

Pharmacy Drug Policy & Procedure

Policy Name:	VPRIV (velaglucerase alfa)	Policy #:	2483P
---------------------	-----------------------------------	------------------	--------------

Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of VPRIV (velaglucerase alfa).

Statement of the Policy

Health Alliance Medical Plans will approve the use of VPRIV (velaglucerase alfa) under the Specialty Medical benefit when the following criteria have been met.

Criteria

1. Coverage Criteria for the Treatment of Gaucher disease

- 1.1 Diagnosis of type 1 Gaucher disease confirmed by gene testing or enzyme assay
- 1.2 Prescribed by a Geneticist (gene specialist)
- 1.3 Age 4 years or older

2. Exclusion Criteria

- 2.1 Not used in combination with Zavesca, Elelyso, Cerdelga, or Cerezyme

3. Approval Period

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

CPT Codes

--	--

HCPCS Codes

J3385	Injection, velaglucerase alfa, 100 units
-------	--

References

1. VPRIV (velaglucerase alfa) [prescribing information]. Lexington, MA: Takeda Pharmaceuticals USA Inc; July 2024.
2. Ben Turkia H, Gonzalez DE, Barton NW, et al. Velaglucerase alfa enzyme replacement therapy compared with imiglucerase in patients with Gaucher disease. *Am J Hematol* 2013; 88:179.
3. Charrow J, Andersson HC, Kaplan P, et al. Enzyme replacement therapy and monitoring for children with type 1 Gaucher disease: consensus recommendations. *J Pediatr*. 2004;144(1):112-120.
4. Gonzalez DE, Turkia HB, Lukina EA, et al. Enzyme replacement therapy with velaglucerase alfa in Gaucher disease: Results from a randomized, double-blind, multinational, Phase 3 study. *Am J Hematol* 2013; 88:166.



5. Pastores GM, Rosenbloom B, Weinreb N, et al. A multicenter open-label treatment protocol (HGT-GCB-058) of velaglucerase alfa enzyme replacement therapy in patients with Gaucher disease type 1: safety and tolerability. *Genet Med* 2014; 16:359.
6. Weinreb NJ, Aggio MC, Andersson HC, et al; International Collaborative Gaucher Group (ICGG). Gaucher disease type 1: revised recommendations on evaluations and monitoring for adult patients. *Semin Hematol.* 2004;41(4 Suppl 5):15-22.
7. Zimran A, Pastores GM, Tylki-Szymanska A, et al. Safety and efficacy of velaglucerase alfa in Gaucher disease type 1 patients previously treated with imiglucerase. *Am J Hematol* 2013; 88:172.

Created Date: 04/06/16

Effective Date: 04/06/16

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.