Hemophilia Factor VIII
Extended Half-Life Products
Prior Authorization with Quantity Limit
Program Summary

This program applies to FlexRx Open, FlexRx Closed, GenRx Open, GenRx Closed, Health Insurance Marketplace, KeyRx, and FocusRx formularies.

This is a FlexRx standard and GenRx standard prior authorization.

The BCBS MN Step Therapy Supplement also applies to this program for all Commercial/HIM lines of business

Program specific denial language for prerequisite step therapy component does not apply. Instead, supplemental program denial language will apply.

### FDA APPROVED INDICATIONS AND DOSAGE

<table>
<thead>
<tr>
<th>Recombinant Factor VIII Concentrates</th>
<th>Indication</th>
<th>Dosing</th>
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<tbody>
<tr>
<td><strong>Adynovate®</strong> [Antihemophilic Factor (recombinant) PEGylated]</td>
<td>Children and adults with hemophilia A (congenital factor VIII deficiency) for:</td>
<td>One unit/kg body weight will raise the factor VIII level by 2% IU/dL</td>
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<tr>
<td></td>
<td>• On-demand treatment and control of bleeding episodes</td>
<td>• On-demand treatment and control of bleeding episodes and perioperative management: Estimated Increment of factor VIII (IU/dL or % of normal) = [Total Dose (IU)/body weight (kg)] x 2 (IU/dL per IU/kg) -Dose (IU) = Body Weight (kg) x Desired factor VIII Rise (IU/dL or % of Normal) x 0.5 (IU/kg per IU/dL)</td>
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<td></td>
<td>• Perioperative management</td>
<td>• Routine prophylaxis: Administer 40-50 IU/kg 2 times/week (starting dose of 55 IU/kg 2 times/week for patients &lt;12 years of age with a maximum of 70 IU/kg)</td>
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<td></td>
<td>• Routine prophylaxis to reduce the frequency of bleeding episodes</td>
<td>• Calculating Required Dose:</td>
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<tr>
<td></td>
<td>Limitation of Use:</td>
<td></td>
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<tr>
<td></td>
<td>Not indicated for von Willebrand disease.</td>
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<tr>
<td><strong>Afstyla®</strong> [antihemophilic Factor (recombinant), Single Chain]</td>
<td>Adults and children with hemophilia A (congenital Factor VIII deficiency) for:</td>
<td>One unit/kg body weight will raise the factor VIII level by 2 IU/dL</td>
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<tr>
<td><strong>Eloctate® [Antihemophilic Factor (recombinant), Fc Fusion Protein]</strong></td>
<td><strong>Adults and children with Hemophilia A (congenital Factor VIII deficiency) for:</strong></td>
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<td>• On-demand treatment and control of bleeding episodes</td>
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<td></td>
</tr>
<tr>
<td>• Routine prophylaxis to reduce the frequency of bleeding episodes</td>
<td>• Routine prophylaxis and perioperative management: Required Dose (IU) = Body Weight (kg) x Desired Factor VIII Rise (IU/dL or % of normal) x 0.5 (IU/kg per IU/dL)</td>
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<tr>
<td>• Perioperative management of bleeding</td>
<td>• Routine prophylaxis: ≥12 years: The recommended starting regimen is 20 to 50 IU/kg administered 2 to 3 times weekly</td>
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<tr>
<td>Limitation of Use: Not indicated for von Willebrand disease.</td>
<td>&lt;12 years: The recommended starting regimen is 30 to 50 IU/kg of administered 2 to 3 times weekly. More frequent or higher doses may be required in children &lt;12 years of age to account for the higher clearance in this age group</td>
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<tr>
<td></td>
<td>Adults and children with Hemophilia A (congenital Factor VIII deficiency) for:</td>
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<tr>
<td></td>
<td>• On-demand treatment and control of bleeding episodes</td>
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<td></td>
<td>Limitation of Use: Not indicated for von Willebrand disease.</td>
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</table>
### Jivi® [antihemophilic factor (recombinant), PEFylated-auc1]

- On-demand treatment and control of bleeding episodes
- Perioperative management of bleeding
- Routine prophylaxis to reduce the frequency of bleeding episodes

Limitations of use:
- Jivi is not indicated for use in children < 12 years of age due to a greater risk for hypersensitivity reactions
- Jivi is not indicated for use in previously untreated patients (PUPs)
- Jivi is not indicated for the treatment of von Willebrand disease

### Control of bleeding episodes and perioperative management:

Expected recovery: one unit per kilogram body weight of Jivi will increase the Factor VIII level by 2 international units per decilitr (IU/dL)

Required dose (IU) = body weight (kg) X desired Factor VIII rise (% of normal or IU/dL) X reciprocal of expected recovery (or observed recovery, if available)

### Routine prophylaxis:

The recommended initial regimen is 30-40 IU/kg twice weekly. Based on the bleeding episodes, the regimen may be adjusted to 45-60 IU/kg every 5 days. A regimen may be further individually adjusted to less or more frequent dosing.

