Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:
Medical Benefit Drugs
Hemlibra® (emicizumab-kxwh)

Effective: January 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Public Plans Products

☒ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☒ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☒ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☒ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Hemophilia is an inherited, lifelong bleeding disorder caused by a deficiency of coagulation factors. The two most common types of hemophilia are hemophilia A (Factor VIII deficiency) and B (Factor IX deficiency), and either type can lead to spontaneous bleeding and prolonged bleeding following an injury or surgical procedure. There are varying severities of hemophilia A depending on the level of factor produced by the patient. Severe hemophilia frequently results in bleeding even in the absence of trauma; moderate hemophilia is associated with less bleeding, and mild hemophilia usually results in bleeding only after obvious trauma. Historically hemophilia A treatment involves replacing the deficient coagulation factor through episodic (on-demand) treatment or prophylaxis. Newer, easier-to-administer products have provided options for the management of patients with hemophilia A and include Hemlibra. Hemlibra is a bispecific Factor IXa- and Factor X-directed Antibody. Prophylaxis is recommended for patients at least one year of age with severe hemophilia A.

Approval of Hemlibra for the treatment of hemophilia A with inhibitors was based on the HAVEN 1 and HAVEN 2 clinical trials. HAVEN 1 included patients at least 12 years of age and results demonstrated that patients treated with Hemlibra experienced 2.9 treated bleeding episodes per year compared to 23.3 treated bleeding episodes per year in patients receiving no prophylactic treatment (equates to an 87% reduction in rate of treated bleeds). HAVEN 2 enrolled patients less than 12 years of age and those treated with Hemlibra did not experience a bleeding episode that required treatment.

Approval of Hemlibra was expanded to treatment of hemophilia A in patients without inhibitors based on the HAVEN 3 and HAVEN 4 trials. In HAVEN 3, patients were at least 12 years of age and those that received Hemlibra prophylaxis every week or every 2 weeks showed a 96% ($p<0.0001$) and 97% ($p<0.001$) reduction in treated bleeds compared to those who received no prophylaxis. In addition, 60% of patients who received Hemlibra prophylaxis every 2 weeks and 55.6% of patients treated with Hemlibra prophylaxis every week encountered 0 bleeds compared to 0% of patients treated with no prophylaxis. HAVEN 4 was an open-label trial in patients at least 12 years of age and evaluated every 4-week dosing. Results demonstrated Hemlibra prophylaxis every 4 weeks can provide clinically meaningful control of bleeding. There was a median annualized bleed rate for treated bleeds of 0.0, with 56.1% of patients experiencing treated bleeds and 90.2% experiencing 3 or fewer treated bleeds.

Food and Drug Administration - Approved Indications:

Hemlibra (emicizumab-kxwh) is a bispecific factor IXa- and factor X-directed antibody 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 deficiency) with or without factor VIII inhibitors.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Hemlibra for Members when **ALL** the following criteria is met:

Initial Authorization Criteria

1. Documented diagnosis of hemophilia A

AND

2. Documented use for routine prophylaxis to prevent or reduce the frequency of bleeding episodes

AND

3. Documentation of severe disease as evidenced by less than 1% of endogenous factor VIII

AND

4. Prescribed by or in consultation with a hematologist

Reauthorization Criteria

1. Prescribed by or in consultation with a hematologist

AND

2. Documentation the patient has experienced a positive therapeutic response from Hemlibra as defined by at least one (1) of the following:
    a. Reduced frequency of bleeds
    b. Reduced severity of bleeds

Limitations

- Coverage of Hemlibra will be authorized for 12 months
- Members new to the plan stable on Hemlibra should be reviewed against Reauthorization Criteria.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

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

References

1. Hemlibra (emicizumab-kxwh) [package insert]. San Francisco, CA; Genentech, Inc.: January 2024.
2. Mahlangu J et al. Emicizumab Prophylaxis in Patients Who Have Hemophilia A without Inhibitors. N Engl J Med 2018; 379:811-822.
3. National Hemophilia Foundation. Hemophilia A. Accessed July 1, 2024. https://www.hemophilia.org/bleedingdisorders-a-z/types/hemophilia-a.

Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T).

September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC).

Subsequent endorsement date(s) and changes made:

- September 12, 2023: Administrative update to remove the following Limitation: “The health plan considers Hemlibra (emicizumab-kxwh) as experimental/investigational and not medically necessary for all other indications” and removed the language of “with or without inhibitors” from diagnosis requirements. Added provider specialty requirements. Added Reauthorization Criteria (effective 12/1/2023).
- November 2023: Administrative Updates: Rebranded from Tufts Health Unify to Tufts Health One Care for 2024 and administrative update in support of calendar year 2024 Medicare Advantage and PDP Final Rule.
- August 13, 2024: No changes (eff 10/1/24).
- September 2024: Joint Medical Policy and Health Care Services UM Committee review (eff 10/1/24)
- March 11, 2025: Added “Documentation of severe disease as evidenced by less than 1% of endogenous factor VIII” Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template. (eff 6/1/25)
- March 2025: Joint Medical Policy and Health Care Services UM Committee review (eff 6/1/25).
- December 9, 2025: No changes (eff 1/1/26
- December 2025: Joint Medical Policy and Health Care Services UM Committee review (effective 1/1/26)

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature,

Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guidelines not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.