



MASSACHUSETTS

Blue Cross Blue Shield of Massachusetts is an independent  
Licensee of the Blue Cross and Blue Shield Association

## Pharmacy Medical Policy Human Anti-hemophilic Factor

### Table of Contents

- [Policy: Commercial](#)
- [Policy: Medicare](#)
- [Coding Information](#)
- [Policy History](#)
- [Information Pertaining to All Policies](#)
- [References](#)
- [Endnotes](#)
- [Forms](#)

### Policy Number: 360

BCBSA Reference Number: 2.01.13

### Related Policies

None

### Policy

#### Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

**Note:** All requests for indications listed and not listed on the medical policy guidelines may be submitted to BCBSMA Pharmacy Operations by completing the Prior Authorization Form on the last page of this document. Physicians may also submit requests for exceptions via the web using Express PAtH which can be found on the BCBSMA provider portal or directly on the web at <https://provider.express-path.com>.

This medication is not covered by the pharmacy benefit. It is covered by the Medical Benefit or as a Home Infusion Therapy.

We may cover:

#### Factor VII

- Coagulation factor indicated for the treatment of bleeding episodes and perioperative management in adults and children with hemophilia A or B with inhibitors, congenital Factor VII (FVII) deficiency, and Glanzmann's thrombasthenia with refractoriness to platelet transfusions, with or without antibodies to platelets & Treatment of bleeding episodes and perioperative management in adults with acquired hemophilia.

#### Factor VIII

- Human anti-hemophilic factor (AHF) maintenance therapy (prophylaxis) as needed to maintain trough levels at 1% or greater in patients with severe Hemophilia A (AHF activity less than 1% of normal).<sup>1</sup>
- Human anti-hemophilic factor (AHF) for treatment and/or management of bleeding episodes in surgical patients with mild hemophilia (AHF activity 5%-30%) or moderately severe hemophilia (AHF activity 1%-5%)<sup>2</sup>.

- Human anti-hemophilic factor (AHF) for treatment of moderate to severe Von Willebrand's disease in appropriate settings, for example, major surgery, trauma.<sup>2</sup>
- Human anti-hemophilic factor (AHF) for acquired factor VIII deficiency.<sup>3</sup>
- On-demand treatment and control of bleeding episodes

#### **Factor IX**

- Coagulation Factor IX concentrate indicated in adults and children with hemophilia B (congenital Factor IX deficiency) control and prevention of bleeding episodes, perioperative management, and routine prophylaxis control and prevention of bleeding episodes.
- Coagulation Factor IX [Recombinant] is an antihemophilic factor indicated in adults and children with hemophilia B for: Control and prevention of bleeding episodes, perioperative management, on-demand treatment, and routine prophylaxis.
- Blood coagulation factor replacement indicated for the urgent reversal of acquired coagulation factor deficiency induced by Vitamin K antagonist (VKA, e.g., warfarin) therapy in adult patients.

#### **Factor X**

- Plasma-derived human blood coagulation Factor X indicated in adults and children (aged 12 years and above) with hereditary Factor X deficiency for On-demand treatment and control of bleeding episodes
- Plasma-derived human blood coagulation Factor X indicated in adults and children (aged 12 years and above) with hereditary Factor X deficiency for Perioperative management of bleeding in patients with mild or moderate hereditary Factor X deficiency.

#### **Factor XIII**

- Routine prophylaxis for bleeding in patients with congenital factor XIII A-subunit deficiency.

#### **Fibrinogen Concentrate**

- Fibrinogen Concentrate indicated for the treatment of acute bleeding episodes in patients with congenital fibrinogen deficiency.

#### **Anti-Inhibitor**

- Anti-Inhibitor Coagulant Complex is indicated for the control of spontaneous bleeding episodes or to cover surgical interventions in hemophilia A and hemophilia B patients.

#### **Factor IXa- and factor X-directed antibody**

- Factor IXa- and factor X-directed antibodies are indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients with hemophilia A (congenital factor VIII deficiency) with or without factor VIII inhibitors.

We do not cover Human Anti-hemophilic Factor for conditions other than those listed above.

### **CPT Codes / HCPCS Codes / ICD Codes**

*Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.*

*Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.*

*The following codes are included below for informational purposes only; this is not an all-inclusive list.*

**The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:**

## CPT Codes

There is no specific CPT code for this service.

