UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 2154-6
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
Effective Date	12/1/2023

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.[1]

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) Diagnosis of hemophilia A

-AND-

(2) Patient has developed high-titer factor VIII inhibitors (≥ 5 Bethesda units [BU])

-AND-

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

Authorization of therapy 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) **One** of the following:

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

i. Diagnosis of severe hemophilia A

-AND-

ii. Documentation of endogenous factor VIII levels less than 1% of normal factor VIII (< 0.01 IU/mL)

-OR-

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

i. **One** of the following

1. **Both** of the following

a. Diagnosis of moderate hemophilia A

-AND-

b. Documentation of endogenous factor VIII level ≥1% < 5% (greater than or equal to 0.01 IU/mL to less than 0.05 IU/mL)

-OR-

2. **Both** of the following

a. Diagnosis of mild hemophilia A

-AND-

b. Documentation of endogenous factor VIII level ≥ 5% (greater than or equal to 0.05 IU/mL)

-AND-

ii. Submission of medical records (e.g., chart notes, laboratory values) documenting a failure to meet clinical goals (e.g., continuation of spontaneous bleeds, inability to achieve appropriate trough level, previous history of inhibitors) after a trial of prophylactic factor VIII replacement products

-OR-

(c) **All** of the following:

i. Patient is currently on Hemlibra therapy

-AND-

ii. Diagnosis of hemophilia A

-AND-

iii. Patient has **not** received a manufacturer supplied sample at no cost in prescriber office, or any form of assistance from the Genentech Patient Foundation or the Genentech sponsored Hemlibra Co-pay Card program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of **Hemlibra***

-AND-

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

-AND-

(3) Prescriber attestation that the patient is not to receive extended half-life factor VIII replacement products (e.g., Eloctate, Adynovate, Afstyla, Jivi) for the treatment of breakthrough bleeding episodes

* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Genentech Patient Foundation or the Genentech Hemlibra Co-pay Card program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization of therapy will be issued for 12 months.

2. **Reauthorization**

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

(1) Documentation of positive clinical response to Hemlibra therapy

-AND-

(2) Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient is not receiving Hemlibra in combination with an extended half-life factor VIII replacement product (e.g., Eloctate, Adynovate, Afstyla, Jivi) for the treatment of breakthrough bleeding episodes. [Prescription claim history that does not show any concomitant extended half-life factor VIII replacement product claim within 60 days of reauthorization request may be used as documentation]

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., March 2023.
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.