

Von Willebrand Factors

(Vonvendi [von Willebrand factor {recombinant}],
Wilate [von Willebrand factor/coagulation factor VIII complex {human}])

When requesting Vonvendi® or Wilate®, the individual requiring treatment must be diagnosed with one of the following FDA-approved indications and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indications

Vonvendi

Vonvendi is a recombinant von Willebrand factor 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
- Routine prophylaxis to reduce the frequency of bleeding episodes

Wilate

Wilate is indicated in children and adults with von Willebrand disease for:

- On-demand treatment and control of bleeding episodes
- Perioperative management of bleeding
- Routine prophylaxis to reduce the frequency of bleeding episodes (age 6 years and older)

Wilate is indicated in adolescents and adults with hemophilia A for:

- Routine prophylaxis to reduce the frequency of bleeding episodes
- On-demand treatment and control of bleeding episodes

Coverage Guidelines

Vonvendi

Von Willebrand Disease

The individual must meet the following criteria for authorization:

- Vonvendi is being requested for one of the following:
 - On demand treatment and control of bleeding episodes; OR
 - Perioperative management of bleeding; OR
 - Routine prophylaxis to reduce frequency of bleeding episodes;
- Vonvendi is prescribed by or in consultation with a hematologist or a hemophilia specialist.

Wilate

Von Willebrand Disease

The individual must meet the following criteria for authorization:

- Wilate is being requested for one of the following:
 - On demand treatment and control of bleeding episodes; OR
 - Perioperative management of bleeding; OR
 - Routine prophylaxis to reduce the frequency of bleeding episodes;
- Wilate is prescribed by or in consultation with a hematologist or a hemophilia specialist.

Hemophilia A

The individual must meet the following criteria for authorization:

- Wilate is being requested for one of the following:
 - On demand treatment and control of bleeding episodes; OR
 - Routine prophylaxis to reduce frequency of bleeding episodes;
- Wilate is prescribed by or in consultation with a hematologist or a hemophilia specialist.

Approval duration: 12 months

Dosing Recommendations

For intravenous use only

Vonvendi

On-demand treatment and control of bleeding episodes: the recommended initial dose is 40-80 IU/kg. Adjust the dosage based on the extent and location of bleeding.

Bleeding Episode	Initial Dose	Subsequent Dose
Minor	40-50 IU/kg	40-50 IU/kg every 8-24 hours
Major	50-80 IU/kg	40-60 IU/kg every 8-24 hours for approximately 2-3 days

Perioperative management of bleeding:

For elective surgical procedure:

- A dose of Vonvendi 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 U/dL (major surgery).
- Assess FVIII:C levels within 3 hours prior to surgery; If the FVIII:C levels are at or above the recommended minimum target levels, administer a dose of Vonvendi alone within 1 hour prior to the procedure. If the FVIII:C levels are below the recommended minimum target levels, administer recombinant factor VIII in addition to Vonvendi to raise VWF:RCo and FVIII:C.

For emergency surgery:

- Assess baseline VWF:RCo and FVIII:C levels within 3 hours prior to surgery. If not available, use weight based dosing calculation.
- Administer Vonvendi one hour before surgery with or without recombinant factor VIII and adjust the dose to raise VWF:RCo and FVIII:C to adequate level.

Routine prophylaxis to reduce the frequency of bleeding episodes in patients:

- The recommended initial dose is 40 to 60 IU/kg administered twice weekly. The dose may be adjusted up to 60 IU/kg twice weekly based on frequency of bleeding episodes.

Wilate

Von Willebrand disease:

Required IU = body weight (BW) in kg x desired VWF:RCo rise (%) (IU/dL) x 0.5 (IU/kg per IU/dL)

Types of hemorrhages/surgery	Loading Dose	Maintenance Dose
Minor Hemorrhages	20-40 IU/kg	20-30 IU/kg every 12-24 hours
Major Hemorrhages	40-60 IU/kg	20-40 IU/kg every 12-24 hours
Minor Surgeries	30-60 IU/kg	15-30 IU/kg or half the loading dose every 12-24 hours for up to 3 days
Major Surgeries	40-60 IU/kg	20-40 IU/kg or half the loading dose every 12-24 hours for up to 6 days or more

For routine prophylaxis to reduce the frequency of bleeding episodes:

The recommended dose is 20-40 IU/kg two or three times per week.

Hemophilia A:

Required IU: body weight (BW) in kg x desired Factor VIII rise (%) (IU/dL) x 0.5 (IU/kg per IU/dL)

For on-demand treatment and control of bleeding episodes:

Types of hemorrhages	Recommended dosage (IU/kg body weight)	Frequency of Doses (hours)
Minor	30-40	Repeat every 12-24 hours

Moderate	30-40	Repeat every 12-24 hours
Major	35-50	Repeat every 12-24 hours
Life threatening	35-50	Repeat every 8-24 hours

For routine prophylaxis:

The recommended dose is 20-40 IU/kg every 2 to 3 days.

References

1. Wilate prescribing information. Hoboken, NJ; Octapharma USA, Inc. November 2024.
2. Vonvendi prescribing information. Lexington, MA; Baxalta US Inc.; September 2025.
3. Gill JC, Castaman G, Windyga J, et al. Hemostatic efficacy, safety, and pharmacokinetics of a recombinant von Willebrand factor in severe von Willebrand disease. *Blood*. 2015;126(17):2038-2046.
4. Franchini M, Mannucci PM. Von Willebrand factor (Vonvendi®): the first recombinant product licensed for the treatment of von Willebrand disease. *Expert Rev Hematol*. 2016;9(9):825-830.
5. National Bleeding Disorders Foundation. MASAC (Medical and Scientific Advisory Council) recommendations concerning products licensed for the treatment of hemophilia and selected disorders of the coagulation system (October 2024). MASAC Document #290. Available at: <https://www.hemophilia.org/sites/default/files/document/files/MASAC-Products-Licensed.pdf>. Accessed on August 11, 2025.
6. Srivastava A, Santagostino E, Dougall A, et al, on behalf of the WFH guidelines for the management of hemophilia panelists and coauthors. WFH guidelines for the management of hemophilia, 3rd edition. *Haemophilia*. 2020;26 Suppl 6:1-158.
7. Connell NT, Flood VH, Brignardello-Petersen R, et al. ASH ISTH NHF WFH 2021 guidelines on the management of von Willebrand Disease. *Blood Adv*. 2021;5(1):301-325.
8. National Hemophilia Foundation. MASAC (Medical and Scientific Advisory Council) recommendations regarding doses of clotting factor concentrate in the home (Revised June 7, 2016). MASAC Document #242. Adopted on September 3, 2020. Available at: <https://www.hemophilia.org/sites/default/files/document/files/242.pdf>. Accessed on August 11, 2025.