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**Antihemophilic and Clotting Factors**

DRUG.00066

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*FHK- Florida Healthy Kids*
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III. For the treatment of bleeding episodes and peri-operative management in individuals with Glanzmann’s thrombasthenia and a documented refractoriness to platelet transfusions with or without antibodies to platelets.

Recombinant coagulation Factor VIIa (NovoSeven RT) may not be approved when the above criteria are not met and for all other indications.

Note: NovoSeven, NovoSeven RT [coagulation Factor VIIa (recombinant)] has a black box warning for serious arterial and venous thrombotic events following administration. Individuals should be monitored for signs and symptoms of activation of the coagulation system and for thrombosis.

Antihemophilic factor (factor VIII) Human plasma-derived (HEMOFIL M, Koate-DVI, Monoclate-P)

Requests for antihemophilic factor (Factor VIII) human plasma-derived agents (HEMOFIL M, Koate-DVI, Monoclate-P) may be approved for the following:

I. For the treatment of bleeding episodes in an individual with hemophilia A and factor VIII deficiency. OR
II. As routine prophylaxis to prevent or reduce the frequency of bleeding episodes when the following criteria are met:
   A. Individual has severe hemophilia A (defined as less than 1 International Unit per deciliter [IU/dL] or 1% endogenous Factor VIII); OR
   B. Individual has mild to moderate hemophilia A (defined as endogenous Factor VIII less than 40 IU/dL [less than 40%], but greater than or equal to 1 IU); AND
   C. When the individual has documented history of one of the following:
      1. 1 or more episodes of spontaneous bleeding into joint; OR
      2. 1 or more episodes of spontaneous bleeding into the central nervous system; OR
      3. 4 or more episodes of soft tissue bleeding in an 8 week period.

Requests for antihemophilic factor (Factor VIII) human plasma-derived agents (Koate-DVI, Monoclate-P) may be approved for the following:

I. As peri-procedural management for surgical, invasive or interventional radiology procedures in an individual with hemophilia A and factor VIII deficiency.

Antihemophilic factor (Factor VIII) human plasma-derived agents (HEMOFIL M, Koate-DVI, Monoclate-P) may not be approved when the above criteria are not met including, but not limited to treatment of individuals with von Willebrand disease (VWD).

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Requests for Antihemophilic factor (Factor VIII) recombinant agents (ADVATE, Afstyla, Helixate FS, Kogenate FS, Kovaltry, Novoeight, Nuwiq, RECOMBINATE, Xyntha) may be approved for the following:

I. For the treatment of bleeding episodes in an individual with hemophilia A and factor VIII deficiency; OR

II. For the treatment of bleeding episodes in an individual with von Willebrand disease (VWD) when the following criteria are met:
   A. Antihemophilic Factor VIII Recombinant is used in combination with recombinant von Willebrand factor, when medically necessary as per Vonvendi criteria below; AND
   B. Baseline factor VIII levels are less than 40 IU/dL [less than 40%] or are unknown.

III. As peri-procedural management for surgical, invasive or interventional radiology procedures for an individual with hemophilia A and Factor VIII deficiency.

Requests for Antihemophilic Factor VIII Recombinant (ADVATE, Afstyla, Helixate FS, Kovaltry, Novoeight, Nuwiq) may be approved as routine prophylaxis to prevent or reduce the frequency of bleeding episodes when the following criteria are met (I alone OR II&III):

I. Individual has severe hemophilia A (defined as less than 1 International Unit per deciliter [IU/dL] or 1% endogenous Factor VIII); OR

II. Individual has mild to moderate hemophilia A (defined as endogenous Factor VIII less than 40 IU/dL [less than 40%], but greater than or equal to 1 IU); AND

III. When the individual has documented history of one of the following:
   A. 1 or more episodes of spontaneous bleeding into joint; OR
   B. 1 or more episodes of spontaneous bleeding into the central nervous system; OR
   C. 4 or more episodes of soft tissue bleeding in an 8 week period.

Requests for Antihemophilic Factor VIII Recombinant (Helixate FS, Kogenate FS) may be approved for the following:

I. As routine prophylaxis for children (age 0-16 years) with hemophilia A and factor VIII deficiency to reduce the risk of joint damage in those without pre-existing joint damage.

Requests for Antihemophilic Factor VIII Recombinant (Recombinate) may be approved for the following:

I. As treatment of individuals with acquired Factor VIII inhibitors not exceeding 10 Bethesda Unit (BU) per milliliter (mL).

