Reference number(s)
4868-A

Standard Medicare Part B Management Vonvendi

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Vonvendi	von Willebrand factor [recombinant]

Indications

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 Indications[1]

Vonvendi is indicated for use in adult and pediatric patients with von Willebrand disease (VWD) for:

- On-demand treatment and control of bleeding episodes.
- Perioperative management of bleeding.

Vondendi is indicated for use in adults with von Willebrand disease (VWD) for:

- Routine prophylaxis to reduce the frequency of bleeding episodes.

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

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Coverage Criteria

Von Willebrand Disease[1-3]

Authorization of 12 months may be granted for members with VWD when any of the following criteria is met:

- 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).
- Member has type 2B or type 3 VWD.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication.
- The requested medication is being used to treat an indication listed in the coverage criteria section.
- The member is receiving 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[2-6]

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

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Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Vonvendi.
- The available compendium
  - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
  - Micromedex DrugDex
  - American Hospital Formulary Service-Drug Information (AHFS-DI)
  - Lexi-Drugs
  - Clinical Pharmacology
- The diagnosis, evaluation, and management of von Willebrand disease.
- MASAC recommendations concerning products licensed for the treatment of hemophilia and selected disorders of the coagulation system.

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Vonvendi are covered.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Vonvendi to treat von Willebrand disease can be found in the National Institutes of Health publication called the "Diagnosis, Evaluation, and Management of von Willebrand Disease". Type 2B and type 3 VWD do not respond consistently to DDAVP therapy and therefore DDAVP is not considered clinically useful in these patients.

The guideline from the National Bleeding Disorders Foundation (previously the National Hemophilia Foundation) also recommends using Vonvendi in VWD. Vonvendi is used to treat patients with type 2B and type 3 VWD; it can also be used in patients with types 1, 2A, 2M, and 2N VWD who are not responsive to DDAVP and in children under 2 years of age regardless of VWD type.

References

1. Vonvendi [package insert]. Lexington, MA: Baxalta US Inc.; September 2025.
2. National Hemophilia Foundation. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Selected Disorders of the Coagulation System. Revised October 2024. MASAC Document #290. https://www.bleeding.org/sites/default/files/document/files/MASAC-Products-Licensed.pdf. Accessed October 16, 2025.
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, 2025.

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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.

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