TRUECARE

PHARMACY POLICY STATEMENT
Mississippi Medicaid

DRUG NAME	Hemophilia and Other Clotting Disorders
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Hemophilia is the most common severe hereditary hemorrhagic disorder. Both hemophilia A and B result from factor VIII and factor IX protein deficiency or dysfunction, respectively, and is characterized by prolonged and excessive bleeding after minor trauma or sometimes even spontaneously. Hemophilia A is more common than hemophilia B, representing 80–85% of the total hemophilia population.

Hemophilia and Other Clotting Disorders will be considered for coverage when the following criteria are met:

Hemophilia A (Factor VIII Deficiency)

For **initial** authorization:

1. Member has diagnosis of Hemophilia A (congenital Factor VIII deficiency); AND
2. For Jivi, member must be 7 years of age or older; AND
3. Medication is being prescribed by or in consultation with a hematologist; AND
4. Medication will be used for applicable situations listed in Table A or for Immune Tolerance Induction (ITI); AND
5. If request is for ITI, member must have severe hemophilia (factor level < 1%) with inhibitors (FVIII titre > 0.6 BU), and meet one of the following:
    a. Inhibitor titre < 10 BU/mL or titre fails to fall below 10 BU/mL within a year;
    b. Member is having severe or life-threatening bleeding;
    c. Member is having frequent bleeding and is being considered for bypassing agent prophylaxis; AND
6. If request is for Altuviiio, member has had a trial and failure of a standard half-life FVIII product OR extended half-life FVIII product; AND
7. Documentation of member's most recent weight (must be taken by a healthcare provider) within the past 90 days, history of bleeds, number of as needed doses on hand, and inhibitor status have been provided for review.
8. **Dosage allowed:** Per package insert of individual drug. For ITI, dosages may range from 50 IU/kg three times weekly to 200 IU/kg daily depending on titer inhibitor levels.

If all the above requirements are met, the medication will be approved for 30 days for perioperative management or 6 months for all other cases.

Note: Approval will be for requested dosage, but no more than +/- 3% of prescribed assays. For patients on prophylaxis: the number of as needed doses the patient has on hand will be taken into consideration for treatment of acute bleeding episodes. A maximum of 5 as needed doses will be permitted at a time.

For **reauthorization**:

1. Documentation of member's most recent weight (must be taken by a healthcare provider) within the past 90 days, history of bleeds, number of as needed doses on hand, and inhibitor status have been provided for review; AND
2. Member has experienced positive clinical response from the use of factor; AND
3. If request is for a dosage increase, provider must submit a clinical rationale supported by chart notes; AND
4. For ITI, chart notes have been provided to show both of the following:
    a. Member continues to need ITI (e.g., inhibitor is detectable (> 0.6 BU), FVIII recovery < 66% of expected, FVIII half-life is < 7 hours); AND
    b. Member has shown at least 20% decline in the inhibitor titre level since the previous approval.

If all the above requirements are met, the medication will be approved for an additional 6 months.

Hemophilia B (Factor IX Deficiency)

For **initial** authorization:

1. Member has diagnosis of Hemophilia B (congenital Factor IX deficiency); AND
2. For Ixnity, member must be 12 years of age or older; AND
3. For AlphaNine, member must be 17 years of age or older; AND
4. Medication is being prescribed by or in consultation with a hematologist; AND
5. Medication will be used for applicable situations listed in Table A or for Immune Tolerance Induction (ITI); AND
6. If request is for ITI, member must have inhibitors (FIX titre ≥ 0.3 BU) and prescriber must attest that benefit outweighs the risk of starting therapy; AND

7. Documentation of member's most recent weight (must be taken by a healthcare provider) within the past 90 days, history of bleeds, number of as needed doses on hand, and inhibitor status have been provided for review.
8. **Dosage allowed:** Per package insert of individual drug.

If all the above requirements are met, the medication will be approved for 30 days for perioperative management or 6 months for all other cases.

Note: Approval will be for requested dosage, but no more than +/- 3% of prescribed assays. For patients on prophylaxis: the number of as needed doses the patient has on hand will be taken into consideration for treatment of acute bleeding episodes. A maximum of 5 as needed doses will be permitted at a time.

For **reauthorization**:

1. Documentation of member's most recent weight (must be taken by a healthcare provider) within the past 90 days, history of bleeds, number of as needed doses on hand, and inhibitor status have been provided for review; AND
2. Member has experienced positive clinical response from the use of factor; AND
3. If request is for a dosage increase, provider must submit a clinical rationale supported by chart notes.

