

Vonvendi®
(von Willebrand factor)

Date of Origin: 01/22/2020

Last Review Date: 01/22/2020

Effective Date: 02/01/2020

Dates Reviewed: 01/22/2020

Developed By: Medical Criteria Committee

I. Length of Authorization

- Initial: 6 months (for on-demand); 1 month (for perioperative)
- Renewal: 12 months (for on-demand)

II. Dosing Limits

Product Name	Dosage Form	Indication/ FDA Labeled Dosing	Quantity Limit
Vonvendi, von Willebrand factor (recombinant)	650, 1300 IU	<p>On-demand treatment and control of bleeding episodes:</p> <ul style="list-style-type: none"> • <i>Minor:</i> Up to 50 IU/kg for the initial dose, subsequent doses of up to 50 IU/kg every eight to 24 hours as clinically required • <i>Major:</i> Up to 80 IU/kg for the initial dose, subsequent doses of up to 60 IU/kg every eight to 24 hours for approximately two to three days, as clinically required <p>Perioperative management of bleeding: A dose may be given 12 to 24 hours prior to surgery to allow the endogenous factor VIII levels to increase to at least 30 IU/dL (minor surgery) or 60 IU/dL (major surgery)</p>	<p>On-demand treatment and control of bleeding episodes: Up to the number of doses requested every 28 days</p> <p>Perioperative management of bleeding: Up to the number of doses requested every 28 days</p>

III. Initial Approval Criteria

- Vonvendi may be considered medically necessary when the following criteria below are met:
 - Treatment is prescribed by or in consultation with a hematologists; **AND**
 - A diagnosis of von Willebrand disease (vWD) has been confirmed by blood coagulation and von Willebrand factor testing; **AND**
 - Use is planned for one of the following indications:

1. On-demand treatment and control of bleeding when one of the following is met:
 - i. Member has severe vWD; **OR**
 - ii. Member has mild or moderate vWD and the use of desmopressin is known or suspected to be ineffective or contraindicated; **OR**
 2. Perioperative management of bleeding
- II. Vonvendi is considered investigational when used for any other condition.

IV. Renewal Criteria

- I. Documentation of clinical benefit, including decreased incidence of bleeding episodes or stability of bleeding episodes relative to baseline

VI. Billing Code/Availability Information

Drug	Manufacturer	J-Code	1 Billable Unit Equiv.	Vial Size	NDC
Vonvendi	Baxalta US Inc	J7179	1 IU	450-850 units	00944-7551
				900-1700 units	00944-7553

VII. References

1. Vonvendi® [Prescribing Information]. Westlake Village, CA: Baxalta US Inc; February 2019
2. National Hemophilia Foundation. MASAC Recommendations Concerning products Licensed for the Treatment of Hemophilia and Other Bleeding Disorders. Available from: <https://www.hemophilia.org/Researchers-Healthcare-Providers/Medical-and-Scientific-Advisory-Council-MASAC/MASAC-Recommendations>. Accessed July 5, 2019.
3. UpToDate, Inc. Hemophilia A and B: Routine management including prophylaxis Treatment of von Willebrand disease. UpToDate [database online]. Last updated July 19, 2019.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
D68.0	Von Willebrand's disease

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corporation (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corporation (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Cahaba Government Benefit Administrators, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC