CarePartners of Connecticut MEDICARE ADVANTAGE

Medical Necessity Guidelines

Medical Benefit Drugs

Factor Products

Effective: December 1, 2023

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

☒ CarePartners of Connecticut Medicare Advantage HMO plans, Fax 617-673-0956

☒ CarePartners of Connecticut Medicare Advantage PPO plans, Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Hemophilia A (factor VIII [factor 8] deficiency) and hemophilia B (factor IX [factor 9] deficiency) are X-linked coagulation factor disorders associated with bleeding of variable severity, from life-threatening to clinically silent. The severity of bleeding manifestations in hemophilia generally correlates with the degree of the clotting factor deficiency. The primary clinical hallmarks of hemophilia are prolonged spontaneous and/or traumatic hemorrhages, most commonly within the musculoskeletal system and predominantly intra-articular bleeding into the large synovial joints. The aim of management of specific hemorrhages is to treat the bleed and prevent bleed recurrence, limit complications, and restore tissue and/or organ function to a pre-bleed state. The ideal is for patients to not experience any bleeds (i.e., achieve “zero” bleeds); therefore, all forms of prophylaxis provide superior benefits over episodic therapy. Prophylaxis in hemophilia consists of regular administration of therapeutic products aimed at maintaining hemostasis to prevent bleeding, especially joint hemorrhages, which would lead to arthropathy and disability. The severity of bleeding manifestations in hemophilia generally correlates with the degree of the clotting factor deficiency. For patients with hemophilia (clotting factor level <1% of normal) A or B with a severe phenotype (clotting factor level <1% of normal), it is recommended that such patients be on prophylaxis sufficient to prevent bleeds at all times. Prophylaxis should be individualized, taking into consideration patient bleeding phenotype, joint status, individual pharmacokinetics, and patient self assessment and preference. All forms of prophylaxis provide superior benefits over episodic therapy. Per the World Health Federation, in order to optimize treatment and make economically sound clinical decisions, objective evidence of both short and long-term outcomes of hemophilia treatment regimens is required. Frequency of bleeding (particularly joint and muscle bleeds) and response to treatment have been the most important indicators of the effectiveness of hemostatic therapy and the best surrogate predictors of long-term musculoskeletal outcomes.

von Willebrand disease (VWD) is a common, inherited bleeding disorder. Patients with VWD experience excessive mucocutaneous bleeding, including heavy menstrual bleeding, epistaxis, easy bruising, prolonged bleeding from minor wounds and the oral cavity, and gastrointestinal bleeding, as well as bleeding after dental work, childbirth, and surgery, with musculoskeletal bleeding also seen in the most severe cases. Treatment includes adjunctive therapies, such as tranexamic acid, and therapies that directly increase the levels of VWF, such as desmopressin and VWF concentrates. Treatment is individualized based on specific diagnosis, bleeding phenotype, and specific clinical context.

Antihemophilic Coagulation Factor VIII (Recombinant) agents

- Advate, Adynovate, Afstyla®, Eloctate®, Espercot®, Jivi®, Kovaltry®, Novoeight®, Nuwiq®, Obizur®, Recombinate, and Xyntha®

Antihemophilic Coagulation Factor VIII (Plasma-derived) agents

- Hemofil M, Koate® DVI, and Monoclate-P®

Antihemophilic Coagulation Factor VIII/von Willebrand factor Complex (Plasma-derived) agents

- Alphanate®, Humate-P®, and Wilate®

Coagulation Factor IX (Recombinant) agents

- Alprolix®, BeneFIX®, Idelvion®, Ixinity®, Rebinyn®, and Rixubis

Coagulation Factor IX (Plasma-derived) agents

- AlphaNine® SD and Mononine®

Factor IX Complex (Plasma-derived) agents

- Profilnine® SD

Coagulation Factor X (Plasma-derived) agent

- Coagadex®

Factor XIII Concentrate (Recombinant) agent

- Tretten®

Factor XIII Concentrate (Plasma-derived) agent

- Corifact®

Coagulation Factor VIIa (Recombinant) agent

- NovoSeven® RT, Sevenfact®

Anti-inhibitor Coagulant Complex (Plasma-derived) agent

- FEIBA NF

Von Willebrand factor (Recombinant) agent

- Vovendi

Clinical Guideline Coverage Criteria

Initial Authorization Criteria:

