AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Jivi	Page:	1 of 4
Effective Date:	4/23/2026	Last Review Date:	4/2026
Applies to:	☒Illinois ☒Maryland	☒Florida Kids ☒Pennsylvania Kids	☒New Jersey ☒Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Jivi under the patient's prescription drug benefit.

Description:

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.

Table: Factor VIII Concentrates and Covered Uses

Brand	Generic	FDA-Approved Indication
Extended Half-life Recombinant Factor VIII Concentrates		
Jivi	antihemophilic factor [recombinant], PEGylated-aucl	Hemophilia A

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

Applicable Drug List:

Jivi

Policy/Guideline:

Prescriber Specialty:
Must be prescribed by or in consultation with a hematologist.

Criteria for Initial Approval:

Hemophilia A
Authorization of 12 months of Jivi may be granted for treatment of hemophilia A when BOTH of the following criteria are met:

1. Member has previously received treatment for hemophilia A with a factor VIII product.
2. Member is ≥ 7 years of age.

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

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

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

Approval Duration and Quantity Restrictions:

Approval: 12 months

References:

1. Advate [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; March 2025.
2. Jivi [package insert]. Whippany, NJ: Bayer HealthCare LLC; May 2025.
3. Kogenate FS [package insert]. Whippany, NJ: Bayer HealthCare LLC; May 2016.
4. Kogenate FS with BIO-SET [package insert]. Whippany, NJ: Bayer HealthCare LLC; May 2016.
5. Kogenate FS with Vial Adapter [package insert]. Whippany, NJ: Bayer HealthCare LLC; December 2019.
6. Kovaltry [package insert]. Whippany, NJ: Bayer Healthcare LLC; December 2022.
7. Novoeight [package insert]. Plainsboro, NJ: Novo Nordisk Inc., July 2020.
8. Nuwiq [package insert]. Paramus, NJ: Octapharma USA, Inc., December 2024.
9. Recombinate with 5 mL Sterile Water for Injection using BAXAJECT II [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; March 2025.
10. Xyntha [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals LLC; July 2022.
11. Xyntha Solufuse [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals LLC; July 2022.
12. Adynovate [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; October 2025.

13. Afstyla [package insert]. Kankakee, IL: CSL Behring LLC.; June 2023.
14. Eloctate [package insert]. Waltham, MA: Bioverativ Therapeutics Inc.; May 2023.
15. Hemofil M [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; February 2025.
16. Alphanate [package insert]. Los Angeles, CA: Grifols Biologicals LLC; November 2022.
17. Humate-P [package insert]. Kankakee, IL: CSL Behring LLC; June 2020.
18. Koate [package insert]. Research Triangle Park, NC: Grifols Therapeutics LLC; January 2022.
19. Koate-DVI [package insert]. Research Triangle Park, NC: Grifols Therapeutics LLC; August 2012.
20. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed December 2, 2025.
21. 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.
22. Tiede A, Rand J, Budde U, et al. How I treat the acquired von Willebrand syndrome. Blood. 2011;117(25):6777-85.
23. 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.
24. Srivastava A, Santagostino E, Dougall A, et al. WFH Guidelines for the Management of Hemophilia, 3rd edition. Haemophilia. 2020;26 Suppl 6:1-158. doi:10.1111/hae.14046.
25. National Hemophilia Foundation. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Selected Disorders of the Coagulation System. Revised August 2023. MASAC Document #290. https://www.hemophilia.org/sites/default/files/document/files/MASAC-Products-Licensed.pdf. Accessed December 2, 2025.
26. 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 December 2, 2025.
27. Acquired hemophilia. World Federation of Hemophilia. http://www1.wfh.org/publications/files/pdf-1186.pdf. Accessed December 2, 2025.
28. Tiede A, Collins P, Knoebl P, et al. International recommendations on the diagnosis and treatment of acquired hemophilia A. Haematologica. 2020;105(7):1791-1801. doi:10.3324/haematol.2019.230771.
29. Franchini M, Mannucci PM. Acquired haemophilia A: a 2013 update. Thromb Haemost. 2013;110(6):1114-20.
30. National Hemophilia Foundation. Hemophilia A (Factor VIII Deficiency). Available at: http://www.hemophilia.org/NHFWeb/MainPgs/MainNHF.aspx?menuid=180&contentid=45&rptname=bleeding. Accessed December 2, 2025.
31. Stimate [package insert]. King of Prussia, PA: CSL Behring LLC; June 2021.
32. Leissinger C, Carcao M, Gill JC, et al. Desmopressin (DDAVP) in the management of patients with congenital bleeding disorders. Haemophilia. 2014;20:158-167.
33. Reding MT, NG HJ, Poulsen LH, et al. Safety and efficacy of BAY 94-9027, a prolonged-half-life factor VIII. Journal of thrombosis and Haemostasis. 2017; 15: 411-9.
34. Esperoct [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; July 2024.

35. Altuviiio [package insert]. Waltham, MA: Bioverativ Therapeutics Inc.; March 2025.