### CLINICAL RATIONALE

Hemophilia A is an X-linked congenital bleeding disorder caused by a deficiency of coagulation factor VIII (FVIII), with a prevalence of approximately 1 in 5,000 births.\(^\text{16}\)

Bleeding disorder patients require treatment with clotting factor concentrates for prevention and treatment of bleeding. Prophylaxis is recommended as the optimal treatment modality for individuals with severe hemophilia as recommended by the Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation.\(^\text{18,20}\)

The MASAC suggests the number of doses required for provision of home therapy varies greatly and is dependent upon the type of hemophilia (FVIII, FIX), the level of severity (severe, moderate, mild), the presence of an inhibitor, the prescribed regimen (on-demand, prophylaxis, immune tolerance), the number of bleeding episodes experienced regardless of the prescribed regimen, individual pharmacokinetics, the products utilized, and the level of physical activity.\(^\text{15}\) For patients on prophylaxis, a minimum of one major dose and two minor doses should be available in addition to the prophylactic doses utilized monthly. For patients with severe or moderate hemophilia treated on-demand, the number of doses required to be
available at home may be based upon historical bleeding patterns, with at least one major and two minor doses added to assure a level of safety.17

A major dose is defined as a correction of clotting factor that achieves a level of 60-100+% clotting factor activity that is utilized to treat a bleeding episode that is deemed to require a higher hemostatic level such as occurs when bleeds occur in a target joint, or joint/area with a risk of significant sequelae (e.g., hip, head, GI bleed, etc.). A minor dose is defined as a correction of clotting factor that achieves a level of 30-60% clotting factor activity that is utilized to treat a bleeding episode that is deemed early, in a non-critical area and treatable with a lower hemostatic level (e.g., early non-major joints, small muscle bleeds, and skin/soft tissue, etc.).17

**Hemophilia A**

Recombinant FVIII (rFVIII) products are treatment of choice for hemophilia A as recommended by MASAC.20 Desmopressin acetate (DDAVP) should be used whenever possible for patients with mild hemophilia A.20,21 First generation rFVIII products contain animal and/or human plasma-derived proteins in the cell culture medium and in the final formulation vial (Recombinate). Second generation rFVIII contains animal or human plasma proteins in the culture medium but not in the final formulation (Helixate, Kogenate). Third/fourth generation rFVIII does not contain any animal or human plasma-derived proteins in the culture medium or in the final formulation vial.

In view of the demonstrated benefits of prophylaxis (regular/scheduled administration of clotting factor concentrate to prevent bleeding) begun at a young age in persons with hemophilia A or B, MASAC recommends that prophylaxis be considered optimal therapy for individuals with severe hemophilia A (factor VIII <1%). Prophylactic therapy should be instituted early (prior to the onset of frequent bleeding), with the aim of keeping the trough FVIII level above 1% between doses. Optimal dosing and frequency should be determined for each individual by appropriate laboratory monitoring. It is also recommended that individuals on prophylaxis have regular follow-up visits to evaluate joint status, to document any complications such as inhibitors, and to record any bleeding episodes that occur during prophylaxis.19

Extended half-life (EHL) factor VII agents were developed to extend the half-life and allow for longer infusion intervals. To extend the time in circulation, the factor molecule is fused with either polyethylene glycol (PEG) or the Fc portion of immunoglobulin G (IgG). This fusion allows for a half-life prolongation of 1.4 to 1.6 fold. The integration of EHL Factor VIII products into routine clinical practice continues to be evaluated.22