Factor Products (excluding Coagadex, Corifact, Tretten, and Vovendi)
The plan may authorize coverage of a Factor Product for Members when all of the following criteria are met:

1. Documented diagnosis of hemophilia A, hemophilia B, or von Willebrand disease

AND

2. Documentation of **one (1)** of the following:
    a. Treatment and/or management of acute bleeding in Members with severe hemophilia, and maintenance therapy as needed to maintain trough factor levels at 1% or greater
    b. Treatment and/or management of acute bleeding episodes for Members with mild hemophilia (factor levels > 5% and <30%) or moderate hemophilia (factor levels of 1% - 5%), such as bleeding episodes associated with surgery or trauma
    c. Treatment and/or management of acute bleeding in Members with von Willebrand disease, and in clinical situations in which patients with von Willebrand disease are at increased risk of bleeding (i.e., surgery or trauma)
    d. Treatment and/or management of significant menorrhagia in women with von Willebrand disease

Coagadex (Coagulation Factor X [Human])
The plan may authorize coverage of Coagadex for Members when the following criteria are met:

1. Documented diagnosis of hereditary Factor X (FX) deficiency

AND

2. Documentation of **one (1)** of the following:
    a. Use as on-demand treatment and control of bleeding episodes
    b. Use as perioperative management of bleeding in patients with mild hereditary Factor X deficiency

AND

3. The patient is at least 12 years of age

Corifact (Factor XIII Concentrate [Human])
The plan may authorize coverage of Corifact for Members when the following criteria are met:

1. Documented diagnosis of congenital Factor XIII (FXIII) deficiency

AND

2. Documentation of **one (1)** of the following:
    a. Use as routine prophylactic treatment of congenital FXIII deficiency in clinical situations in which Members are at increased risk of bleeding (i.e., surgery)
    b. Use as perioperative management of surgical bleeding

NovoSeven or NovoSeven RT (Coagulation Factor VIIa [recombinant])

In addition to the above Factor Products criteria, the plan may authorize coverage of NovoSeven or NovoSeven RT for Members when the following criteria are met:

1. Documented diagnosis of acquired hemophilia or congenital factor VII deficiency

AND

2. Documented use as treatment and/or management of acute bleeding episodes or in clinical situations in which patients are at increased risk of bleeding (e.g., surgery, trauma)

Tretten (Coagulation Factor XIII A-Subunit [Recombinant])

The plan may authorize coverage of Tretten for Members when all of the following criteria are met:

1. Documented diagnosis of congenital factor XIII A-subunit deficiency

AND

2. Documented use as routine prophylaxis of bleeding

Vonvendi (von Willebrand Factor [Recombinant])

The plan may authorize coverage of Vonvendi for Members when all of the following criteria are met:

1. Documented diagnosis of von Willebrand disease

AND

2. The patient is at least 18 years old

AND

3. Documentation why treatment with Alphanate, Humate-P, and Wilate is not clinically appropriate

Reauthorization Criteria:

The plan may authorize coverage of a Factor Product, Coagadex, Corifact, NovoSeven/NovoSeven RT, and Tretten for Members when all of the following criteria are met:

1. Documentation the Member has experienced a therapeutic response from therapy with the requested medication as defined by at least **one (1)** of the following:
    a. Reduced frequency of bleeds
    b. Reduced severity of bleeds

Limitations

- Coverage of Factor Products for routine prophylaxis to reduce the frequency of bleeding episodes and on-demand treatment and control of bleeding episodes will be authorized for 12 months.
- Coverage of Factor Products for perioperative management of bleeding will be authorized for three (3) months.
- Members new to the plan stable on a Factor Product should be reviewed against Reauthorization Criteria.