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Antihemophilic Factor VIII Recombinate (ADAVATE, Helixate FS, Kogenate, Kovaltry, Novoeight, Nuwiq, Recombinate, Xyntha) may not be approved when the above criteria are not met and for all other indications.

**Antihemophilic Factor (factor VIII) Recombinant, pegylated (Adynovate)**

Requests for Antihemophilic Factor (factor VIII) Recombinant, pegylated may be approved for the following:

I. Individuals with severe hemophilia A (congenital factor VIII deficiency); AND
   A. Individual has less than 1 International Unit per deciliter (IU/dL) (less than 1%) endogenous factor VIII; AND
   B. Use is planned for one of the following indications:
      1. Control and prevention of acute bleeding episodes; OR
      2. Perioperative management; OR
      3. Routine prophylaxis to prevent or reduce the frequency of bleeding episodes.
   OR

II. Individuals with mild to moderate hemophilia A (congenital factor VIII deficiency); AND
   A. Individual has endogenous factor VIII level less than 40 IU/dl (less than 40%) but greater than or equal to 1 IU/dl; AND
   B. Use is planned for one of the following indications:
      1. Control of acute bleeding episodes; OR
      2. Perioperative management; OR
      3. Routine prophylaxis to prevent or reduce the frequency of bleeding episodes when the member has documented history of one of the following:
         a. 1 or more episodes of spontaneous bleeding into joint; OR
         b. 1 or more episodes of spontaneous bleeding into the central nervous system; OR
         c. 4 or more episodes of soft tissue bleeding in an 8 week period.

Requests for Antihemophilic Factor (factor VIII) Recombinant, pegylated may not be approved when the above criteria are not met and for all other indications including, but not limited to treatment of individuals with VWD.

**Antihemophilic Factor Recombinant, Fc Fusion Protein (Eloctate)**

Requests for Antihemophilic Factor Recombinant, Fc Fusion Protein ([rFViiiFc]) may be approved for the following:

I. Individual has severe hemophilia A (congenital Factor VIII deficiency); AND

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Requests for Antihemophilic Factor VIII/von Willebrand Factor Complex (Alphanate, Humate-P, Wilate) may be approved as treatment for individuals with von Willebrand disease when the following criteria are met (I alone OR II & III):

I. VWD is severe; OR
II. VWD is mild to moderate and use of desmopressin is known or suspected to be inadequate; AND
III. Individual is being treated for either:
   A. Spontaneous or trauma-induced bleeding episodes; OR
   B. Peri-procedural management for surgical, invasive or interventional radiology procedures.

Requests for Antihemophilic Factor VIII/von Willebrand Factor Complex (Alphanate, Humate-P) may be approved for the following:

I. For treatment of bleeding episodes in an individual with hemophilia A and Factor VIII deficiency; OR
II. As routine prophylaxis to prevent or reduce the frequency of bleeding episodes when the following criteria are met:
   A. Individual has severe hemophilia A (defined as less than 1 International Unit per deciliter [IU/dL] or 1% endogenous Factor VIII); OR
   B. Individual has mild to moderate hemophilia A (defined as endogenous Factor VIII less than 40 IU/dL [less than 40%], but greater than or equal to 1 IU); AND
   C. When the individual has documented history of one of the following:
      1. 1 or more episodes of spontaneous bleeding into joint; OR
      2. 1 or more episodes of spontaneous bleeding into the central nervous system; OR
      3. 4 or more episodes of soft tissue bleeding in an 8 week period.

Requests for Antihemophilic Factor VIII/von Willebrand Factor Complex (Alphanate) may be approved for the following:

I. For treatment of bleeding episodes in an individual with acquired Factor VIII deficiency.

Antihemophilic Factor/von Willebrand Factor Complex (Alphanate, Humate-P, Wilate) may not be approved when the above criteria are not met and for any of the following:

I. All other indications including, but not limited to prophylaxis therapy in individuals with VWD.
II. Alphanate for individuals with severe VWD (Type 3) undergoing major surgery.

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Factor IX Complex, Human plasma-derived (Bebulin, Profilnine SD)

Requests for Human plasma-derived Factor IX complex (Bebulin, Profilnine SD) may be approved for the following:

I. For treatment of bleeding episodes in an individual with hemophilia B (congenital factor IX deficiency or Christmas disease); OR

II. As routine prophylaxis to prevent or reduce the frequency of bleeding episodes when the following criteria are met:
   A. Individual has severe hemophilia B (defined as less than 1 IU/dL or 1% endogenous Factor IX); OR
   B. Individual has mild to moderate hemophilia B (defined as endogenous Factor IX less than 40 IU/dL [less than 40%], but greater than or equal to 1 IU/dL); AND
   C. When the member has documented history of one of the following:
      1. 1 or more episodes of spontaneous bleeding into joint; OR
      2. 1 or more episodes of spontaneous bleeding into the central nervous system; OR
      3. 4 or more episodes of soft tissue bleeding in an 8 week period.

