UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2154-9
Program	Prior Authorization/Medical Necessity
Medication	Hemlibra® (emicizumab-kxwh)
P&T Approval Date	11/2018, 11/2019, 9/2020, 9/2021, 9/2022, 9/2023, 9/2024, 5/2025, 8/2025
Effective Date	10/1/2025

1. Background:

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.

2. Coverage Criteria[a]:

A. Hemophilia A With Inhibitors

1. **Initial Authorization**

a. **Hemlibra** will be approved based on **all** of the following criteria

(1) **Both** of the following:

(a) Diagnosis of hemophilia A

-AND-

(b) Patient has developed high-titer factor VIII inhibitors (i.e., patient has developed factor VIII inhibitors greater than or equal to 5 Bethesda units [BU])

-AND-

(2) Prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis)

Authorization will be issued for 12 months.

2. **Reauthorization**

a. Documentation of positive clinical response to Hemlibra therapy

Authorization will be issued for 12 months.

B. Hemophilia A Without Inhibitors

1. **Initial Authorization**

a. **Hemlibra** will be approved based on **all** of the following criteria

(1) **Both** of the following:

(a) Diagnosis of hemophilia A

-AND-

(b) Patient has not developed high-titer factor VIII inhibitors (i.e., patient has NOT developed factor VIII inhibitors greater than or equal to 5 Bethesda units [BU])

-AND-

(2) Hemlibra is prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis)

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Hemlibra** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Hemlibra therapy

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4. References:

1. Hemlibra® [package insert]. South San Francisco, CA: Genentech, Inc., January 2024.
2. Oldenburg, J, Mahlangu JN, Kim, B, et al. Emicizumab Prophylaxis in Hemophilia A with Inhibitors. N Engl J Med 2017; 377:809-818.
3. Mahlangu J, Oldenburg J, Paz-Priel I, et al. Emicizumab Prophylaxis in Patients Who Have Hemophilia A without Inhibitors. N Engl J Med. 2018;379:811-22.
4. Blanchette VS, Key NS, Ljung LR, Manco-Johnson MJ, van Den Berg HM, Srivastava A, for the Subcommittee on Factor VIII, Factor IX and Rare Coagulation Disorders. Definitions in hemophilia: communication from the SSC of the ISTH. J Thromb Haemost 2014;12:1935–9.
5. MASAC Recommendation on the Use and Management of Emicizumab-kxwh (Hemlibra®) for Hemophilia A with and without Inhibitors. MASAC Document #268, April 27, 2022.

Program	Prior Authorization/Medical Necessity - Hemlibra (emicizumab-kxwh)
Change Control	
11/2018	New program
11/2019	Annual review. No changes to clinical coverage criteria. Updated reference.
9/2020	Annual review. No changes to clinical coverage criteria.
9/2021	Annual review. No changes to clinical coverage criteria. Updated reference.
9/2022	Annual review. Updated name of Genentech Access to Care Foundation to Genentech Patient Foundation with no change to clinical intent. Updated references.
9/2023	Annual review. Modified physician attestation to prescriber attestation. Updated references.
9/2024	Annual review. Updated list of examples of extended half-life factor VIII replacement products. Updated references.
5/2025	Removed criteria that patient is not to receive extended half-life factor VIII replacement products for the treatment of breakthrough bleeding episodes.
8/2025	Removed criteria of failure to meet clinical goals after a trial of prophylactic factor VIII replacement products. Clarified high titer inhibitor criteria.