Codes

Table 1: HCPCS Codes

HCPCS Codes	Description
J7175	Injection, factor X, (human), 1 IU (Coagadex)
J7179	Injection, Von Willebrand Factor (recombinant), (Vonvendi), 1 IU
J7180	Injection, factor XIII (antihemophilic factor, human), 1 IU
J7181	Injection, factor XIII A-subunit, (recombinant), per IU
J7182	Injection, factor VIII, (antihemophilic factor, recombinant), (Novoeight), per IU
J7183	Injection, von Willebrand factor complex (human), Wilate, 1 IU
J7185	Injection, factor VIII (antihemophilic factor, recombinant) (Xyntha), per IU
J7186	Injection, antihemophilic factor VIII/Von Willebrand factor complex (human), per factor VIII I.U.
J7187	Injection, Von Willebrand factor complex (Humate-P), per IU
J7188	Injection, factor VIII (antihemophilic factor, recombinant), (Obizur), per IU

HCPCS Codes	Description
J7189	Factor VIIa (antihemophilic Factor, recombinant), per 1mcg
J7190	Factor VIII (antihemophilic factor [human]) per IU
J7192	Factor VIII (antihemophilic factor, recombinant) per IU, not otherwise specified
J7193	Factor IX (antihemophilic factor, purified, non-recombinant) per IU
J7194	Factor IX, complex, per IU
J7195	Factor IX (antihemophilic factor, recombinant) per IU
J7198	Anti-inhibitor, per IU
J7199	Hemophilia clotting factor, not otherwise classified
J7200	Injection, factor IX, (antihemophilic factor, recombinant), Rixubis, per IU
J7201	Injection, factor IX, Fc fusion protein (recombinant), Alprolix, per IU
J7202	Injection, factor IX, albumin fusion protein, (recombinant), Idelvion, 1 IU
J7203	Injection factor ix, (antihemophilic factor, recombinant), glycopegylated, (rebinyn), 1 iu
J7205	Injection, factor VIII, Fc fusion protein, (recombinant), per IU
J7207	Injection, factor VIII, (antihemophilic factor, recombinant), pegylated, 1 IU (Adynovate)
J7208	Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl, (jivi), 1 i.u
J7209	Injection, factor VIII, (antihemophilic factor, recombinant), (Nuwiq), 1 IU
J7210	Injection, factor VIII, (antihemophilic factor, recombinant), (Afstyla), 1 IU
J7211	Injection, factor VIII, (antihemophilic factor, recombinant), (Kovaltry), 1 IU
J7212	Factor viia (antihemophilic factor, recombinant)-jncw (sevenfact), 1 microgram
J7204	Injection, Factor VIII, antihemophilic factor (recombinant), (Esperoct), glycopegylated-exei, per IU

