Clinical Policy: Emicizumab-kxwh (Hemlibra)

Reference Number: CP.PHAR.370
Effective Date: 03.01.18
Last Review Date: 02.26
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Emicizumab-kxwh (Hemlibra®) is a bispecific factor IXa- and factor X-directed antibody.

FDA Approved Indication(s)

Hemlibra is indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients ages newborn and older with hemophilia A (congenital factor VIII [FVIII] deficiency) with or without FVIII inhibitors.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Hemlibra is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Congenital Hemophilia A Without Inhibitors (must meet all)**:**

1. Prescribed for routine prophylaxis of bleeding episodes in patients with congenital hemophilia A (FVIII deficiency) WITHOUT inhibitors;
2. Prescribed by or in consultation with a hematologist;
3. Member meets one of the following (a or b):^
   ^For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395
   a. Failure of a FVIII product (e.g., Advate®, Adynovate®, Eloctate®) used for routine prophylaxis as assessed and documented by prescriber (*see Appendix D*), unless clinically significant adverse effects are experienced or all are contraindicated;
      **Prior authorization is required for FVIII products*
   b. Member has poor venous access, does not tolerate frequent venous access, or has central line or port placement;
4. For members who are new to Hemlibra therapy and have not previously used FVIII products for routine prophylaxis: Member meets one of the following (a or b):
   a. Member has severe hemophilia (defined as FVIII level of < 1%);
   b. Member has experienced at least one serious spontaneous bleed (*see Appendix D*);
5. Hemlibra is not prescribed concurrently with another hemophilia prophylaxis agent (e.g., FVIII products as prophylactic therapy,* Qfitlia®, Hympavzi™, Alhemo®);
   **On-demand usage of a FVIII product may be continued*
6. Documentation of member's current body weight (in kg);

7. Dose does not exceed 3 mg/kg per week during the first four weeks of therapy, followed by either 1.5 mg/kg per week, 3 mg/kg once every two weeks, or 6 mg/kg once every four weeks thereafter.

Approval duration:
Medicaid/HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Congenital Hemophilia A With Inhibitors (must meet all)**:**

1. Prescribed for routine prophylaxis of bleeding episodes in patients with congenital hemophilia A (FVIII deficiency) WITH inhibitors;
2. Prescribed by or in consultation with a hematologist;
3. Member has inhibitor level ≥ 5 Bethesda units (BU);
4. Hemlibra is not prescribed concurrently with another hemophilia prophylaxis agent (e.g., bypassing agents, FVIII products as prophylactic therapy,* Qfitlia, Hympavzi, Alhemo);
   **On-demand usage of a FVIII product may be continued*
5. Documentation of member's current body weight (in kg);
6. Dose does not exceed 3 mg/kg per week during the first four weeks of therapy, followed by either 1.5 mg/kg per week, 3 mg/kg once every two weeks, or 6 mg/kg once every four weeks thereafter.

Approval duration:
Medicaid/HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

C. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Congenital Hemophilia A With or Without Inhibitors (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;

b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B)*;

2. Member is responding positively to therapy;
3. Hemlibra is not prescribed concurrently with another hemophilia prophylaxis agent (e.g., bypassing agents, FVIII products as prophylactic therapy,* Qfitlia, Hympavzi, Alhemo);
   **On-demand usage of a FVIII product may be continued*
4. If request is for a dose increase, both (a and b):
   a. Documentation of member's current body weight in kg (if requesting a higher dose than previously requested);
   b. New dose does not exceed 3 mg/kg per week during the first four weeks of therapy, followed by either 1.5 mg/kg per week, 3 mg/kg once every two weeks, or 6 mg/kg once every four weeks thereafter.

Approval duration:
Medicaid/HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

aPCC: activated prothrombin complex concentrate
BU: Bethesda unit
FDA: Food and Drug Administration

FEIBA: factor eight inhibitor bypassing activity

FVIII: factor VIII

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): none reported
- Boxed warning(s): thrombotic microangiopathy and thromboembolism

