

## 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 with Inhibitors

The individual must meet **ALL** of the following criteria for initial authorization:

1. The request is for routine prophylaxis to prevent or reduce the frequency of bleeding episodes;
2. Prophylactic use of bypassing agents will be discontinued (*Note: Use of bypassing agents for the treatment of breakthrough bleeding is permitted*);
3. The patient is not undergoing immune tolerance induction therapy;
4. Hemlibra is prescribed by or in consultation with a hemophilia specialist.

The individual must meet **ALL** of the following criteria for re-authorization:

1. The request is for routine prophylaxis to prevent or reduce the frequency of bleeding episodes;
2. Prophylactic use of bypassing agents will not occur while receiving Hemlibra (*Note: Use of bypassing agents for the treatment of breakthrough bleeding is permitted*);
3. The patient is not undergoing immune tolerance induction therapy;
4. The patient experienced beneficial responses to therapy (e.g., reduction in bleeding events, reduction in the severity of bleeding episodes, reduction in the number of bleeding events that required treatment, and/or reduction in the number of spontaneous bleeds);
5. Hemlibra is prescribed by or in consultation with a hemophilia specialist.

#### Hemophilia A without Inhibitors

The individual must meet **ALL** of the following criteria for initial authorization:

1. The request is for routine prophylaxis to prevent or reduce the frequency of bleeding episodes;
2. Prophylactic use of Factor VIII products will be discontinued no later than 4 weeks following the initial Hemlibra dose (*Note: Use of Factor VIII products for the treatment of breakthrough bleeding is permitted*);

3. Hemlibra is prescribed by or in consultation with a hemophilia specialist.

The individual must meet **ALL** of the following criteria for re-authorization:

1. The request is for routine prophylaxis to prevent or reduce the frequency of bleeding episodes;
2. Prophylactic use of Factor VIII products will not occur while receiving Hemlibra (*Note: Use of Factor VIII products for the treatment of breakthrough bleeding is permitted*);
3. The patient experienced beneficial responses to therapy (e.g., reduction in bleeding events, reduction in the severity of bleeding episodes, reduction in the number of bleeding events that required treatment, and/or reduction in the number of spontaneous bleeds);
4. Hemlibra is prescribed by or in consultation with a 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 June 14, 2026.
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](https://www.hemophilia.org/sites/default/files/document/files/268_Emicizumab.pdf). Accessed on June 14, 2026.
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.
10. Konkle BA, Nakaya Fletcher S. Hemophilia A. 2000 Sep 21 [Updated 2025 Aug 7]. In: Adam MP, Bick S, Mirzaa GM, et al., editors. *GeneReviews*® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2026.