## HCPCS Codes

HCPCS codes:	Code Description
C9132	Factor IX : Prothrombin complex concentrate (human), per i.u. of Factor IX activity (Kcentra)
C9136	Injection, factor VIII, Fc fusion protein, (recombinant), per IU
C9399	Unclassified drugs or biologicals ( <b>NOC</b> ) (i.e. Hemlibra)
J7170	Injection, emicizumab-kxwh, 0.5 mg
J7175	Injection, factor x, (human), 1 i.u.
J7177	Injection, human fibrinogen concentrate (fibryga), 1 mg
J7179	Injection, Von Willebrand factor (recombinant), 1 i.u. vwf:rc0 (Vonvendi)
J7178	Injection, human fibrinogen concentrate, not otherwise specified, 1 mg
J7180	Injection, factor XIII (antihemophilic factor, human), 1 IU (Corifact)
J7181	Injection, factor XIII A-subunit, (recombinant), per IU (Tretten)
J7182	Injection, factor VIII, (antihemophilic factor, recombinant), (NovoEight), per IU
J7183	Injection, von Willebrand factor complex (human), 1 IU VWF (Wilate)
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 VWF:RCO
J7188	Injection, factor viii (antihemophilic factor, recombinant), (OBIZUR), per i.u.
J7189	Factor VIIa (antihemophilic factor, recombinant), per 1 microgram (Novoseven RT)
J7190	Factor VIII (antihemophilic factor [human]) per IU (Hemofil, Koate, Monoclate)
J7191	Factor VIII (antihemophilic factor [porcine]) per IU
J7192	Factor VIII (antihemophilic factor, recombinant) per IU, not otherwise specified (Advate, Helixate FS, Kogenate FS, Kovaltry, Recombinate)
J7193	Factor IX (antihemophilic factor, purified, non-recombinant) per IU (Alphanine, Mononine)
J7194	Factor IX, complex, per IU (Profilnine, Bebulin)
J7195	Factor IX (antihemophilic factor, recombinant) per IU (Benefix, Ixinity) ( <b>NOC</b> )
J7198	Anti-inhibitor, per IU ( <b>NOC</b> )
J7199	Hemophilia clotting factor, not otherwise classified ( <b>NOC</b> ) (Rebinyin)
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), 1 i.u. (Idelvion)
J7203	Injection factor ix, (antihemophilic factor, recombinant), glycopegylated, (rebinyin), 1 iu
J7205	Injection, factor viii fc fusion (recombinant), per iu (Eloctate)
J7207	Injection, factor viii, (antihemophilic factor, recombinant), pegylated, 1 i.u. (Adynovate)
J7209	Injection, factor viii, (antihemophilic factor, recombinant), 1 i.u. (NuwiQ)
J7210	Injection, factor viii, (antihemophilic factor, recombinant), (afstyla), 1 i.u.
J7211	Injection, factor viii, (antihemophilic factor, recombinant), (kovaltry), 1 i.u.
J3590	Unclassified biologics ( <b>NOC</b> ) (i.e. Hemlibra)
Q9975	Injection, Factor VIII, FC Fusion Protein (Recombinant), per iu

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT codes above if medical necessity criteria are met:

## ICD-10 Diagnosis Codes

ICD-10-CM diagnosis codes:	Code Description
D66	Hereditary Factor VIII Deficiency
D67	Hereditary Factor IX Deficiency
D68.0	Von Willebrand's Disease
D68.1	Hereditary Factor XI Deficiency
D68.311	Acquired Hemophilia

## Other Information

### Preferred Home Infusion Therapy Network

Referring providers are encouraged to use these preferred Home Infusion providers to obtain these medications.

#### Preferred Home Infusion Therapy Provider Contact Information:

Accredo<sup>SM</sup>

Phone: 1-877-988-0058

Website: [www.accredo.com](http://www.accredo.com)

Boston Hemophilia Center

*(only for members who receive medical care with their affiliated clinics at Boston Children's Hospital and Brigham and Women's Hospital)*

Phone: 1-617-355-6101 (Boston Children's Hospital/pediatric)

Website: [Boston Hemophilia Center](#)

Phone: 1-617-278-0707 (Brigham & Women's Hospital/adult)

Website: [Boston Hemophilia Center](#)

Caremark, LLC.