References

1. Advate [package insert]. Westlake Village, CA; Baxter Healthcare Corporation; December 2018.
2. Adynovate [package insert]. Westlake Village, CA; Baxalta US Inc; June 2021.
3. Alphanate [package insert]. Los Angeles, CA; Grifols Biologicals Inc.; March 2021.
4. AlphaNine SD [package insert]. Los Angeles, CA; Grifols Biologicals Inc.; March 2021.
5. Alprolix [package insert]. Cambridge Center, Cambridge, MA: Biogen Idec, Inc.; October 2020.
6. Astermark J, Donfield SM, DiMichele DM et al. A randomized comparison of bypassing agents in hemophilia complicated by an inhibitor: the FEIBA NovoSeven (FENCO) comparative study. *Blood*. 2007b; 109:546-51.
7. BeneFIX [package insert]. Philadelphia, PA; Wyeth Pharmaceuticals Inc.; September 2021.
8. Berntorp E. Von Willebrand disease. *Pediatr Blood Cancer.* 2013; 60 Suppl 1:S34-6.
9. Berntorp E, Astermark J, Baghaei F et al. Treatment of hemophilia A and B and von Willebrand's disease: summary and conclusions of a systematic review as part of a Swedish health-technology assessment. *Haemophilia*. 2012; 18:158-65.
10. Bickert B, Witmer C, Pruemer J. Coagulation disorders. In DiPiro JT, Talbert RL, Yee GC et al., eds. Pharmacotherapy: A Pathophysiologic Approach. 9th ed. New York: McGraw-Hill; 2014.
11. Bitting RL, Bent S, Yongmei L et al. The prognosis and treatment of acquired hemophilia: a systematic review and meta-analysis. *Blood Coagul Fibrinolysis*. 2009; 20:517-523.
12. Blanchette VS. Prophylaxis in the hemophilia population. *Haemophilia*. 2010; 16(Suppl 5):181- 188.
13. Bolton-Maggs PHB, Psai KJ. Haemophilias A and B. *Lancet*. 2003; 361:1801-09.
14. Brown DL, Kouides PA. Diagnosis and treatment of inherited factor X deficiency. *Haemophilia*. 2008 Nov;14(6):1176-82.
15. Case Management Resource Guide. Hemophilia. URL: cmrg.com/dnhemophilia.htm. Available from Internet. Accessed 2013 March 7.
16. Castaman G, Rodeghiero. Advances in the diagnosis and management of type 1 von Willebrand disease. Expert Rev. *Hemotol*. 2011; 4(1):95-106.
17. Centers for Disease Control and Prevention. Hemophilia. Data and statistics. Last updated July 8, 2015. URL: cdc.gov/ncbddd/hemophilia/data.html. Available from Internet. Accessed 2016 January 14.
18. Centers for Disease Control and Prevention. von Willebrand Disease. Data and statistics. Last updated March 14, 2014. URL: cdc.gov/ncbddd/hemophilia/data.html. Available from Internet. Accessed 2016 January 14.
19. Coagadex [package insert]. Durham, NC; Bio Products Laboratory USA, Inc.; November 2020.

