4 years;
3. Member is symptomatic (e.g., anemia, thrombocytopenia, bone disease, hepatomegaly, splenomegaly);
4. Vpriv® is not prescribed concurrently with Elelyso® (taliglucerase alfa) or Cerezyme® (imiglucerase).

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Gaucher Disease (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy as evidenced by increased or stabilized platelet count or hemoglobin, reduced or stabilized spleen or liver volume, decreased bone pain;
3. Vpriv® is not prescribed concurrently with Elelyso® (taliglucerase alfa) or Cerezyme® (imiglucerase).

Approval Duration
Commercial: 6 months
Medicaid: 12 months

References

1. Charrow J, Andersson HC, Kaplan P. Enzyme replacement therapy and monitoring for children with type 1 Gaucher disease: consensus recommendations. J Pediatr. 2004; 144: 112-20. Available at: https://www.researchgate.net/publication/8919699_Enzyme_replacement_therapy_and_monitoring_for_children_with_type_1_Gaucher_disease_Consensus_recommendations. Accessed July 26, 2022.
2. Vellodi A, Tylki-Szymanska A, Davies E, et al. Management of neuronopathic Gaucher disease: Revised recommendations. J Inherit Metab Dis. 2009;32:660-664. Available at: https://pubmed.ncbi.nlm.nih.gov/19655269/. Accessed July 26, 2022.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Policy title table was updated: Line of business policy applies was updated to all lines of business. 2. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…". 3. References were updated.	10/05/2020	12/07/2020
Policy was reviewed: 1. Initial approval criteria I.A.1 was updated to remove "Type 3 Gaucher disease". 2. Continuation therapy criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance". 3. References were reviewed and updated.	10/06/2021	12/07/2021
Policy was reviewed: 1. References were reviewed and updated.	07/26/2022	10/19/2022
Policy was reviewed.	10/19/2023	10/19/2023