Guidelines for long acting recombinant formulations from the U.K. (2016) state many patient groups were excluded from clinical trials with these formulations (e.g., those with history of inhibitor formation) and there are limited data published on children. Previously untreated patients (PUPs) should not routinely use these formulations, except as part of a clinical trial. In severely affected minimally treated patients (MTPs), switching to a long acting agent can be considered after 50 exposure days (EDs) on a standard half-life clotting factor. In mild/moderate patients switching could be considered after fewer EDs. A limited half-life study should be performed, and patients should be tested for an inhibitor before and at approximately 10 EDs after switching product.21

The Canadian National Advisory Committee on blood and blood products lists specific criteria for starting an extended half-life factor product. Criteria for switching to an extended half-life product includes any of the following: evidence that peripheral infusion of standard factor VIII concentrates cannot be accomplished without the placement of a central line which could be avoided by using an extended half-life agent, a less than expected half-life of the standard
factor VIII concentrate with no evidence of inhibitor formation in the patient, to improve compliance with a prophylactic regimen of an extended half-life agent, to improve quality of life by using an extended half-life agent, to decrease frequent breakthrough bleeds or other rationale provided by the treating prescriber.\textsuperscript{22}

The National Hemophilia Foundation of America states that keeping an accurate treatment log is an essential part of managing bleeding disorders and should include the following information:

For bleeding episodes: 1) date and time of the bleed 2) location and severity of the bleed 3) how quickly the bleed was treated 4) the treatment used with brand name, expiration date, lot number, and number of units administered noted 5) additional steps taken to manage the bleed, and 6) level of pain. For infusions not in response to a bleed should include: 1) date and time of the infusion 2) the treatment used with brand name, expiration date, lot number, and number of units administered noted, and 3) reason for the infusion such as prophylaxis, pre-surgery, etc.\textsuperscript{19}

**Inhibitor Development**

Within the hemophilia A population, inhibitors to Factor VIII develop in approximately 15–30% of patients. Development of inhibitors usually occurs shortly after replacement therapy has been initiated. These inhibitors are antibodies (primarily IgG) directed against the specific deficient factor.\textsuperscript{23} Patients with inhibitors are at increased risk for difficult-to-control bleeding and complications; therefore, bleed prevention or reduction is of crucial importance. Repeated bleeding leads to inflammation, erosion, arthritis, and high rates of disability.

The current World Hemophilia Federation Guidelines for the Management of Hemophilia state that treatment of patients with inhibitors depends on several factors including the titer of the inhibitor, records of clinical response to product, and site and nature of the bleed. Patients with a low responding inhibitor or those with a high responding inhibitor but low titer may be treated with factor product at a much higher dose. With an inhibitor level \( \geq 5 \) BU, the likelihood that specific factor replacement will be effective in overwhelming the inhibitor without ultra-high dose continuous infusion therapy and alternative agents include bypassing agents such as recombinant factor VIIa and activated Prothrombin Complex Concentrate (aPCC) is extremely low.\textsuperscript{24} For high-titer inhibitors, MASAC recommends immune tolerance induction (ITI), also known as immune tolerance therapy (ITT) as the best option for inhibitor eradication or depending on type of inhibitor (low or high-responding), current titer of inhibitor, location of the bleed, and previous response, bypassing agents could be used.\textsuperscript{25}

ITT can take several months to several years to be effective. The Hemophilia Federation of America recommends that if success has within 33 months of beginning ITT and there is a lack of a 20% decrease in the inhibitor titer over a 6 month period, that it is considered a failure.\textsuperscript{26}

**Hemlibra (emicizumab-kxwh)**

A new therapeutic option for patients with hemophilia A is emicizumab-kxwh. At this time the Medical and Scientific Advisory Council (MASAC) recommends that providers discuss this therapeutic option with any patient with hemophilia A (with or without inhibitors). This discussion should include assessment of the risks and benefits of emicizumab-kxwh compared to their existing therapy. Emizizumab-kxwh is a recombinant, humanized, bispecific immunoglobulin G4 monoclonal antibody that substitutes for part of the cofactor function of activated factor VIII by bridging activated factor IX and Factor X. Factor VIII and emicizumab-kxwh are fundamentally different proteins and are regulated differently. These differences should also be a part of the discussion on treatment.\textsuperscript{27}

Despite its significant reduction in annualized bleeding rates at all doses for all age groups with or without inhibitors, emicizumab-kxwh is not recommend as first line therapy for patients with
hemophilia A with or without inhibitors. MASAC recommends for patients with hemophilia A with inhibitors be treated with immune tolerance therapy (ITT) in an attempt to overcome the inhibitors. For patients with hemophilia A without inhibitors Factor VIII products should be used initially.  

