Pharmacy Medical Policy
Human Anti-hemophilic Factor

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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.

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

☒ Prior Authorization  ☐ Step Therapy  ☐ Quality Care Dosing

Pharmacy Operations:
Tel: 1-800-366-7778  Fax: 1-800-583-6289
Policy last updated 7/1/2023

Pharmacy (Rx) or Medical (MED) benefit coverage
☐ Rx  ☒ MED

To request for coverage: Physicians may call, fax, or mail the attached form (Formulary Exception/Prior Authorization form) to the address below.

Blue Cross Blue Shield of Massachusetts
Pharmacy Operations Department
25 Technology Place
Hingham, MA 02043

Individual Consideration: Policy for requests that do not meet clinical criteria of this policy, see section labeled Individual Consideration

Policy applies to Commercial Members:
• Managed Care (HMO and POS),
• PPO and Indemnity
• MEDEX with Rx plan
• Managed Major Medical with Custom BCBSMA Formulary
• Comprehensive Managed Major Medical with Custom BCBSMA Formulary
• Managed Blue for Seniors with Custom BCBSMA Formulary

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).¹
• 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%)².
• Human anti-hemophilic factor (AHF) for treatment of moderate to severe Von Willebrand’s disease in appropriate settings, for example, major surgery, trauma.²
• Human anti-hemophilic factor (AHF) for acquired factor VIII deficiency.³
• 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

Fibrogen 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

<table>
<thead>
<tr>
<th>HCPCS codes:</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C9132</td>
<td>Factor IX : Prothrombin complex concentrate (human), per i.u. of Factor IX activity (Kcentra)</td>
</tr>
<tr>
<td>C9399</td>
<td>Unclassified drugs or biologicals (NOC) (i.e. Hemlibra)</td>
</tr>
<tr>
<td>J7170</td>
<td>Injection, emicizumab-kxwh, 0.5 mg</td>
</tr>
<tr>
<td>J7175</td>
<td>Injection, factor x, (human), 1 i.u.(Coagadex)</td>
</tr>
<tr>
<td>J7177</td>
<td>Injection, human fibrinogen concentrate (fibryga), 1 mg</td>
</tr>
<tr>
<td>J7179</td>
<td>Injection, Von Willebrand factor (recombinant), 1 i.u. vwf:rco (Vonvendi)</td>
</tr>
<tr>
<td>J7178</td>
<td>Injection, human fibrinogen concentrate, not otherwise specified, 1 mg</td>
</tr>
<tr>
<td>J7180</td>
<td>Injection, factor XIII (antihemophilic factor, human), 1 IU (Corifact)</td>
</tr>
<tr>
<td>J7181</td>
<td>Injection, factor XIII A-subunit, (recombinant), per IU (Tretten)</td>
</tr>
<tr>
<td>J7182</td>
<td>Injection, factor VIII, (antihemophilic factor, recombinant), (NovoEight), per IU</td>
</tr>
<tr>
<td>J7183</td>
<td>Injection, von Willebrand factor complex (human), 1 IU VWF (Wilate)</td>
</tr>
<tr>
<td>J7185</td>
<td>Injection, factor VIII (antihemophilic factor, recombinant) (XYNTHA), per IU</td>
</tr>
<tr>
<td>J7186</td>
<td>Injection, antihemophilic factor VIII/von Willebrand factor complex (human), per factor VIII i.u.</td>
</tr>
<tr>
<td>J7187</td>
<td>Injection, von Willebrand factor complex (Humate-P), per IU VWF:RCO</td>
</tr>
<tr>
<td>J7188</td>
<td>Injection, factor viii (antihemophilic factor, recombinant), (OBIZUR), per i.u.</td>
</tr>
<tr>
<td>J7189</td>
<td>Factor VIIa (antihemophilic factor, recombinant), per 1 microgram (Novoseven RT, SevenFact)</td>
</tr>
<tr>
<td>J7190</td>
<td>Factor VIII (antihemophilic factor [human]) per IU (Hemofil, Koate, Monoclate)</td>
</tr>
<tr>
<td>J7191</td>
<td>Factor VIII (antihemophilic factor [porcine]) per IU</td>
</tr>
<tr>
<td>J7192</td>
<td>Factor VIII (antihemophilic factor, recombinant) per IU, not otherwise specified (Advate, Helixate FS, Kogenate FS, Kovaltry, Recombinate)</td>
</tr>
<tr>
<td>J7193</td>
<td>Factor IX (antihemophilic factor, purified, non-recombinant) per IU (Alphanine, Mononine)</td>
</tr>
<tr>
<td>J7194</td>
<td>Factor IX, complex, per IU (Profilnine, Bebulin)</td>
</tr>
<tr>
<td>J7195</td>
<td>Factor IX (antihemophilic factor, recombinant) per IU (Benefix, Ixinity) (NOC)</td>
</tr>
<tr>
<td>J7198</td>
<td>Anti-inhibitor, per IU (NOC)</td>
</tr>
<tr>
<td>J7199</td>
<td>Hemophilia clotting factor, not otherwise classified (NOC) (Rebinyin, Esperoct, or Altuviiio)</td>
</tr>
<tr>
<td>J7200</td>
<td>Injection, factor IX, (antihemophilic factor, recombinant), Rixubis, per IU</td>
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<tr>
<td>J7201</td>
<td>Injection, factor IX, FC fusion protein (recombinant) (Alprolix), per IU</td>
</tr>
<tr>
<td>J7202</td>
<td>Injection, factor ix, albumin fusion protein, (recombinant), 1 i.u. (Idelvion)</td>
</tr>
<tr>
<td>J7203</td>
<td>Injection factor ix, (antihemophilic factor, recombinant), glycopegylated, (rebinyn), 1 iu</td>
</tr>
<tr>
<td>J7205</td>
<td>Injection, factor viii fc fusion (recombinant), per iu (Eloctate)</td>
</tr>
<tr>
<td>J7207</td>
<td>Injection, factor viii, (antihemophilic factor, recombinant), pegylated, 1 i.u. (Adynovate)</td>
</tr>
<tr>
<td>J7208</td>
<td>Injection, factor viii, (antihemophilic factor, recombinant), pegylated-auc, (jivi), 1 i.u.</td>
</tr>
<tr>
<td>J7209</td>
<td>Injection, factor viii, (antihemophilic factor, recombinant), 1 i.u. (NuwiQ)</td>
</tr>
<tr>
<td>J7210</td>
<td>Injection, factor viii, (antihemophilic factor, recombinant), (afstyla), 1 i.u.</td>
</tr>
<tr>
<td>J7211</td>
<td>Injection, factor viii, (antihemophilic factor, recombinant), (kovaltry), 1 i.u.</td>
</tr>
<tr>
<td>J7212</td>
<td>Factor viii (antihemophilic factor, recombinant)-jncw (sevenfact), 1 microgram</td>
</tr>
<tr>
<td>J3590</td>
<td>Unclassified biologics (NOC) (i.e. Hemlibra)</td>
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</tbody>
</table>

