AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Vonvendi	Page:	1 of 2
Effective Date:	4/21/2025	Last Review Date:	3/26/2025
Applies to:	☒Illinois ☒Florida Kids ☒New Jersey ☒Maryland ☒Pennsylvania Kids ☐Virginia		

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Vonvendi under the patient's prescription drug benefit.

Description:

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

Vonvendi is indicated for use in adults (age 18 and older) diagnosed with von Willebrand disease (VWD) for:

1. On-demand treatment and control of bleeding episodes
2. Perioperative management of bleeding.
3. Routine Prophylaxis to reduce the frequency of bleeding episodes in patients with severe Type 3 VWD receiving on-demand therapy

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Vonvendi

Policy/Guideline:

Prescriber Specialty:
Must be prescribed by or in consultation with a hematologist.

Criteria for Initial Approval:

Von Willebrand Disease
Authorization of 12 months may be granted for VWD when ANY of the following criteria is met:

A. Member has type 1, 2A, 2M, or 2N VWD and has had an insufficient response to desmopressin or a documented clinical reason for not using desmopressin (see Appendix).
B. Member has type 2B or type 3 VWD.

Continuation of Therapy:

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in criteria for initial approval when the member is experiencing benefit from therapy (e.g., reduced frequency or severity of bleeds).

Appendix:

Clinical Reasons for Not Utilizing Desmopressin in Patients with Type 1, 2A, 2M and 2N VWD

A. Age < 2 years
B. Pregnancy
C. Fluid/electrolyte imbalance
D. High risk for cardiovascular or cerebrovascular disease (especially the elderly)
E. Predisposition to thrombus formation
F. Trauma requiring surgery
G. Life-threatening bleed
H. Contraindication or intolerance to desmopressin
I. Severe type 1 von Willebrand disease
J. Stimate Nasal Spray is unavailable due to backorder/shortage issues (where applicable)

Approval Duration and Quantity Restrictions:

Approval: 12 months

References:

1. Vonvendi [package insert]. Lexington, MA: Baxalta US Inc.; March 2023.
2. National Hemophilia Foundation. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Selected Disorders of the Coagulation System. Revised April 2024. MASAC Document #284. https://www.bleeding.org/sites/default/files/document/files/MASAC-Products-Licensed.pdf. Accessed October 16, 2024.
3. National Hemophilia Foundation. MASAC recommendations regarding the treatment of von Willebrand disease. Revised February 2021. MASAC Document #266. https://www.hemophilia.org/sites/default/files/document/files/266.pdf. Accessed October 16, 2024.
4. National Institutes of Health. The diagnosis, evaluation, and management of von Willebrand disease. Bethesda, MD: US Dept of Health and Human Services, National Institutes of Health; 2007. NIH publication No. 08-5832.
5. Stimate [package insert]. King of Prussia, PA: CSL Behring LLC; June 2021.
6. Leissinger C, Carcao M, Gill JC, et al. Desmopressin (DDAVP) in the management of patients with congenital bleeding disorders. Haemophilia. 2014;20:158-167.