

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2024 P 1240-8
Program	Prior Authorization/Notification
Medication	Hemlibra® (emicizumab-kxwh)
P&T Approval Date	2/2018, 11/2018, 11/2019, 11/2020, 11/2021, 11/2022, 11/2023, 11/2024
Effective Date	2/1/2025

**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<sup>a</sup>:**

<p><b>A. Hemophilia A</b></p> <p>1. <b><u>Initial Authorization</u></b></p> <p>a. <b>Hemlibra</b> will be approved based on <b><u>both</u></b> of the following criteria</p> <p>(1) Diagnosis of hemophilia A</p> <p style="text-align: center;"><b>-AND-</b></p> <p>(2) Prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis)</p> <p><b>Authorization of therapy will be issued for 12 months.</b></p> <p>2. <b><u>Reauthorization</u></b></p> <p>a. Documentation of positive clinical response to Hemlibra therapy</p> <p><b>Authorization will be issued for 12 months.</b></p> <p><sup>a</sup> 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.</p>
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**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.
- Medical Necessity may be in place

**4. References:**

1. Hemlibra® [package insert]. South San Francisco, CA: Genentech, Inc.; January 2024.

Program	Prior Authorization/Notification - Hemlibra (emicizumab-kxwh)
<b>Change Control</b>	
2/2018	New program
11/2018	Updated program to align with new labeled indication in patients with hemophilia A without inhibitors. Updated references.
11/2019	Annual review. No changes to clinical coverage criteria. Updated reference.
11/2020	Annual review. Updated references.
11/2021	Annual review with no changes to clinical coverage criteria. Updated reference.
11/2022	Annual review with no changes to clinical coverage criteria. Updated reference and added state mandate footnote.
11/2023	Annual review with no changes to clinical coverage criteria. Updated reference.
11/2024	Annual review with no changes to clinical coverage criteria. Updated reference.