Phone: 1-866-846-3096

Website: [www.caremark.com](http://www.caremark.com)

Coram<sup>TM</sup> Specialty Infusion Services

Phone: 1-800-678-3442 (for hemophilia therapies only: 1-888-699-7440)

Website: [www.coramhc.com](http://www.coramhc.com)

Mass General Hemophilia and Thrombosis Treatment Center

Phone: 1-877-726-5130 (Adult Hemophilia Program)

Website: [www.massgeneral.org](http://www.massgeneral.org)

Phone: 1-617-726-2737 (Pediatric Hemophilia Program)

Website: [www.massgeneral.org](http://www.massgeneral.org)

## Individual Consideration

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique clinical circumstances may be considered in light of current scientific literature. Physicians may send relevant clinical information for individual patients for consideration to:

Blue Cross Blue Shield of Massachusetts  
 Pharmacy Operations Department  
 25 Technology Place  
 Hingham, MA 02043  
 Tel: 1-800-366-7778  
 Fax: 1-800-583-6289

### Managed Care Authorization Instructions

- Prior authorization is required for all out patient sites of service
- For all outpatient sites of service, physicians may fax or mail the attached form to the address above
- For all outpatient sites of service, physicians may also submit authorization requests via the web using Express PAtH which can be found on the BCBSMA provider portal or directly on the web at <https://provider.express-path.com>

### PPO and Indemnity Authorization Instructions

- Prior authorization **is** required when this medication is processed under the home infusion therapy benefit.
- Prior authorization **is not** required when this medication is purchased by the physician and administered in the office in accordance with this medical policy.
- Physicians may also fax or mail the attached form to the address above.
- Physicians may also submit authorization requests via the web using Express PAtH which can be found on the BCBSMA provider portal or directly on the web at <https://provider.express-path.com>

### Policy History

Date	Action
1/2019	Clarified coding changes.
11/2018	Updated to include a new indication for Factor X deficiency and new indication for Factor IXa- and factor X-directed antibody class.
7/2018	Clarified coding information.
5/2018	Updated to include Hemlibra.
1/2018	Clarified coding information.
6/2017	Updated address for Pharmacy Operations.
1/2017	Updated to add New HCPCS/CPT codes.
10/2016	Updated to include new HCPCS/CPT codes.
4/2016	Updated to include Factor X criteria & new CPT codes.
1/2016	Updated to include Obizur & Eloctate approved HCPCS codes.
6/2015	New Format instituted. Also updated to include Factor VII, Factor IX, Factor XIII, Fibrogen Concentrate, and Anti-Inhibitor to the policy plus add ICD10.
1/2013	Updated 1/2013 to include new FDA approved products AlphaNine® SD, Bebulin® VH, BeneFix®, Corifact® and Wilate®. Updated to add new HCPCS code C9133.
3/2011	Updated 3/11 to include preferred HIT provider contact information.
9/2010	Reviewed 9/2010 MPG-Hematology and Oncology, no changes in coverage were made.
1/2010	Updated, 1/1/2010 to add revised language to J7192 code.
10/2009	Updated 10/09 to reflect UM requirements.
9/2009	Updated 9/09 based on review of BCBSA #2.01.13, no change in policy statement.
10/2008	Reviewed 10/08 MPG – Hematology/Oncology, no changes in coverage were made.
9/2007	Reviewed 9/07 MPG hematology/oncology, no changes in coverage were made.
9/2006	Reviewed 9/06 MPG-Hematology/Oncology, no changes in coverage were made.
2/2006	Updated 2/06 to include preferred home infusion vendor for hemophilia.
9/2005	Reviewed 9/05 MPG Hematology/Oncology, no changes in coverage were made.
9/2003	Reviewed 9/03 MPG hematology/oncology, no changes in coverage were made.
9/2002	Reviewed 9/02 MPG hematology/oncology, no changes in coverage were made.

