Reference number(s)
1952-A

Specialty Guideline Management
Wilate

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
Wilate	von Willebrand factor/coagulation factor VIII complex [human]

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]

- Wilate is indicated in children and adults 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 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

Compendial Uses[2,3,5]

Acquired von Willebrand Syndrome

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

Prescriber Specialties

Must be prescribed by or in consultation with a hematologist.

Coverage Criteria

Von Willebrand Disease[1,2,6]

Authorization of 12 months may be granted for members with VWD when either 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 B).
- Member has type 2B or type 3 VWD.

Acquired Von Willebrand Syndrome[2,3,5]

Authorization of 12 months may be granted for treatment of acquired von Willebrand syndrome.

Hemophilia A[1,9]

Authorization of 12 months may be granted for hemophilia A when the requested medication will be used for either of the following:

- Member has mild disease (see Appendix A) and has had an insufficient response to desmopressin or a documented clinical reason for not using desmopressin (see Appendix B).
- Member has moderate or severe disease (see Appendix A).

Continuation of Therapy

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

Appendix

Appendix A: Classification of Hemophilia by Clotting Factor Level (% Activity) and Bleeding Episodes[4]

Factor assay levels are required to determine the diagnosis and are of value in monitoring treatment response.

Severity	**Clotting Factory Level % activity**	**Bleeding Episodes**
Severe	<1%	Spontaneous bleeding episodes, predominantly into joints and muscles Severe bleeding with trauma, injury or surgery
Moderate	1% to 5%	Occasional spontaneous bleeding episodes Severe bleeding with trauma, injury or surgery
Mild	6% to 40%	Severe bleeding with serious injury, trauma or surgery

Appendix B: Clinical Reasons For Not Utilizing Desmopressin in Patients with Hemophilia A and Type 1, 2A, 2M and 2N VWD[6-9]

- 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)

References

1. Wilate [package insert]. Paramus, NJ: Octapharma USA Inc.; December 2023.
2. 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.
3. Tiede A, Rand J, Budde U, et al. How I treat the acquired von Willebrand syndrome. Blood. 2011;117(25):6777-85.

4. Srivastava A, Santagostino E, Dougall A, et al. WFH Guidelines for the Management of Hemophilia, 3rd edition. Haemophilia. 2020 Aug;26 Suppl 6:1-158.
5. Federici A, Budde U, Castaman G, Rand J, Tiede A. Current diagnostic and therapeutic approaches to patients with acquired von Willebrand syndrome: a 2013 update. Semin Thromb Hemost. 2013;39(2):191-201.
6. 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.
7. 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.
8. Stimate [package insert]. King of Prussia, PA: CSL Behring LLC; June 2021.
9. Leissinger C, Carcao M, Gill JC, et al. Desmopressin (DDAVP) in the management of patients with congenital bleeding disorders. Haemophilia. 2014;20:158-167.