20. Collins P, Faradji A, Morfini M et al. Efficacy and safety of secondary prophylactic vs. on-demand sucrose-formulated recombinant factor VIII treatment in adults with severe hemophilia A: results from a 13-month crossover study. *J Thromb Haemost*. 2011; 8:83-89.
21. Collins PW, Chalmers E, Hart DP et al. Diagnosis and treatment of factor VIII and IX inhibitors in congenital haemophilia: (4th edition). *Brit Journal of Haematology*. 2013; 160:153-170.
22. Corifact [package insert]. Marburg, Germany: CSL Behring: December 2019.
23. Dimichele DM, Hoots WK, Pipe SW et al. International workshop on immune tolerance induction: consensus recommendations. *Haemophilia*. 2007; 13(Suppl 1):1-22.
24. Eloctate [package insert]. Cambridge, MA: Biogen Idec Inc.; December 2020.
25. Espercot [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; 2019 November.
26. Federici AB, James P. Current management of patients with severe von Willebrand disease type 3: a 2012 update. *Acta Haematol.* 2012; 128(2):88-99.
27. FEIBA NF [package insert]. Westlake Village, CA; *Baxter Healthcare Corporation*; February 2020.
28. Feldman BM, Pai M, Rivard GE et al. Tailored prophylaxis in severe hemophilia A: interim results from the first 5 years of the Canadian Hemophilia Primary Prophylaxis Study. *J Thrombo Haemost*. 2006; 4: 1228-36.
29. Food and Drug Administration. FDA approves product to prevent bleeding in people with rare genetic defect. URL: fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm243856.htm. Available from Internet. Accessed 2011 May 31.
30. Franchini M, Frattini F, Crestani S, Bonfanti C. Haemophilia B: current pharmacotherapy and future directions. *Expert Opin Pharmacother*. 2012 Oct;13(14):2053-63.
31. Franchini M, Mannucci PM. Inhibitors of propagation of coagulation (factors VIII, IX and XI): a review of current therapeutic practice. *Br J Clin Pharmacol*. 2011 Oct; 72(4):553-62.
32. Giangrande P. Acquired hemophilia. 2012. URL: wfh.org/publications/files/pdf-1186.pdf. Available from Internet. Accessed 2016 January 14.
33. Girolami A, Scarparo P, Scandellari R, Allemand E. Congenital factor X deficiencies with a defect only or predominantly in the extrinsic or in the intrinsic system: a critical evaluation. *Am J Hematol*. 2008 Aug;83(8):668-71.
34. Gouw S, van der Born J, RODIN Study Group et al. Factor VIII products and inhibitor development in severe hemophilia A. *N Engl J Med*. 2013; 368(3):231-39.
35. Gringeri A. Lundin B, von Mackensen S et al. A randomized clinical trial of prophylaxis in children with hemophilia A (the ESPRIT study). *J Thromb Haemost*. 2011; 9:700-710.
36. Hemofil M [package insert]. Westlake Village, CA; Baxter Healthcare Corporation; June 2018.
37. Hsieh L, Nugent D. Factor XIII deficiency. *Haemophila* 2008; 14: 1190-1200.
38. Humate-P [package insert]. Kankakee, IL; CSL Behring LLC; June 2020.
39. Inbal A, Oldenburg J, Carcao M et al. Recombinant factor XIII: a safe and novel treatment for congenital factor XIII deficiency. *Blood*. 2012;119(22): 5111-5117.
40. Ixinity [package insert]. Winnipeg, Manitoba, Canada: Cangene Corporation; September 2021.
41. Jivi (antihemophilic factor [recombinant], PEGylated-aucl). ; Whippany, NJ: Bayer HealthCare LLC; 2018 August.
42. Kasper C. Registry of Clotting factor Concentrates. *Pharmacy Practice News Special Edition*. 2006; 33-41.
43. Kavakli K, Makris M, Zulfikar B et al. Home treatment of hemarthroses using a single dose regimen of recombinant activated factor VII in patients with hemophilia and inhibitors. A multi- centre, randomized, double-blind, cross-over trial. *Thromb Haemost*. 2006; 95:600-5.
44. Key NS, Negrier C. Coagulation factor concentrates: past, present, and future. *Lancet*. 2007; 370:439-48.
45. Koate DVI [package insert]. Research triangle Park, NC; Talecris Biotherapeutics, Inc.; 2012 August.
46. Kruse-Jarres R. Inhibitors: our greatest challenge. Can we minimize the incidence? *Haemophilia*. 2013; 1:2-7.
47. Kruse-Jarres R, St-Louise J, Greist A, et al. Treatment of serious bleeds with a B-domain deleted recombinant porcine sequence factor VIII (OBI-1) in patients with acquired hemophilia A: a prospective clinical trial. *Blood*. 2013; 122:21.
48. Kulkarni R, Karim FA, Glamocanin S et al. Results from a large multinational clinical trial (guardian 3) using prophylactic treatment with turoctocog alfa in pediatric patients with severe hemophilia A: safety, efficacy, and pharmacokinetics. *Haemophilia*. 2013; 19(5):698-705.
49. Lapecorella M, Mariani G. Factor VII deficiency: defining the clinical picture and optimizing therapeutic options. *Haemophilia*. 2008; 14:1170-1175.
50. Leissinger C, Gringeri A, Bulent A et al. Anti-inhibitor coagulant complex prophylaxis in hemophilia with inhibitors. *N Engl J Med*. 2013; 365(18):1684-92.
51. Lentz SR, Misgav M, Ozelo M et al. Results from a large multinational clinical trial (guardian 1) using prophylactic treatment with turoctocog alfa in adolescent and adult patients with severe hemophilia A: safety and efficacy. *Haemophilia*. 2013; 19(5):691-97.
52. Lillicrap D. von Willebrand disease: advances in pathogenetic understanding, diagnosis, and therapy. *American Society of*

