Mass General Brigham
Health Plan

Hemlibra (emicizumab-kxwh)
Effective 01/01/2026

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview
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. The prophylactic use of factor VIII (FVIII) products may be continued during the first week of Hemlibra prophylaxis.

Coverage Guidelines
Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted when all of the following criteria are met:

1. Member has a diagnosis of hemophilia A (congenital factor VIII deficiency)
2. Requested medication is being used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes.
3. Member meets ONE of the following criteria:
    a. Member has a mild disease (See Appendix A) and has had an insufficient response to desmopressin or a documented clinical reason for not using desmopressin (See Appendix B).
    b. Member has moderate or severe disease (See Appendix A).
4. Prophylactic use of factor VIII products (e.g., Advate, Adynovate, Eloctate) will be discontinued after the first week of starting therapy with the requested medication.
5. Requested medication is prescribed by or in consultation with a hematologist

Continuation of Therapy
Requests for reauthorization will be approved when the following criteria are met:

1. Member is experiencing benefit from therapy (e.g., reduced frequency or severity of bleeds)
2. Member is not using the requested medication in combination with factor VIII products (e.g., Advate, Adynovate, Eloctate, etc.) for prophylactic use

Limitations

1. Initial approvals and reauthorizations will be granted for 12 months.

Appendix

Appendix A: Classification of Hemophilia by Clotting Factor Level (% Activity) and Bleeding Episodes

Severity	Clotting Factor Level % activity*	Bleeding Episodes
Severe	<1%	Spontaneous bleeding episodes, predominantly into joints and muscles Severe bleeding with trauma, injury or surgery
Moderate	1% to 5%	Occasional spontaneous bleeding episodes Severe bleeding with trauma, injury or surgery
Mild	6% to 40%	Severe bleeding with serious injury, trauma or surgery

Appendix B: Clinical Reasons For Not Utilizing Desmopressin in Patients with Hemophilia A

A. Age < 2 years
B. Pregnancy
C. Fluid/electrolyte imbalance
D. High risk for cardiovascular or cerebrovascular disease (especially the elderly)
E. Predisposition to thrombus formation
F. Trauma requiring surgery
G. Life-threatening bleed
H. Contraindication or intolerance to desmopressin
I. Stimate Nasal Spray is unavailable due to backorder/shortage issues (where applicable)

References

1. Hemlibra (emicizumab-kxwh) [prescribing information]. South San Francisco, CA: Genentech, Inc.; January 2024.
2. Leissinger C, Carcao M, Gill JC, et al. Desmopressin (DDAVP) in the management of patients with congenital bleeding disorders. *Haemophilia*. 2014;20:158-167.
3. National Hemophilia Foundation. Hemophilia A (Factor VIII Deficiency). Available at: http://www.hemophilia.org/NHFWeb/MainPgs/MainNHF.aspx?menuid=180&contentid=45&rptname=bleeding. Accessed December 2, 2022.
4. National Hemophilia Foundation. MASAC recommendations concerning products licensed for the treatment of hemophilia and other bleeding disorders. Revised March 2022. MASAC Document #272. https://www.hemophilia.org/sites/default/files/document/files/272_Treatment.pdf. Accessed December 2, 2022.
5. Srivastava A, Santagostino E, Dougall A, et al. WFH Guidelines for the Management of Hemophilia, 3rd edition. *Haemophilia*. 2020;26 Suppl 6:1-158. doi:10.1111/hae.14046.

Review History

12/13/2023: Reviewed at Dec P&T, switched from SGM to Custom. Effective 1/1/2024

04/09/2025 – Reviewed and updated at April P&T. Updated initial criteria to require diagnosis of hemophilia A (congenital factor VIII deficiency). Removed dosing requirements from initial and reauthorization criteria. Removed requirement for documentation from reauthorization criteria. Effective 07/01/2025.
10/08/2025 – Reviewed and updated at October P&T. Updated policy to indicate it no longer applies to the medical benefit. Effective 01/01/2026.