If all the above requirements are met, the medication will be approved for an additional 6 months.

FEIBA (anti-inhibitor coagulant complex)

For **initial** authorization:

1. Member has a diagnosis of Hemophilia A or B with confirmed inhibitors (FVIII titre > 0.6 BU for hemophilia A or FIX titre ≥ 0.3 BU for hemophilia B); AND
2. Medication is being prescribed by or in consultation with a hematologist; AND
3. Medication will be used in one of the following situations:
    a. On-demand treatment of acute bleeding episodes;
    b. Perioperative management of bleeding;
    c. Routine prophylaxis to prevent or reduce the frequency of bleeding episodes; AND
4. Documentation of member's most recent weight (must be taken by a healthcare provider) within the past 90 days, history of bleeds, and inhibitor status have been provided for review; AND
5. If member is using Hemlibra, must have a clinical reason why a recombinant activated factor VII (rFVIIa) such as NovoSevenRT or Sevenfact cannot be used.
6. **Dosage allowed:** Per package insert.

If member meets all the requirements listed above, the medication will be approved for 30 days for perioperative management or 6 months for all other cases.

Note: Approval will be for requested dosage, but no more than +/- 3% of prescribed assays.

For **reauthorization**:

1. Documentation of member's most recent weight (must be taken by a healthcare provider) within the past 90 days, history of bleeds, and inhibitor status have been provided for review; AND
2. Member has experienced positive clinical response from the use of factor; AND
3. If request is for a dosage increase, provider must submit a clinical rationale supported by chart notes.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 months.

Von Willebrand Disease (VWD)

For **initial** authorization:

1. Member has a diagnosis of Von Willebrand Disease (VWD); AND
2. For Vonvendi, member must be 18 years of age or older; AND
3. Medication is being prescribed by or in consultation with a hematologist; AND
4. Medication will be used for applicable situations listed in Table A; AND
5. Member has severe vWD (except Alphanate) OR Member has mild or moderate vWD and the use of desmopressin is known or suspected to be ineffective or contraindicated; AND
6. Documentation of member's most recent weight (must be taken by a healthcare provider) within the past 90 days and history of bleeds have been provided for review.
7. **Dosage allowed:** Per package insert of individual drug.

If member meets all the requirements listed above, the medication will be approved for 30 days for perioperative management, or 6 months for all other cases.

Note: Approval will be for requested dosage, but no more than +/- 3% of prescribed assays.

For **reauthorization**:

1. Documentation of member's most recent weight (must be taken by a healthcare provider) within the past 90 days and history of bleeds have been provided for review; AND
2. Member has experienced positive clinical response from the use of factor; AND
3. If request is for a dosage increase, provider must submit a clinical rationale supported by chart notes.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 months.

Miscellaneous Factors (Coagadex, Fibryga, RiaSTAP)

For **initial** authorization:

1. For Obizur, member must be 18 years of age or older with a baseline anti-porcine factor VIII inhibitor titer less than 20 BU; AND
2. Member has an FDA approved indication for use as listed in Table A; AND

3. Medication is being prescribed by or in consultation with a hematologist; AND
4. Documentation of member's most recent weight (must be taken by a healthcare provider) within the past 90 days, history of bleeds, and fibrinogen level (if available, Fibryga and RiaSTAP only) have been provided for review.
5. **Dosage allowed:** Per package insert.

If member meets all the requirements listed above, the medication will be approved for 30 days for perioperative management or 6 months for all other cases.

Note: Approval will be for requested dosage, but no more than +/- 3% of prescribed assays.

For **reauthorization**:

1. Documentation of member's most recent weight (must be taken by a healthcare provider) within the past 90 days and history of bleeds have been provided for review.
2. Member has experienced positive clinical response from the use of factor; AND
3. If request is for a dosage increase, provider must submit a clinical rationale supported by chart notes.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 months.

Anti-Clotting Products (ATryn, Ceprotin)

For **initial** authorization:

1. Member has an FDA approved indication for use as listed in Table A; AND
2. Medication is being prescribed by or in consultation with a hematologist; AND
3. Documentation of member's most recent weight (must be taken by a healthcare provider) within the past 90 days and chart notes supporting diagnosis have been provided for review.
4. **Dosage allowed:** Per package insert.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Documentation of member's most recent weight (must be taken by a healthcare provider) within the past 90 days and documentation of positive clinical response have been submitted for review; AND
2. If request is for a dosage increase, provider must submit a clinical rationale supported by chart notes.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 months.