Hematol. 2013; 2013(1):254-260.
53. Mahlangu J, Powell JS, Ragni MV et al. Phase 3 study of recombinant factor VIII Fc fusion protein in severe hemophilia A. *Blood*. 2014; 123(3):317-25.
54. Manco-Johnson MJ. Update on treatment regimens: prophylaxis versus on-demand therapy. *Semin Hematol*. 2003; 40(3 Suppl 3):3-9.
55. *Mannucci P. Treatment of von Willebrand's disease. N* Eng J Med. 2004; 321:683-94.
56. Meeks SL, Josephson CD. Should hemophilia treaters switch to albumin-free recombinant factor VIII concentrates. *Curr Opin Hematol*. 2006; 13:457-61.
57. Menegatti M, Peyvandi F. Factor X deficiency. *Semin Thromb Hemost*. 2009 Jun;35(4):407-15.
58. Monoclate P [package insert]. Kankakee, IL; CSL Behring; 2014 February.
59. Mononine [package insert]. Kankakee, IL; CSL Behring; July 2021.
60. Morfini M, Longo G, Messori A et al for the Recombinate study group. Pharmacokinetic properties of recombinant factor VIII compared with a monoclonally purified concentrate (Hemofil M). *Thromb Haemost*. 1992; 68(4):433-35.
61. National Hemophilia Foundation. Factor I deficiency. 2015b. URL: hemophilia.org/NHFWeb/MainPgs/MainNHF.aspx?menuid=184&contentid=44&rptname=bleeding. Available from Internet. Accessed 2016 January 14.
62. National Hemophilia Foundation. Factor XIII deficiency. URL: hemophilia.org/NHFWeb/MainPgs/MainNHF.aspx?menuid=71&contentid=58. Available from Internet. Accessed 2016 January 14.
63. National Hemophilia Foundation. Medical and Scientific Advisory Council. URL: hemophilia.org/NHFWeb/MainPgs/MainNHF.aspx?menuid=57&contentid=335. Available from Internet. Accessed 2013 March 7.
64. National Hemophilia Foundation's (NHF) Medical And Scientific Advisory Council (MASAC) Recommendations Concerning the Treatment of Hemophilia and Other Bleeding Disorders (Updated June 2015). URL: hemophilia.org/NHFWeb/MainPgs/MainNHF.aspx?menuid=57&contentid=693. Available from internet. Accessed 2016 January 14.
65. Novoeight [package insert]. Plainsboro, NJ; Novo Nordisk; October 2019.
66. NovoSeven RT [package insert]. Princeton, NJ; Novo Nordisk Inc.; July 2020.
67. Nuwiq [package insert]. Hoboken, NJ: Octapharma USA, Inc.; September 2020.
68. Obizur [package insert]. Westlake Village, CA: Baxter Healthcare Corporation; September 2021.
69. Oldenburg J. Optimal treatment strategies for hemophilia: achievements and limitations of current prophylactic regimens. *Blood*. 2015; 125(13):2038-2044.
70. Peyvandi F, Bolton-Maggs PH, Batorova A, De Moerloose P. Rare bleeding disorders. *Haemophilia.* 2012 Jul; 18 Suppl 4:148-53.
71. Peyvandi F, Klamroth R, Carcao M et al. Management of bleeding disorders in adults. *Haemophilia*. 2012 May; 18 Suppl 2:24-36.
72. Pipe SW. Recombinant clotting factors. *Thromb Haemost*. 2008; 99:840-50.
73. Poonnoose PM, Manigandan C, Thomas R et al. Functional independence score in hemophilia: a new performance-based instrument to measure disability. *Haemophilia*. 2005; 11:598-602.
74. Powell J, Pasi J, Ragni M et al. Phase 3 Study of Recombinant Factor IX Fc Fusion Protein in Hemophilia B. *N Engl J Med*. 2013; 369:2313-23.
75. Profilnine SD [package insert]. Los Angeles, CA; Grifols Biologicals Inc.; 2014 May.
76. Recombinate [package insert]. Westlake Village, CA; Baxter HealthCare Corporation; June 2018.
77. Rixubis [package insert]. Westlake Village, CA: Baxter Healthcare Corporation; June 2020.
78. Santagostino E. More than a decade of international experience with a pdFVIII/VWF concentrate in immune tolerance. *Haemophilia*. 2013; 9:8-11.
79. Sevenfact (coagulation factor VIIa [recombinant]-jncw) [prescribing information]. Louisville, KY: April 2020.
80. Shord S, Lindley C. Coagulation products and their uses. *Am J Health-Syst Pharm*. 2000; 57(15):1403-17.
81. Smith K, Lusher J, Cohen A et al. Initial clinical experience with a new pasteurized monoclonal antibody purified factor VIIIc. *Semin Hematol*. 1990; 27(2):25-9.
82. Tretten [package insert]. Plainsboro, NJ: Novo Nordisk A/S; June 2020.
83. Tziomalos K, Vakalopoulou S, Perifanis V et al. Treatment of congenital fibrinogen deficiency: overview and recent findings. *Vascular Health and Risk Management*. 2009; 5:843-848.
84. Varadi K, Negrier C, Berntorp E et al. Monitoring the bioavailability of FEIBA with a thrombin generation assay. *J Thromb Haemost*. 2003; 1:2374-80.