9/2001	Reviewed 9/01, no changes in coverage were made.
8/2000	Updated 8/00 to include coverage for acquired factor VIII deficiency, effective 2/01.
8/1999	Reviewed 8/99 to include coverage for human anti-hemophilic factor (AHF) for treatment and/or management of bleeding episodes in surgical patients with mild hemophilia (AHF activity 5%-30%) or moderately severe hemophilia (AHF activity 1%-5%) and for treatment of moderate to severe Von Willebrand's disease in appropriate settings, for example, major surgery, trauma.
8/1998	Updated 8/98 to clarify that Human Anti-hemophilic Factor is not covered for conditions other than Factor VIII deficiency. No changes in coverage were made. .
2/1997	Reviewed 2/97 following a literature search for 1996; additional scientific background information was added.
9/1995	Issued 9/95.

## References

1. Advate® [package insert] Westlake Village, CA: Baxter Healthcare Corporation.; April 2014.
2. Alphanate® [package insert]. Los Angeles, CA: Grifols Biologicals Inc.; June 2014.
3. Alphanate® SD [package insert]. Los Angeles, CA: Grifols Biologicals Inc.; Jan 2013.
4. Profilnine® [package insert]. Los Angeles, CA: Grifols Biologicals Inc.; Nov 2013.
5. Rixubis® [package insert] Westlake Village, CA: Baxter Healthcare Corporation.; Sept. 2014.
6. Alphanine® SD [package insert] . Los Angeles, CA: Grifols Biologicals Inc.; Jan 2004.
7. Alprolix™ [package insert] ]. Cambridge, MA: Biogen Idec, Inc.; Mar 2014.
8. Bebulin® [package insert] Westlake Village, CA: Baxter Healthcare Corporation.; July 2012.
9. Benefix® [package insert] Philadelphia, PA: Wyeth Pharmaceuticals Inc.; Mar 2012.
10. Cortifact® [package insert] Kankakee, IL: CSL Behring LLC.; Jan 2013.
11. Eloctate™ [package insert] . Cambridge, MA: Biogen Idec, Inc.; June 2014.
12. Feiba® [package insert] Westlake Village, CA: Baxter Healthcare Corporation.; Nov 2013.
13. Feiba® NF [package insert] Westlake Village, CA: Baxter Healthcare Corporation.; Feb 2011.
14. Feiba® VH [package insert] Westlake Village, CA: Baxter Healthcare Corporation.; Apr 2005
15. Helixate® FS [package insert] Kankakee, IL: CSL Behring LLC.; May 2014.
16. Hemofil® M [package insert] Westlake Village, CA: Baxter Healthcare Corporation.; April 2012.
17. Humate-P® [package insert] Kankakee, IL: CSL Behring LLC.; Aug 2013.
18. Kcentra® [package insert] Kankakee, IL: CSL Behring LLC.; Dec 2013.
19. Koate-DVI® [package insert]. Los Angeles, CA: Grifols Biologicals Inc.; Aug 2012.
20. Kogenate™ FS [package insert]. Tarrytown, NY: Bayer Healthcare.; May 2014.
21. Monoclate-P® [package insert] Kankakee, IL: ZLB Behring LLC.; Aug 2004
22. Mononine® [package insert] Kankakee, IL: CSL Behring LLC.; Feb 2013.
23. Novoseven® RT [package insert]. Bagsvaerd, Denmark: Novo Nordisk A/S.; May 2014.
24. Obizur® [package insert] Westlake Village, CA: Baxter Healthcare Corporation.; Oct 2014
25. Recombinate® [package insert] Westlake Village, CA: Baxter Healthcare Corporation.; Dec 2010.
26. RiaSTAP® [package insert] Kankakee, IL: CSL Behring LLC.; Dec 2011..
27. Tretten® [package insert]. Bagsvaerd, Denmark: Novo Nordisk A/S.; Apr 2014.
28. Wilate® [package insert] Hoboken, NJ: Octapharma USA Inc.; Aug 2010.
29. Xyntha® [package insert] Philadelphia, PA: Wyeth Pharmaceuticals Inc.; Oct 2014.
30. Idelvion® [package insert] Kankakee, IL: CSL Behring LLC.; Mar 2016.
31. NuwiQ® [package insert] Hoboken, NJ: Octapharma USA Inc.; Sept 2015.
32. VonVendi® [package insert] Westlake Village, CA: Baxalta US Inc.; Dec 2015.
33. Hemlibra® [package insert] South San Francisco, CA: Genentech, Inc.; Nov 2017.

