

Vonvendi (von Willebrand factor [recombinant])
Effective 01/01/2024

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Medical and Specialty Medications		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
Exceptions	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	N/A		

Overview
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.

Coverage Guidelines

Authorization may be granted for members new to the plan who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for VWD when the medication is prescribed by or in consultation with a hematologist AND 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 may be granted for continued treatment in members requesting reauthorization for an indication listed above when the member is experiencing benefit from therapy (e.g., reduced frequency or severity of bleeds)

Limitations

Approvals will be granted for 12 months.

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. Stimite Nasal Spray is unavailable due to backorder/shortage issues (where applicable)

References

1. Vonvendi [package insert]. Lexington, MA: Baxalta US Inc.; January 2022.
2. National Hemophilia Foundation. MASAC recommendations concerning products licensed for the treatment of hemophilia and other bleeding disorders. Revised March 2022. MASAC Document #272. https://www.hemophilia.org/sites/default/files/document/files/272_Treatment.pdf. Accessed October 3, 2022.
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 3, 2022.
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. Stimite [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.

Review History

12/13/2023: Reviewed at Dec P&T, switched from SGM to Custom. Effective 1/1/2024

