UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 1240-5
Program	Prior Authorization/Notification
Medication	Hemlibra® (emicizumab-kxwh)
P&T Approval Date	2/2018, 11/2018, 11/2019, 11/2020, 11/2021
Effective Date	2/1/2022; Oxford only: N/A

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. Hemophilia A

1. Initial Authorization

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

(1) Diagnosis of hemophilia A

-AND-

(2) 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.

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.; March 2021.

Program	Prior Authorization/Notification - Hemlibra (emicizumab-kxwh)
Change Control	
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.