



<p>Hemophiliaⁱ</p> <p>Factor VIIa Factor VIII Factor IX</p> <p>Obizur</p> <p>Hemlibra</p>	<p>Factor replacement is authorized for Members who meet the following criteria when prescribed by hematology specialist:</p> <p>**Approve x 14 days for member with hemophilia A or B, or Von Willebrand disease and current serious or life-threatening bleed (central nervous system bleed, ocular bleeding, bleeding into hip, intra-abdominal bleeding, bleeding into neck or throat, iliopsoas bleeding, significant bleeding from trauma)</p> <p><u>Inherited Hemophilia A (Factor VIII deficiency):</u></p> <p>Requires attestation of less than 1% of normal factor VIII (less than 0.01 IU/ml) or documented history of 1 or more episodes of spontaneous bleeding into joints</p> <p>Routine bleeding prophylaxis, hemorrhage, perioperative bleeding:</p> <ul style="list-style-type: none"> • Advate, Afstyla, Helixate FS, Kogenate FS, Novoeight, Nuwiq, Eloctate, Adynovate, Hemofil M, Recombinate, Humate P, Koate, Monoclate P, Xyntha, Kovaltry, Alphanate <p><u>Hemophilia B (Factor IX deficiency)</u></p> <p>Requires attestation of less than 1% of normal factor IX (less than 0.01 IU/ml)) or documented history of 1 or more episodes of spontaneous bleeding into joints</p> <p>Perioperative bleeding, hemorrhage, routine bleeding prophylaxis</p> <ul style="list-style-type: none"> • Alprolix, Benefix, Idelvion, Ixinity, Rixubis, Alphanine, Mononine, Profilnine, Bebulin 	<p><u>Initial Approval:</u> 3 months</p> <p><u>Renewal:</u> 1 year</p> <p><u>Factors VIII and IX:</u> Requires attestation member has been screened for inhibitors since last approval <u>If inhibitor present:</u> Documentation or attestation of treatment plan to address inhibitors as appropriate, such as changing product, monitoring if transient inhibitor or low responder, OR if > 5 Bethesda units, increase dose and/or frequency for Immune Tolerance Induction, change to bypassing agent, and/or, addition of immunomodulator(s)</p>
---	---	--

Von-Willebrand disease:

Requires attestation of laboratory confirmed diagnosis, and history of bleeding (prolonged wound bleeding, post-surgical or dental bleeding, nosebleeds, menorrhagia, excessive bruising), or family history of bleeding or bleeding disorder)

- Vonvendi: adults 18 years of age and older
- Wilate, Humate P, Alphanate

Novoseven RT (Factor VIIa)

Treatment of hemorrhagic complications or prevention of bleeding in surgical or invasive procedures for members with one of the following Food and Drug Administration (FDA) approved indications:

- Acquired hemophilia
- Hemophilia A or B with Inhibitors
- Glanzman's thrombasthenia when refractory to platelet transfusions with or without antibodies to platelets
- Congenital Factor VII deficiency

Feiba (aPCC)

Treatment of hemorrhagic complications or prevention of bleeding in surgical or invasive procedures or routine prophylaxis in members with hemophilia A or hemophilia B with inhibitors

Obizur

- Adults with acquired Hemophilia A
- Documentation or attestation member does not have baseline anti-porcine factor VIII inhibitor titer of greater than 20 Bethesda Units (BU)

	<p>Hemlibra</p> <ul style="list-style-type: none"> • Prophylaxis for members with Hemophilia A with inhibitors not approved for treatment of acute bleeding • Attestation activated Prothrombin Complex 100u/kg/24 hours or greater will not be used concomitantly 	
--	---	--

Hemophilia Factor References:

1. Blanchette VS. Prophylaxis in the haemophilia population. *Haemophilia*. 2010;16:181-188.
2. Fischer K, Van der Boom JG, Molho P, Negrier C, Mauser-Bunschoten EP, Roosendaal G, et al. Prophylactic versus on-demand treatment strategies for severe haemophilia: a comparison of costs and long-term outcome. *Haemophilia*. 2002;8:745-752.
3. Hay CRM. Prophylaxis in adults with haemophilia. *Haemophilia*. 2007;13:10-15.
4. Manco-Johnson MJ, Abshire TC, Shapiro AD, Riske B, Hacker MR, Kilcoyne R, et al. Prophylaxis versus episodic treatment to prevent joint disease in boys with severe hemophilia. *N Eng J Med*. 2007;357:535-544.
5. National Hemophilia Foundation Medical and Scientific Advisory Council. MASAC recommendation concerning prophylaxis (regular administration of clotting factor concentrate to prevent bleeding), document #179. November 2007. <http://www.hemophilia.org/NHFWeb/Resource/StaticPages/menu0/menu5/menu57/masac179.pdf>. Accessed January 25, 2018.
6. Walsh CE, Valentino LA. Factor VIII prophylaxis for adult patients with severe haemophilia A: results of a US survey of attitudes and practices. *Haemophilia*. 2009;15:1014-1021.
7. Novoseven RT. [package insert]. Plainsboro, NJ: Novo Nordisk; revised July 2014.
8. FEIBA NF (Anti-Inhibitor Coagulant Complex). [package insert]. Westlake Village, CA: Baxter Healthcare Corporation; revised April 2017.
9. Guidelines for the management of hemophilia. 2nd ed. Montreal (Quebec): World Federation of Hemophilia; 2012; 1-74.
10. Medical and Scientific Advisory Council (MASAC). MASAC Recommendation Regarding the Use of Bypassing Agents in Patients with Hemophilia A or B and Inhibitors. MASAC Document #167. Adopted by the NHF Board of Directors on June 3, 2006. Accessed January 25, 2018. Available from <http://www.hemophilia.org/sites/default/files/document/files/167.pdf>
11. Hoots W.K., Shapiro A.D. (Aug 2015). Treatment of hemophilia. UpToDate. (D.H. Mahoney, J.S. Tirnauer, Eds.) Waltham, MA. Retrieved January 25, 2018, from http://www.uptodate.com/contents/treatment-of-hemophilia?source=search_result&search=hemophilia&selectedTitle=2%7E150
12. Hoots W.K., Shapiro A.D. (Aug 2015). Factor VIII and factor IX inhibitors in patients with hemophilia. UpToDate. (L.K. Leung, D.H. Mahoney, J.S. Tirnauer, Eds.) Waltham, MA. Retrieved August 27, 2015, from http://www.uptodate.com/contents/factor-viii-and-factor-ix-inhibitors-in-patients-with-hemophilia?source=search_result&search=hemophilia&selectedTitle=3%7E150
13. Medical and Scientific Advisory Council (MASAC) MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Other Bleeding Disorders. MASAC document #250. Accessed January 25, 2018. Available at <https://www.hemophilia.org/Researchers-Healthcare-Providers/Medical-and-Scientific-Advisory-Council-MASAC/MASAC-Recommendations/MASAC-Recommendations-Concerning-Products-Licensed-for-the-Treatment-of-Hemophilia-and-Other-Bleeding-Disorders>

-
14. Medical and Scientific Advisory Council (MASAC) Recommendations Regarding the Treatment of von Willebrand Disease. MASAC document #244. Accessed January 25, 2018 at <https://www.hemophilia.org/Researchers-Healthcare-Providers/Medical-and-Scientific-Advisory-Council-MASAC/MASAC-Recommendations/MASAC-Recommendations-Regarding-the-Treatment-of-von-Willebrand-Disease>
 15. Nichols WL, Hultin MB, James AH, et al. von Willebrand disease (VWD): evidence-based diagnosis and management guidelines, the National Heart, Lung, and Blood Institute (NHLBI) Expert Panel report (USA). *Haemophilia*. 2008; 14(2):171-232
 16. Hoots W.K., Shapiro A.D. (Jan 2018). Hemophilia A and B: Routine management including prophylaxis Accessed January 25, 2018. Available at https://www.uptodate-com.p.atsu.edu/contents/hemophilia-a-and-b-routine-management-including-prophylaxis?sectionName=Recombinant%20human%20factor%20VIII&anchor=H2244517956&source=see_link#H2244517956
 17. Valentino LA, Kempton CL, Kruse-Jarres R, Mathew P, Meeks SL, Reiss UM on Behalf of the International Immune Tolerance Induction Study Investigators. US Guidelines for immune tolerance induction in patients with haemophilia A and inhibitors. *Haemophilia* 2015. DOI: 10.1111/hae.12730.
 18. Medical-and-Scientific-Advisory-Council-MASAC/MASAC-Recommendations/MASAC-Recommendations-on-Standardized-Testing-and-Surveillance-for-Inhibitors-in-Patients-with-Hemophilia-A-and-B. Accessed January 25, 2018 at <https://www.hemophilia.org/Researchers-Healthcare-Providers/Medical-and-Scientific-Advisory-Council-MASAC/MASAC-Recommendations/MASAC-Recommendations-on-Standardized-Testing-and-Surveillance-for-Inhibitors-in-Patients-with-Hemophilia-A-and-B>
 19. Hemlibra [package insert]. South San Francisco, CA: Genentech, Inc.; 2017 Nov.
 20. Obizur (antihemophilic factor [recombinant], porcine sequence) package insert. Westlake Village, CA: Baxter Healthcare Corporation; 2017 Mar.