Table A

Drug Class	Drug Name	Indications
Recombinant Factor VIII (Hemophilia A)	Advate	• On-demand treatment and control of bleeding episodes • Perioperative management • Routine prophylaxis to reduce the frequency of bleeding episodes
	Afstyla	• On-demand treatment and control of bleeding episodes • Perioperative management • Routine prophylaxis to reduce the frequency of bleeding episodes
	Kovaltry	• On-demand treatment and control of bleeding episodes • Perioperative management • Routine prophylaxis to reduce the frequency of bleeding episodes
	Novoeight	• On-demand treatment and control of bleeding episodes • Perioperative management • Routine prophylaxis to reduce the frequency of bleeding episodes
	Nuwiq	• On-demand treatment and control of bleeding episodes • Perioperative management • Routine prophylaxis to reduce the frequency of bleeding episodes
	Recombinate	• On-demand treatment and control of bleeding episodes • Perioperative management • Routine prophylaxis to reduce the frequency of bleeding episodes
	Xyntha	• On-demand treatment and control of bleeding episodes • Perioperative management • Routine prophylaxis to reduce the frequency of bleeding episodes
Extended Half-Life Recombinant Factor VIII (Hemophilia A)	Adynovate	• On-demand treatment and control of bleeding episodes • Perioperative management • Routine prophylaxis to reduce the frequency of bleeding episodes
	Altuviiio	• On-demand treatment and control of bleeding episodes • Perioperative management • Routine prophylaxis to reduce the frequency of bleeding episodes
	Eloctate	• On-demand treatment and control of bleeding episodes • Perioperative management • Routine prophylaxis to reduce the frequency of bleeding episodes
	Esperoct	• On-demand treatment and control of bleeding episodes • Perioperative management • Routine prophylaxis to reduce the frequency of bleeding episodes
	Jivi	• On-demand treatment and control of bleeding episodes • Perioperative management • Routine prophylaxis to reduce the frequency of bleeding episodes
Plasma-Derived Factor VIII (Hemophilia A)	Hemofil M	• Prevention and control of hemorrhagic episodes
	Koate	• Prevention and control of bleeding episodes

Recombinant Factor IX (Hemophilia B)	Benefix	**Hemophilia B** (congenital factor IX deficiency) for: • On-demand treatment and control of bleeding episodes • Perioperative management of bleeding • Routine prophylaxis to reduce the frequency of bleeding episodes
	Ixinity	• On-demand treatment and control of bleeding episodes • Perioperative management • Routine prophylaxis to reduce the frequency of bleeding episodes
	Rixubis	• On-demand treatment and control of bleeding episodes • Perioperative management • Routine prophylaxis to reduce the frequency of bleeding episodes
Extended Half-Life Recombinant Factor IX (Hemophilia B)	Alprolix	• On-demand treatment and control of bleeding episodes • Perioperative management • Routine prophylaxis to reduce the frequency of bleeding episodes
	Idelvion	• On-demand treatment and control of bleeding episodes • Perioperative management • Routine prophylaxis to reduce the frequency of bleeding episodes
	Rebinyn	• On-demand treatment and control of bleeding episodes • Perioperative management • Prevention and control of bleeding episodes
Plasma-Derived Factor IX (Hemophilia B)	AlphaNine SD	• Prevention and control of bleeding episodes
Factor IX Complex (Hemophilia B)	Profilnine SD	• Prevention and control of bleeding episodes
von Willebrand Factor/Coagulation Factor VIII Complex (Human)	Alphanate	• Control and prevention of bleeding in patients with **hemophilia A** • Surgical and/or invasive procedures in adult and pediatric patients with **von Willebrand Disease** in whom desmopressin (DDAVP) is either ineffective or contraindicated. Not indicated for patients with severe VWD (Type 3) undergoing major surgery
	Humate-P	**Hemophilia A** • Treatment and prevention of bleeding in adults **Von Willebrand disease** • Treatment of spontaneous and trauma-induced bleeding episodes • Perioperative management
	Wilate	Children and adults with **von Willebrand disease** for: • On-demand treatment and control of bleeding episodes • Perioperative management • Routine prophylaxis to reduce the frequency of bleeding episodes Adolescents and adults with **hemophilia A** for: • On-demand treatment and control of bleeding episodes