Appendix D: General Information
- The elimination half-life of Hemlibra is 27.8 ± 8.1 days. Therefore, the "on-demand" use of Hemlibra for the treatment of acute bleeding episodes is inappropriate.
- There is insufficient data to support the use of Hemlibra for the treatment of hemophilia B either with or without inhibitors.
- There is potential for thrombotic microangiopathy and thrombotic events when used concurrently with FEIBA > 100 U/kg/day for 24 hours or more. Additional monitoring is recommended with concomitant use of the two agents. Discontinuation of FEIBA and suspended dosing of Hemlibra is recommended if symptoms occur.
- The World Federation of Hemophilia recommends starting primary prophylaxis before the second clinically evident large joint bleed, and before 3 years of age, to prevent future bleeding episodes and the resulting complications.
- Examples of member responding positively to therapy may include: reduction in number of all bleeds over time, reduction in number of joint bleeds over time, or reduction in number of target joint bleeds over time.
- There are no strict criteria for failing FVIII product for routine prophylaxis; however, the following reasons are acceptable to fulfill the criteria:
  - Prescriber has documented clinical criteria which support his or her assessment that the member has failed FVIII therapy;
  - Clinically significant bleeding, hemarthroses, life-threatening bleeding episodes, joint swelling, upcoming surgery/procedure not responding to current therapy, or other clinical assessment as determined by prescriber.
- Serious bleeding episodes include bleeds in the following sites: intracranial; neck/throat; gastrointestinal; joints (hemarthrosis); muscles (especially deep compartments such as the iliopsoas, calf, forearm); or mucous membranes of the mouth, nose and genitourinary tract.
- A spontaneous bleed is defined as a bleeding episode that occurs without apparent cause and is not the result of trauma.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Routine prophylaxis of bleeding episodes	Loading dose of 3 mg/kg SC weekly for four weeks, followed by a maintenance dose of 1.5 mg/kg SC weekly or 3 mg/kg once every two	3 mg/kg/week for the first 4 weeks, followed by 1.5 mg/kg/week thereafter

Indication	Dosing Regimen	Maximum Dose
	weeks or 6 mg/kg once every four weeks	

VI. Product Availability

Single-dose vials for injection: 12 mg/0.4 mL, 30 mg/mL, 60 mg/0.4 mL, 105 mg/0.7 mL, 150 mg/mL, 300 mg/2 mL

VII. References

1. Hemlibra Prescribing Information. South San Francisco, CA: Genentech, Inc.; July 2025. Available at: https://www.gene.com/download/pdf/hemlibra_prescribing.pdf. Accessed October 21, 2025.
2. Medical and Scientific Advisory Council (MASAC) of the National Bleeding Disorders (formerly National Hemophilia Foundation): Database of treatment guidelines. Available at: https://www.hemophilia.org/healthcare-professionals/guidelines-on-care/masac-documents. Accessed November 24, 2025.
3. Srivastava A, Santagostino E, Dougall A, et al. WFH guidelines for the management of hemophilia. *Haemophilia.* 2020;26(suppl 6):1-158.
4. Rezende SM, Neumann I, Angchaisuksiri P, et al. International Society on Thrombosis and Haemostasis clinical practice guideline for treatment of congenital hemophilia A and B based on the Grading of Recommendations Assessment, Development, and Evaluation methodology. *J Thromb Haemost*. 2024;22(9):2629-2652.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J7170	Injection, emicizumab-kxwh, 0.5 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2022 annual review: no significant changes; updated the language on the continuation of therapy requirement that the member "will discontinue" to "has discontinued" use of bypassing agents or fFVIII products as routine prophylaxis while on Hemlibra therapy; references reviewed and updated.	11.23.21	02.22
For hemophilia A with inhibitors: removed the requirement for FVIII activity level or documentation of bleed history since inhibitors would only be present after previous use of FVIII products, and substantiation of severe disease is not necessary; for hemophilia A without inhibitors: clarified that the requirement for FVIII activity level or documentation	03.03.22	05.22

Reviews, Revisions, and Approvals	Date	P&T Approval Date
of bleed history only applies to requests for new starts to Hemlibra without previous FVIII use for routine prophylaxis.		
Template changes applied to other diagnoses/indications.	09.22.22	
1Q 2023 annual review: Removed "life-threatening" from "life-threatening or serious bleed" criterion as definition of what is serious vs life-threatening may not be mutually exclusive and there exists potential for misinterpretation; references reviewed and updated.	11.08.22	02.23
Extended initial and continued authorization durations for hemophilia prophylaxis from 6 months to 12 months for HIM Texas.	08.28.23	
1Q 2024 annual review: no significant changes; updated sites of serious bleeds per WFH guideline in Appendix D; references reviewed and updated. RT4: added new vial strength of 12 mg/0.4 mL and 300 mg/2 mL.	02.12.24	02.24
For continued therapy clarified that member's current weight is only needed if a higher dose is being requested.	04.10.24	05.24
1Q 2025 annual review: respective diagnosis criterion for each Hemlibra indication was clarified further to add "WITH inhibitors" and "WITHOUT inhibitors" to help prevent reviewer confusion; revised Commercial line of business approval duration to "6 months or to the member's renewal date, whichever is longer;" revised continued approval duration for Medicaid and HIM lines of business from 6 months to 12 months; references reviewed and updated.	10.29.24	02.25
1Q 2026 annual review: revised provider confirmation of discontinuation of bypassing agents and FVIII products as prophylaxis to exclusion for concurrent use of hemophilia prophylaxis agent with more examples; added step therapy bypass for IL HIM per IL HB 5395; for Medicaid/HIM lines of business, revised initial approval durations from 6 months to 12 months; references reviewed and updated.	10.21.25	02.26

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.