Mass General Brigham
Health Plan

Wilate (von Willebrand factor/coagulation factor VII complex [human])
Effective 01/01/2026

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview

FDA-Approved Indication

1. Wilate is indicated in children and adults with von Willebrand Disease (VWD) for:
    a. On-demand treatment and control of bleeding episodes
    b. Perioperative management of bleeding
    c. Routine prophylaxis to reduce the frequency of bleeding episodes
2. Wilate is indicated in adolescents and adults with hemophilia A for:
    a. Routine prophylaxis to reduce the frequency of bleeding episodes
    b. On-demand treatment and control of bleeding episodes

Compendial Use

1. Acquired von Willebrand Syndrome

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

Coverage Guidelines

Authorization may be granted for members new to the plan within the past 90 days 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

Authorizations may be granted for members who meet all diagnosis-specific criteria:

Von Willebrand Disease

1. Requested medication is prescribed by or in consultation with a hematologist
2. Member meets ONE of the following:
    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)
    b. Member has type 2B or type 3 VWD

Acquired von Willebrand Syndrome

1. Requested medication is prescribed by or in consultation with a hematologist
2. Diagnosis of acquired von Willebrand syndrome

Hemophilia A

1. Requested medication is prescribed by or in consultation with a hematologist
2. Diagnosis of hemophilia A
3. Member meets ONE of the following:
    a. 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)
    b. Member has moderate or severe disease (see Appendix A).

Continuation of Therapy

Requests for reauthorization will be approved when the following criteria are met:

1. Member is experiencing benefit from therapy (e.g., reduced frequency or severity of bleeds).

Limitations

1. Initial approvals and reauthorizations will be granted for 12 months.

Appendix

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

Severity	Clotting Factor 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

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

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

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

References

1. 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.
2. Leissinger C, Carcao M, Gill JC, et al. Desmopressin (DDAVP) in the management of patients with congenital bleeding disorders. *Haemophilia*. 2014;20:158-167.
3. 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.
4. 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.
5. 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.
6. 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.
7. Stimate [package insert]. King of Prussia, PA: CSL Behring LLC; June 2021.
8. Tiede A, Rand J, Budde U, et al. How I treat the acquired von Willebrand syndrome. *Blood*. 2011;117(25):6777-85.
9. Wilate [package insert]. Hoboken, NJ: Octapharma USA Inc.; November 2024.

Review History

12/13/2023: Reviewed at Dec P&T, switched from SGM to Custom. Effective 1/1/2024
05/14/2025 – Reviewed and updated at May P&T. Updated background section to include supplemental indication of routine prophylaxis in VWD to reduce the frequency of bleeding episodes. No changes to clinical criteria. Effective 06/01/2025.
10/08/2025 – Reviewed at October P&T. Updated policy to indicate that it no longer applies to the medical benefit. Effective 01/01/2026.