REFERENCES
1. Deleted.
5. Deleted.
6. Deleted.
8. Deleted
10. Deleted.
11. Deleted.
12. Deleted.
14. Deleted
15. Deleted.
20. MASAC recommendations concerning products licensed for the treatment of hemophilia and other bleeding disorders. Document #253. April 2018
27. Medical and Scientific Advisory Committee. MASAC Recommendation on the Use and Management of Emicizumab-kxwh (Hemlibra®) for Hemophilia A with and without Inhibitors. December 2018.
Hemophilia Factor VIII Extended Half-Life Products Prior Authorization with Quantity Limit

TARGET AGENTS
Extended Half-Life Agents
Adynovate®
Afstyla® (longer acting)
Eloctate®
Jivi®

**Extended Half-Life Agents**

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>GPI</th>
<th>Multisource Code</th>
<th>Quantity Limit</th>
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<td><strong>Adynovate</strong></td>
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**PRIOR AUTHORIZATION CRITERIA FOR APPROVAL**

**Initial Evaluation**

The requested agent will be approved for use when ALL of the following are met:

1. The patient has a diagnosis of hemophilia A, is currently bleeding, AND is out of medication (need immediate use)
   **OR**
2. ALL of the following:
   A. ONE of the following:
      i. There is documentation that the patient is currently being treated with the requested agent (starting on samples is not approvable)
      **OR**
      ii. The prescriber states the patient is currently being treated with the requested agent (starting on samples is not approvable) AND is at risk if therapy is changed
      **OR**
      iii. The patient has a diagnosis of hemophilia A and ALL of the following:
         1. If the patient has mild hemophilia A (i.e., factor VIII activity level between 5%-40%), ONE of the following:
            a. The patient has tried and had an inadequate response to desmopressin acetate (DDAVP)
            **OR**
            b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to therapy with desmopressin acetate (DDAVP)
            **AND**
            2. The requested agent is being prescribed for one of the following:
               a. Prophylaxis and the patient is not also using Hemlibra (emicizumab-kxwh)
               **OR**
               b. On-demand use for bleeds
               **OR**
               c. Peri-operative dosing
3. The prescriber has submitted documentation supporting ONE of the following:
   a. The patient has tried and failed to be adequately controlled on a standard half-life clotting factor agent after at least 50 exposure days
      OR
   b. The patient has poor venous access
      OR
   c. The patient failed to achieve an adequate trough level while on clinically optimal dose and frequency of a standard half-life clotting factor agent
      OR
   d. The prescriber has documented clinical reasoning as to why a standard half-life clotting factor agent cannot be utilized by the patient (convenience alone is not acceptable)

4. If the client has a preferred agent(s) then ONE of the following:
   a. The patient has tried and had an inadequate response to all of the preferred agent(s)
      OR
   b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to therapy with all of the preferred agent(s)

B. The prescriber is a specialist in the area of the patient’s diagnosis [e.g., prescriber working in a hemophilia treatment center (HTC), hematologist with hemophilia experience] or has consulted with a specialist in the area of the patient’s diagnosis

C. The prescriber has discussed with the patient the importance of maintaining an accurate treatment log

D. The patient does not have any FDA labeled contraindication(s) to the requested agent

E. The prescriber must provide the **actual prescribed dose** with ALL of the following supporting documentation
   i. Patient’s weight
   AND
   ii. Severity of the factor deficiency (i.e., severe is <1% factor activity, moderate is ≥1 to ≤5% factor activity, mild is >5 to 40% factor activity)
   AND
   iii. Inhibitor status
   AND
   iv. Intended use/regimen: prophylaxis, on-demand, peri-operative

F. ONE of the following:
   i. The patient is not currently using another Factor VIII agent (e.g. Advate, Adynovate, Afstyla, Elocetate, Helixate FS, Hemofil M, Jivi, Koate, Koate DVI, Kogenate FS, Kovaltry, Monoclate-P, NovoEight, Nuwiq, Recombinate, Xyntha, Xyntha Solofuse)
      OR
ii. The other Factor VIII agent will be discontinued prior to beginning therapy with the requested agent
   OR
iii. The prescriber has submitted documentation supporting the use of more than one unique Factor VIII agent
   AND
G. ONE of the following:
   i. The dose is within the FDA labeled dosing
   OR
   ii. The prescriber has provided clinical reasoning with supportive documentation for the higher dosing
   AND
H. The quantity (number of doses) requested is appropriate based on submitted supportive documentation and intended use (e.g., prophylaxis, on-demand)