## Endnotes

1. Based on the TEC (Technology Evaluation Center) 6/95 assessment of medical literature from 1970-1995, including the National Hemophilia Foundation recommendations from 1994. Reports by Aledort (1994, n=477), Manco-Johnson (1994, n=13), Nilsson (1992 n=87), Petrini (1991, n=14), Peterson (1981 n=59), and Schramm (1993, n=87) were reviewed. Joint damage and quality of life were addressed by most studies. Aronstam (1976, 1977, 1979) reported comparisons of multiple

dosing schedules for maintenance therapy. Maintenance therapy was shown to improve frequency of bleeding, orthopedic outcomes, hospitalizations, and school/work attendance primarily through reduction in joint bleeding. Success is best documented for primary prevention, but secondary prevention does appear to result in reduced further damage to joints.

2. A cost-effectiveness analysis entitled, *Episodic versus prophylactic infusions for hemophilia A: a cost-effectiveness analysis* was reported by Smith PS et al. in J Pediatrics 1996 Sep;129(3):424-31. This multi-center analysis collected charge data from 70 patients treated at 11 US hemophilia treatment centers. A model was constructed for hypothetical patients aged 3 to 50, and three different infusion models were considered. The prophylactic group would receive more drug, but sustain fewer bleeding episodes. The total cost of prophylactic care from ages 3 through 50 would equal the cost of episodic care only if the price of the concentrate were reduced by 50%. While prophylactic care markedly reduces bleeding events and should preserve joint function, a substantial cost is incurred..
3. Recommendations through Electric Blue Review from Peter Marks, MD Brigham and Women's Hospital, Boston, Massachusetts; Douglas Taylor, MD, Lawrence Memorial Hospital.
4. Recommendations through Electric Blue Review from Margot Kruskall, MD, Beth Israel Hospital.
5. Guidelines for the Management of Hemophilia -2nd Edition - Treatment Guidelines Working Group World Federation of Hemophilia (WFH)

**To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below:**

[http://www.bluecrossma.com/common/en\\_US/medical\\_policies/023%20E%20Form%20medication%20prior%20auth%20instruction%20prn.pdf](http://www.bluecrossma.com/common/en_US/medical_policies/023%20E%20Form%20medication%20prior%20auth%20instruction%20prn.pdf)

**Home Infusion Therapy**  
Prior Authorization Form



Please complete and fax with the physician's prescription to: (888) 641-5355. If the patient is a BCBSMA employee, please fax the form to: (617)246-4013.

Company name:		Contact Name:	
Phone #:		Provider #:	
Fax#		Address:	
Patient name:		Address:	
Patient_ID#:		DOB: ___/___/___	Diagnosis:
Prescribing Physician/addr:	_____		Telephone:
PCP name/address:	_____		Telephone:

Is this fax number 'secure' for PHI receipt/transmission per HIPAA requirements? (circle one) Yes No

Place of Service  Home  SNF  MD office  other (specify) \_\_\_\_\_

Primary Therapy

Primary drug name: \_\_\_\_\_ Approximate duration: \_\_\_/\_\_\_/\_\_\_ to \_\_\_/\_\_\_/\_\_\_  
 Dose: \_\_\_\_\_  
 Frequency: \_\_\_\_\_ Route of Administration: \_\_\_\_\_ pump: Y N

Other Therapy

Other drug name: \_\_\_\_\_ Approximate duration: \_\_\_/\_\_\_/\_\_\_ to \_\_\_/\_\_\_/\_\_\_  
 Dose: \_\_\_\_\_  
 Frequency: \_\_\_\_\_ Route of Administration: \_\_\_\_\_ pump: Y N

If this is a "drug only" authorization request, indicate other services the nursing agency is providing:

\_\_\_\_\_

Nursing provided by: \_\_\_\_\_ Contact: \_\_\_\_\_  
 Phone: \_\_\_\_\_ Fax: \_\_\_\_\_

Request for 7 Day Coverage: Date of occurrence: \_\_\_\_\_ request dates: \_\_\_\_\_  
 Occurrence type:  Hospitalization  Death  Change of Therapy

Physician signature: \_\_\_\_\_ Date: \_\_\_\_\_

**OR Copy of prescription REQUIRED with this request**