85. Vonvendi [package insert]. Westlake Village, CA: Baxalta US Inc.; January 2022.
86. Wilate [package insert]. Hoboken, NJ: Octapharma USA Inc.; March 2020.
87. Wong T, Recht M. Current options and new developments in the treatment of hemophilia. *Drugs*. 2011; 71(3):305-320.
88. World Federation of Hemophilia. Protocols for the treatment of hemophilia and von Willebrand disease. February 2018. URL: hog.org/publications/page/protocols-for-the-treatment-of- hemophilia-and-von-willebrand-disease-2. Available from Internet. Accessed 2019 January 23.
89. Xyntha [package insert]. Philadelphia, PA: Pfizer/Wyeth Pharmaceuticals Inc.; August 2020.
90. Xyntha SOLOFUSE [package insert]. Philadelphia, PA: Pfizer/Wyeth Pharmaceuticals Inc.; August 2020.
91. Young G, Shafer FE, Rojas P et al. Single 270 microg kg(-1)-dose rFVIIa vs. standard 90 microg kg(-1)-dose rFVIIa and APCC for home treatment of joint bleeds in haemophilia patients with inhibitors: a randomized comparison. *Haemophilia*. 2008; 14(2):287-94
92. Srivastava A, Santagostino E, Dougall A, et al. WFH Guidelines for the Management of Hemophilia, 3rd edition. Haemophilia. 2020: 26(Suppl 6): 1-158. https://doi.org/10.1111/hae.14046.
93. James PD, et al. ASH ISTH NHF WFH 2021 guidelines on the diagnosis of von Willebrand disease. Blood Adv (2021) 5 (1): 280–300.
94. Connell NT, et al. ASH ISTH NHF WFH 2021 guidelines on the management of von Willebrand disease. Blood Adv (2021) 5 (1): 301–325.

Approval And Revision History

September 12, 2023: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- November 2023: Administrative Updates: Rebranded from Tufts Health Unify to Tufts Health One Care for 2024 and administrative update in support of calendar year 2024 Medicare Advantage and PDP Final Rule.

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guidelines not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.