Factor VIII Concentrates – Hemophilia A
Effective 06/01/2021

Plan	☐ MassHealth ☒ MassHealth (PUF) ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy when filled through the pharmacy benefit.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Hemophilia A (factor VIII [factor 8] deficiency) and hemophilia B (factor IX [factor 9] deficiency) are X-linked inherited coagulation factor deficiencies that result in lifelong bleeding disorders. The availability of factor replacement products has dramatically improved care for individuals with these conditions. Factor VIII products are used to control and prevent bleeding episodes in adults and children with Hemophilia A, for perioperative management in adults and children with Hemophilia A, and for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children with Hemophilia A

Hemophilia A	
Recombinant Factor VIII Concentrates	
Advate antihemophilic factor [recombinant]	Novoeight antihemophilic factor [recombinant]
Afstyla antihemophilic factor [recombinant]	Nuwiq antihemophilic factor [recombinant]
	Recombinate antihemophilic factor [recombinant]
Kogenate FS antihemophilic factor [recombinant]	Xyntha antihemophilic factor [recombinant] *
Kovaltry antihemophilic factor [recombinant]	
Extended Half-life Recombinant Factor VIII Concentrate	
Adynovate antihemophilic factor [recombinant], PEGylated	Jivi antihemophilic factor [recombinant], PEGylated-aucl
Eloctate antihemophilic factor [recombinant], Fc fusion protein	Esperoct antihemophilic factor [recombinant], Glycopegylated-exei
Human Plasma-Derived Factor VIII Concentrates	
Hemofil M antihemophilic factor [human] monoclonal antibody purified	

Human Plasma-Derived Factor VIII Concentrates That Contain Von Willebrand Factor	
Humate-P antihemophilic factor/von Willebrand factor complex [human]	Alphanate antihemophilic factor/von Willebrand factor complex [human]
Koate antihemophilic factor [human]	

* Preferred Drug

Coverage Guidelines

Hemophilia A
Authorization may be granted for members who members new to AllWays Health Partners are currently receiving treatment with the requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted when ONE the following criteria are met, and documentation is provided:
1. 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).
2. Member has moderate or severe disease (see Appendix A).

Von Willebrand Disease (VWD)
Authorization of Alphanate, Humate-P, or Koate may be granted for treatment of VWD when ONE of the following criteria is met:
1. 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).
2. Member has type 2B or type 3 VWD.

Acquired Hemophilia A
Authorization of Kogenate FS, Advate, Alphanate, Hemofil M, Humate-P, Koate, Kogenate FS, Recombinate, or Xyntha* when used for the diagnosis of Acquired Hemophilia A.
* Preferred Drug

Acquired von Willebrand Syndrome
Authorization of Alphanate or Humate-P may be granted for treatment of acquired von Willebrand syndrome.

Continuation of Therapy
All members (including new members) requesting authorization for continuation must meet initial authorization criteria.

Limitations
Approvals will be granted for 36 months.

Appendices
Appendix A: Classification of Hemophilia by Clotting Factor (% activity) and Bleeding Episodes

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

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

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

References

1. Advate [package insert]. Lexington, MA: Baxalta US Inc.; December 2018.
2. Jivi [package insert]. Whippany, NJ: Bayer HealthCare LLC; August 2018.
3. Kogenate FS [package insert]. Whippany, NJ: Bayer HealthCare LLC; May 2016.
4. Kovaltry [package insert]. Whippany, NJ: Bayer Healthcare LLC; March 2016.
5. Novoeight [package insert]. Plainsboro, NJ: Novo Nordisk Inc., November 2018.
6. Nuwiq [package insert]. Hoboken, NJ: Octapharma USA, Inc., July 2017.
7. Xyntha [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals Inc.; August 2019.
8. Xyntha Solufuse [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals Inc.; August 2020.
9. Adynovate [package insert]. Lexington, MA: Baxalta US Inc.; May 2018.
10. Afstyla [package insert]. Marburg, Germany: CSL Behring GmbH. September 2017R.
11. Eloctate [package insert]. Waltham, MA: Bioverativ Therapeutics Inc.; September 2019.
12. Hemofil M [package insert]. Lexington, MA: Baxalta US Inc.; June 2018
13. Humate-P (antihemophilic factor/von Willebrand factor complex) [prescribing information]. Kankakee, IL: CSL Behring; September 2017
14. Recombinate (antihemophilic factor [recombinant]) [prescribing information]. Lexington MA: Baxalta US Inc; June 2018
15. Alphanate [package insert]. Los Angeles, CA: Grifols Biologicals Inc.; June 2018.
16. Koate [package insert]. Research Triangle Park, NC: Grifols Therapeutics Inc.; December 2018.
17. Koate-DVI [package insert]. Research Triangle Park, NC: Grifols Therapeutics Inc.; August 2012.
18. 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 12, 2019.

19. Peyvandi F, Mamaev A, Wang JD, et al. Phase 3 study of recombinant von Willebrand factor in patients with severe von Willebrand disease who are undergoing elective surgery. J Thromb Haemost 2019; 17:52
20. Escobar MA, Brewer A, Caviglia H, et al. Recommendations on multidisciplinary management of elective surgery in people with haemophilia. Haemophilia 2018; 24:693
21. Brand B, Gruppo R, Wynn TT, et al. Efficacy and safety of pegylated full-length recombinant factor VIII with extended half-life for perioperative haemostasis in haemophilia A patients. Haemophilia 2016; 22:e251
22. Mannucci PM. Treatment of Hemophilia - More Amazing Progress. N Engl J Med 2020; 383:1068
23. National Hemophilia Foundation. MASAC recommendations concerning products licensed for the treatment of hemophilia and other bleeding disorders. Revised April 2018. MASAC Document # 253. https://www.hemophilia.org/sites/default/files/document/files/masac253.pdf. Accessed December 12, 2019.
24. National Hemophilia Foundation. MASAC recommendations regarding the treatment of von Willebrand disease. Revised November 2016. MASAC Document #244
25. Tosetto A, Castaman G. How I treat type 2 variant forms of von Willebrand disease. Blood 2015; 125:907.. https://www.hemophilia.org/sites/default/files/document/files/masac244.pdf.Accessed December 12, 2019.
26. Acquired hemophilia. World Federation of Hemophilia. http://www1.wfh.org/publications/files/pdf-1186.pdf. Accessed December 12, 2019.
27. Huth-Kuhne A, Baudo F, Collins P, et al. International recommendations on the diagnosis and treatment of patients with acquired hemophilia A. *Haematologica*. 2009;94(4):566-75.
28. Franchini M, Mannucci PM. Acquired haemophilia A: a 2013 update. *Thromb Haemost*. 2013;110(6):1114-20.
29. 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 12, 2019.
30. Stimate [package insert]. King of Prussia, PA: CSL Behring LLC; September 2019.
31. Leissinger C, Carcao M, Gill JC, et al. Desmopressin (DDAVP) in the management of patients with congenital bleeding disorders. *Haemophilia*. 2014; 20:158-167.
32. 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.
33. Esperoct [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; October 2019.

Review History

11/18/2020 – Updated and reviewed at Nov P&T Mtg: Moved from SGM to custom template, Separated Comm/Exch vs. MassHealth; changed approval dates from indefinite to 36 months; Documented Xyntha as Preferred Drug
03/17/2021 – Updated and reviewed; Removed Monoclate-P and Helixate FS from criteria as products were discontinued. References updated. Effective 06/01/2021.

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