

PHARMACY POLICY STATEMENT

Marketplace

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:

Hemophili a 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 12 years of age or older; AND
3. Medication is being prescribed by or in consultation with a hematologist; AND
- 4.

taken into consideration

1. 0 H P E H U ↑ V U H F H Q W Z H L J K W N J ~~as needed doses, brand, 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 K H P R S K L O L D \$ R U) , ; W L W U H • % 8 I R U K H P R S K L O L D %
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. 0 H P E H U ↑ V U H F H Q W Z H L J K W ~~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 +/- 5-

For reauthorization :

1. 0 H P E H U ¶ V U H F H Q W Z H L J K W N J K L V W R U \ R I E O H H G V r e v i D Q
 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, t he medication will be approved for an additional 6 months.

Hemlibra (emicizumab -kxwh)

For initial authorization:

1. Member has diagnosis of Hemophilia A, with congenital factor VIII deficiency confirmed by blood coagulation testing; AND
2. Medication is being prescribed by or in consultation with a hematologist; AND
3. 0 H P E H U ¶ V U H F H Q W Z H L J K W N J K L V W R U \ R I E O H H G V D Q
 AND
4. For member with factor VIII inhibitors, member must meet the following:
 - a. Chart notes with documented positive test for inhibitors (titer > 0.6 BU/mL [Bethesda unit per milliliter]); OR
5. For member without factor VIII inhibitors, member must have severe hemophilia A (Factor VIII level <1%); AND
6. Bypassing agents (e.g., Feiba, NovoSeven RT, Sevenfact) are discontinued the day before starting Hemlibra (if applicable); AND
7. Prophylactic use of factor replacements are discontinued after loading dose period is finished.

Note: Factor VIII may be used as on-demand therapy for breakthrough bleeding.

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 FD <</MCID 6/Lang (en-US)>> BDC q 50.475 478.88 526.28 1248 0 04 12.025 1

	Idelvion	<ul style="list-style-type: none"> x On-demand treatment and control of bleeding episodes x Perioperative management x Routine prophylaxis to reduce the frequency of bleeding episodes
	Rebinyn	<ul style="list-style-type: none"> x On-demand treatment and control of bleeding episodes x Perioperative management x Prevention and control of bleeding episodes
Plasma-Derived Factor IX (Hemophilia B)	AlphaNine SD	<ul style="list-style-type: none"> x Prevention and control of bleeding episodes

Factor IX

x Treatment of bleeding episodes and peri-

NovoSeven
RT

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 hemoph L O L D I D F W R U U H S O D F H P H Q W 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 Altuviio 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

References:

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6. Alprolix [package insert]. Cambridge, MA: Biogen Inc.; 2020.
7. Altuviio [package insert]. Waltham, MA: Bioverativ Therapeutics Inc.; 2023.
8. ATryn [package insert]. Framingham, MA: rEVO Biologics, Inc.; 2013.
9. Benefix [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals Inc.; 2021.
10. Ceprotin [package insert]. Lexington, MA: Baxalta US Inc.; 2021.
11. Coagadex [package insert]. Durham, NC: Bio Products Laboratory USA, Inc.; 2023.
12. Corifact [package insert]. Kankakee, IL: CSL Behring LLC; 2019.
13. Eloctate [package insert]. Waltham, MA: Bioverativ Therapeutics Inc.; 2020.
14. Esperoct [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; 2022.
15. Feiba [package insert]. Westlake Village, CA: Baxter Healthcare Corporation; 2020.
16. Fibryga [package insert]. Paramus, NJ: Octapharma USA, Inc.; 2020.
17. Hemlibra [package insert]. South San Francisco, CA: Genentech, Inc.; 2022
18. Hemofil M [package insert]. Lexington, MA: Baxalta US Inc.; 2018.
19. Baxalta US Inc. Lexington, MA Humate-P [package insert]. Kankakee, IL: CSL Behring LLC; 2020.
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