Human plasma-derived Factor IX complex (Bebulin, Profilnine SD) may not be approved when the above criteria are not met and for all other indications including, but not limited to use for treatment of individuals with Factor VII deficiency.

Factor IX Recombinant (Benefix, Ixinity, RIXUBIS)

Requests for Recombinant coagulation Factor IX (Benefix, RIXUBUS) may be approved to treat individuals with hemophilia B (congenital factor IX deficiency or Christmas disease) when the following criteria are met:

I. To treat bleeding episodes; OR

II. For peri-procedural management for surgical, invasive or interventional radiology procedures.

Requests for Recombinant coagulation Factor IX (Benefix, RIXUBIS) may be approved as routine prophylaxis to prevent or reduce the frequency of bleeding episodes when the following criteria are met (I alone OR II & III):

I. Individual has severe hemophilia B (defined as less than 1 IU/dL or 1% endogenous Factor IX); OR

II. Individual has mild to moderate hemophilia B (defined as endogenous Factor IX less than 40 IU/dL [less than 40%], but greater than or equal to 1 IU/dL); AND

III. When the member has documented history of one of the following:

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2. Peri-procedural management for surgical, invasive or interventional radiology procedures; OR

3. Routine prophylaxis to prevent or reduce the frequency of bleeding episodes when the member has documented history of one of the following:
   a. 1 or more episodes of spontaneous bleeding into joint; OR
   b. 1 or more episodes of spontaneous bleeding into the central nervous system; OR
   c. 4 or more episodes of soft tissue bleeding in an 8 week period.

Requests for Recombinant coagulation Factor IX, Fc Fusion [rFIXFc] may not be approved for induction of immune tolerance in individuals with hemophilia B or when the criteria are not met, and for all other indications.

**Coagulation Factor X, Human plasma-derived (Coagadex)**

Requests for Human plasma derived coagulation Factor X (Coagadex) may be approved for individuals aged 12 years or older when the following criteria are met:

I. Individual has severe or moderate hereditary Factor X deficiency (defined as less than 5 International Unit per deciliter (IU/dl) or 5% endogenous Factor X) and the factor is to be used for the treatment of bleeding episodes; OR

II. Individual has mild hereditary Factor X deficiency (defined as greater than or equal to 5 International Unit per deciliter (IU/dl) or 5% endogenous Factor X) and the factor is to be used for peri-procedural management for surgical, invasive or interventional radiology procedures.

Human plasma derived coagulation Factor X (Coagadex) may **not be approved** when the above criteria are not met and for all other indications, including but not limited to perioperative management of bleeding in major surgery in individuals with moderate and severe hereditary Factor X deficiency.

**Factor XIII (Corifact, TRETEN)**

Requests for Human plasma-derived concentrate Factor XIII (Corifact) **may be approved** for individuals with Factor XIII deficiency for the following indications:

I. As routine prophylactic treatment to prevent or reduce the frequency of bleeding episodes; OR

II. Peri-procedural management for surgical, invasive or interventional radiology procedures.

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Requests for Recombinant coagulation Factor XIII A-Subunit (TRETTO) may be approved for the following:

I. As routine prophylaxis for bleeding in individuals with congenital Factor XIII A-subunit deficiency.

Coagulation Factor XIII (Corifact, TRETTO) may not be approved when the above criteria are not met and for all other indications including, but not limited to treatment of individuals with congenital Factor XIII B-subunit deficiency.

**Fibrinogen Concentrate, Human plasma-derived (RiaSTAP)**

Requests for Human plasma-derived fibrinogen concentrate (RiaSTAP) may be approved for the following:

I. For the treatment of acute bleeding episodes in individuals with congenital fibrinogen deficiency (that is, afibrinogenemia or hypofibrinogenemia).

Human plasma-derived fibrinogen concentrate (RiaSTAP) may not be approved when the above criteria are not met and for all other indications including, but not limited to treatment of individuals with dysfibrinogenemia.

**State Specific Mandates**

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<th>State Name</th>
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**Key References:**


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