		• Routine prophylaxis to reduce the frequency of bleeding episodes
vonWillebrand Recombinant Factor	Vonvendi	Adults with **von Willebrand disease** for: • Routine prophylaxis to reduce the frequency of bleeding episodes in patients with severe Type 3 von Willebrand disease receiving on-demand therapy. Adult and pediatric patients with **von Willebrand disease** for: • On-demand treatment and control of bleeding episodes • Perioperative management
Bypassing Agent	Feiba	**Hemophilia A and B with inhibitors** for: • On-demand treatment and control of bleeding episodes • Perioperative management • Routine prophylaxis to reduce the frequency of bleeding episodes
	Coagadex	**Hereditary Factor X deficiency** for: • Routine prophylaxis to reduce the frequency of bleeding episodes • On-demand treatment and control of bleeding episodes • Perioperative management of bleeding in patients with mild, moderate and severe hereditary Factor X deficiency
	Fibryga	• Treatment of acute bleeding episodes in adults and children with **congenital fibrinogen deficiency**, including afibrinogenemia and hypofibrinogenemia • Fibrinogen supplementation in bleeding patients **with acquired fibrinogen deficiency**
	RiaSTAP	• Treatment of acute bleeding episodes in adults and children with **congenital fibrinogen deficiency**, including afibrinogenemia and hypofibrinogenemia
Antithrombin	ATryn	• Prevention of peri-operative and peri-partum thromboembolic events in patients with **hereditary antithrombin deficiency**
Protein C Concentrate	Ceprotin	• Treatment and prevention of venous thrombosis and purpura fulminans in patients with **severe congenital Protein C deficiency**

TrueCare considers Hemophilia and Other Clotting Disorders not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
12/15/2016	Policy issued.
06/12/2018	Policy placed in a new format. Initial authorization length increased to 6 months.
10/05/2018	New drug Jivi added to the list of antihemophilic agents.
08/06/2019	New drug Esperoct added to the list of antihemophilic agents.
10/19/2019	Policy updated to include Hemlibra criteria.
08/01/2020	Hemlibra criteria updated to include hematologist. Requirement changed for members without Factor VIII inhibitors to align better with current practice and clinical trials.
04/02/2021	Title updated to encompass all bleeding disorder products. Table A created for all products, indications, and J codes. Added separate criteria set for hemophilia A, hemophilia B, Feiba, NovoSevenRT, Sevenfact, Von Willebrand Disease, miscellaneous factors, and anti-clotting products (previously only had one set of criteria for hemophilia factor replacement). Updated Hemlibra's weight requirement, reauth criteria, and dosage allowed section. Added approval instruction note for the factors and Hemlibra. Updated initial approval duration for all agents.
09/13/2022	Annual Review. Transferred to new template. Updated references. Removed discontinued medications from policy (Helixate, Kogenate). Updated Table A indications (VonVendi). Added baseline titer requirements for Obizur.
04/10/2023	Added Altuviiio and as needed acute bleed dosing guidance for prophylaxis to hemophilia A. Changed name from bleeding disorder agents to hemophilia and other clotting disorders. Added trial of Jivi (for extended half-life products) and Advate (for standard half-life products) for hemophilia A. Added a note that Hemlibra is preferred for long-term prophylaxis for hemophilia A. Removed trial of factor products, clinical reason factors cannot be used or poor venous access for patients who are not using factor products with Hemlibra.
01/05/2024	Added severe indication for perioperative management of bleeding for Coagadex; added indication of routine prophylaxis to reduce the frequency of bleeding episodes for Wilate; updated references
05/15/2024	Removed age limit for Ixinity.
07/02/2024	Removed Jivi and Advate trials and added a trial of an extended half-life or standard half-life FVIII product for Altuviiio.
10/15/2024	Added acquired fibrinogen deficiency indication for Fibryga.
5/21/2025	Removed non-preferred MS MCD UPDL drugs and Hemlibra.
06/19/2025	Updated references; reduced age limit from 12 to 7 years of age per PI for Jivi
11/25/2026	Updated "approval will be for requested dosage, but no more than +/- 5-10% of prescribed assays" from +/- 5-10% to +/- 3% Vonvendi: expanded age indication to include pediatrics for on-demand treatment and control of bleeding episodes and perioperative management of bleeding; specified routine prophylaxis to reduce the frequency of bleeding episodes for adults only

03/05/2026	Added “within the past 90 days” and “must be taken by a healthcare provider” to criteria with weight reporting requirements

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