**Length of Approval:**
Immediate Use: up to 2 weeks
On-demand: up to 3 months
Prophylaxis: up to 6 months

**Renewal Evaluation**
The requested agent will be approved when ALL of the following are met:

1. The patient has been previously approved through the Prime Therapeutics Prior Authorization process for the requested agent (if current request is for immediate use or if patient ONLY has previous approval(s) for immediate use, must use Initial Evaluation)
   AND
2. The prescriber is a specialist in the area of the patient’s diagnosis [e.g., prescriber working in a hemophilia treatment center (HTC), hematologist with hemophilia experience] or has consulted with a specialist in the area of the patient's diagnosis
   AND
3. If the patient is using the requested agent for prophylaxis, the patient will not use Hemlibra (emicizumab-kxwh) concomitantly with the requested agent
   AND
4. ONE of the following:
   A. The patient has shown clinical improvement (e.g. decreased frequency of infusions and/or decreased number of total units used including on-demand infusions)
   OR
   B. The patient failed to achieve an adequate trough level while on clinically optimal dose and frequency of a standard half-life clotting factor agent
   OR
   C. The prescriber has documented clinical reasoning as to why a standard half-life clotting factor cannot be utilized by the patient (convenience alone is not acceptable)
   AND
5. The patient does not have any FDA labeled contraindication(s) to the requested agent
   AND
6. The prescriber must provide the **actual prescribed dose** with ALL of the following supporting documentation
   A. Patient’s weight
   AND
B. Severity of the factor deficiency (i.e., severe is <1% factor activity, moderate is ≥1 to ≤5% factor activity, mild is >5 to 40% factor activity) AND

C. Inhibitor status AND

D. Intended use/regimen: prophylaxis, on-demand, peri-operative AND

7. ONE of the following:
   A. The prescriber communicated with the patient (via any means) regarding the frequency and severity of the patient’s bleeds and has verified that the patient does not have >5 on-demand doses on hand OR
   B. The prescriber has provided information in support of the patient having more than 5 on-demand doses on hand AND

8. ONE of the following:
   A. The patient is not currently using another Factor VIII agent (e.g. Advate, Adynovate, Afstyla, Eloctate, Helixate FS, Hemofil M, Jivi, Koate, Koate DVI, Kogenate FS, Kovaltry, Monoclate-P, NovoEight, Nuwiq, Recombinate, Xyntha, Xyntha Solofuse) OR
   B. The prescriber has submitted documentation supporting the use of more than one unique Factor VIII agent AND

9. ONE of the following:
   A. The dose is within the FDA labeled dosing OR
   B. The prescriber has provided clinical reasoning with supportive documentation for the higher dosing AND

10. The quantity (number of doses) requested is appropriate based on submitted supportive documentation and the intended use (e.g., prophylaxis, on-demand, peri-operative)

Length of Approval:  On-demand: up to 3 months
                     Prophylaxis: up to 12 months
Step Therapy Supplement

This program applies to FlexRx Closed, FlexRx Open, GenRx Closed, GenRx Open, Health Insurance Marketplace, FocusRx and KeyRx formularies.

Please note, this does not include or apply to quantity limit questions.

STEP THERAPY SUPPLEMENT

OBJECTIVE

The intent of the Step Therapy Supplement is to provide additional questions, to ensure compliance to MN Statute 62Q.184. These questions will apply if the step therapy component within a Prior Authorization or Step Therapy program is not able to be approved.

CONDITIONS FOR APPROVAL

The requested agent will be approved when ONE of the following are met:

1. The patient is currently being treated with the requested agent as indicated by ALL of the following:
   a. A statement by the prescriber that the patient is currently taking the requested agent
      AND
   b. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent
      AND
   c. The prescriber states that a change in therapy is expected to be ineffective or cause harm

OR

2. The patient’s medication history include the required prerequisite/preferred agent(s) as indicated by:
   a. Evidence of a paid claim(s) within the past 999 days
      OR
   b. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) in the past 999 days AND the required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event

OR

3. The prescriber has provided documentation that the required prerequisite/preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

Length of Approval: As per program specific criteria