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**
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)
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

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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</thead>
<tbody>
<tr>
<td>7/2023</td>
<td>Reformatted Policy.</td>
</tr>
<tr>
<td>1/2021</td>
<td>Coding information clarified.</td>
</tr>
<tr>
<td>10/2020</td>
<td>Removed deleted codes.</td>
</tr>
<tr>
<td>2/2020</td>
<td>Added Esperoct® to the policy.</td>
</tr>
<tr>
<td>7/2019</td>
<td>Clarified coding information.</td>
</tr>
<tr>
<td>1/2019</td>
<td>Clarified coding changes.</td>
</tr>
<tr>
<td>11/2018</td>
<td>Updated to include a new indication for Factor X deficiency and new indication for Factor IXa- and factor X-directed antibody class.</td>
</tr>
<tr>
<td>7/2018</td>
<td>Clarified coding information.</td>
</tr>
<tr>
<td>5/2018</td>
<td>Updated to include Hemlibra.</td>
</tr>
<tr>
<td>1/2018</td>
<td>Clarified coding information.</td>
</tr>
<tr>
<td>6/2017</td>
<td>Updated address for Pharmacy Operations.</td>
</tr>
<tr>
<td>1/2017</td>
<td>Updated to add New HCPCS/CPT codes.</td>
</tr>
<tr>
<td>10/2016</td>
<td>Updated to include new HCPCS/CPT codes.</td>
</tr>
<tr>
<td>4/2016</td>
<td>Updated to include Factor X criteria &amp; new CPT codes.</td>
</tr>
<tr>
<td>1/2016</td>
<td>Updated to include Obizur &amp; Eloctate approved HCPCS codes.</td>
</tr>
</tbody>
</table>
New Format instituted. Also updated to include Factor VII, Factor IX, Factor XIII, Fibrogen Concentrate, and Anti-Inhibitor to the policy plus add ICD10.

Updated 1/2013 to include new FDA approved products AlphaNine® SD, Bebulin® VH, Benefix®, Corifact® and Wilate®. Updated to add new HCPCS code C9133.

Updated 3/11 to include preferred HIT provider contact information.

Reviewed 9/2010 MPG-Hematology and Oncology, no changes in coverage were made.

Updated, 1/1/2010 to add revised language to J7192 code.

Updated 10/09 to reflect UM requirements.

Updated 9/09 based on review of BCBSA #2.01.13, no change in policy statement.

Reviewed 10/08 MPG – Hematology/Oncology, no changes in coverage were made.

Reviewed 9/07 MPG hematology/oncology, no changes in coverage were made.

Reviewed 9/06 MPG-Hematology/Oncology, no changes in coverage were made.

Updated 2/06 to include preferred home infusion vendor for hemophilia.

Reviewed 9/05 MPG Hematology/Oncology, no changes in coverage were made.

Reviewed 9/03 MPG hematology/oncology, no changes in coverage were made.

Reviewed 9/02 MPG hematology/oncology, no changes in coverage were made.

Reviewed 9/01, no changes in coverage were made.

Updated 8/00 to include coverage for acquired factor VIII deficiency, effective 2/01.

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.

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.

Reviewed 2/97 following a literature search for 1996; additional scientific background information was added.

Issued 9/95.

References


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.

To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below: http://www.bluecrossma.org/medical-policies/sites/q/files/csphs2091/files/acquiadam-assets/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.

<table>
<thead>
<tr>
<th>Company name:</th>
<th>Contact Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phone #:</td>
<td>Provider #:</td>
</tr>
<tr>
<td>Fax#</td>
<td>Address:</td>
</tr>
<tr>
<td>Patient name:</td>
<td>Address:</td>
</tr>
<tr>
<td>Patient_ID#:</td>
<td>DOB:<strong><strong>/</strong></strong>/____</td>
</tr>
</tbody>
</table>

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