

Hemlibra® (emicizumab-kxwh)

When requesting Hemlibra, the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indication

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 deficiency) with or without factor VIII inhibitors.

Coverage Guidelines

Hemophilia A (Congenital Factor VIII Deficiency)

The individual must meet the following criteria for authorization:

- The request is for routine prophylaxis of bleeding episodes in individuals with congenital hemophilia A;
- Hemlibra is prescribed by or in consultation with a hematologist or hemophilia specialist.

Approval duration: 12 months

Dosing Recommendation

For subcutaneous use only

The recommended loading dose is 3 mg/kg by subcutaneous injection once weekly for the first 4 weeks, followed by a maintenance dose of:

- 1.5 mg/kg once every week, OR
- 3 mg/kg once every two weeks, OR
- 6 mg/kg once every four weeks.

References

1. Hemlibra® subcutaneous injection [prescribing information]. South San Francisco, CA and Tokyo, Japan: Genentech/Roche and Chugai; July 2025.
2. Mancuso ME, Mahlangu JN, Pipe SW. The changing treatment landscape in haemophilia: from standard half-life clotting factor concentrates to gene editing. *Lancet*. 2021;397:630-640.
3. Chowdary P, Carcao M, Kenet G, Pipe SW. Haemophilia. *Lancet*. 2025;405(10480):736-750.
4. Franchini M, Mannucci PM. The more recent history of hemophilia treatment. *Semin Thromb Hemost*. 2022;48(8):904-910.
5. Mannucci PM. Hemophilia treatment innovation: 50 years of progress and more to come. *J Thromb Haemost*. 2023;21(3):403-412.
6. National Bleeding Disorders Foundation. MASAC (Medical and Scientific Advisory Council) recommendations concerning products licensed for the treatment of hemophilia and other selected disorders

of the coagulation system (endorsed by the National Bleeding Disorders Foundation Board of Directors on October 2, 2024). MASAC Document #290. Available at: <https://www.bleeding.org/sites/default/files/document/files/MASAC-Products-Licensed.pdf>. Accessed on August 11, 2025.

7. National Bleeding Disorders Foundation. MASAC (Medical and Scientific Advisory Council) recommendations on the use and management of emicizumab-kxwh (Hemlibra®) for hemophilia A with and without inhibitors. MASAC Document #268. Adopted by the National Hemophilia Foundation Board of Directors on April 27, 2022. Available at: https://www.hemophilia.org/sites/default/files/document/files/268_Emicizumab.pdf. Accessed on August 11, 2025.
8. Srivastava A, Santagostino E, Dougall A, et al, on behalf of the WFH guidelines for the management of hemophilia panelists and co-authors. WFH guidelines for the management of hemophilia, 3rd edition. Hemophilia. 2020;26(Suppl 6):1-158.
9. Rezende SM, Neumann I, Angchaisuksiri P, et al. International Society on Thrombosis and Haemostasis clinical practice guideline for the treatment of congenital hemophilia A and B based on the Grading of Recommendations Assessment, Development, and Evaluation methodology. J Thromb Haemost. 2024;22:2629-2652.