

## **RX.PA.099.MPC Hemlibra (emicizumab-kxwh)**

The purpose of this policy is to define the prior authorization process for Hemlibra™ (subcutaneous injection)

HEMLIBRA 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 inhibitor.

<b>Severity</b>	<b>Clotting Factor Level % Activity</b>	<b>Bleeding Episodes</b>
Severe	< 1%	Spontaneous bleeding episodes, predominantly into joints and muscles Severe bleeding with trauma, injury or surgery
Moderate	1% to 5%	Occasional spontaneous bleeding episodes Severe bleeding with trauma, injury or surgery
Mild	6% to 40%	Severe bleeding with serious injury, trauma or surgery

## **PROCEDURE**

### **A. Initial Authorization Criteria:**

**Hemophilia A (Congenital factor VIII deficiency). All requests must meet the following criteria:**

- Must have a documented diagnosis of hemophilia A with or without inhibitors
  - With inhibitors: Patient has developed high-titer factor VIII inhibitors (> 5 Bethesda units [BU])
  - Without inhibitors:
    - a) Severe: Documentation of endogenous factor VIII levels less than 1% of normal factor VIII (< 0.01 IU/mL)
    - b) Moderate: Documentation of endogenous factor VIII level >1% < 5% (greater than or equal to 0.01 IU/mL to less than 0.05 IU/mL)
    - c) Mild: Documentation of endogenous factor VIII level > 5% (greater than or equal to 0.05 IU/mL)
- Must be using Hemlibra for one of the following:
  - a) Prevention of bleeding episodes/routine prophylaxis

- b) Prevention of bleeding in surgical interventions or invasive procedures (surgical prophylaxis)
  - Must not be using Hemlibra for the treatment of von Willebrand disease
  - If patient has a past trial and failure with other Factor VIII agents (i.e. Adynovate, Eloctate, Jivi, etc.), documentation must be provided that demonstrates failure was not due to a decreased response (clinical signs or symptoms) to the product
  - Must not have a history of CVD, risk of CVD by the ASCVD risk estimator (defined as a subject having >20% risk of a cardiovascular event within the next 10 years if the subject is  $\geq$ 20 years of age) and/or a history of ischemic heart disease
  - Must not have a high risk for TMA (eg, have a previous medical or family history of TMA)
  - Must provide documentation of a platelet count  $> 100,000$  cells/ $\mu$ L (within 60 days)
  - Prophylactic use of factor VIII products (e.g., Advate, Adynovate, Eloctate) will be discontinued after the first week of starting therapy with the requested medication
  - Must monitor the member for potential development of neutralizing antibodies/inhibitors to Factor VIII within the first 50 days of treatment
  - Dose does not exceed FDA approved labeled dosing for indication
  - The medication is prescribed by or in consultation with a hematologist

**B. Reauthorization Criteria:**

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon:

**MPC Renewal:**

- Chart documentation from the prescriber that the member's condition has stabilized or improved based upon the prescriber's assessment while on therapy (e.g., reduced frequency or severity of bleeds)
- Medication is prescribed by or in consultation with a hematologist
- Must not be using other factor VIII products for prophylaxis use
- Must provide documentation of a platelet count  $\geq 100,000$  cells/ $\mu$ L (within 120 days)
- Must monitor the member for potential development of neutralizing antibodies/inhibitors to Factor VIII every 6 months throughout treatment

**Renewal from Previous Insurer:**

- Members who have received prior approval (from insurer other than MPC) and have been using Hemlibra, or have been receiving medication samples, should be considered under criterion A (Initial Authorization Criteria).
- Provider has documented positive clinical response of member's condition which has stabilized or improved based upon the prescriber's assessment (e.g., reduced frequency or severity of bleeds)

**C. Hemlibra will be considered investigational or experimental for any other use and will not be covered.**

<b>Dosing Table</b>	
<b>Initial</b>	3 mg/kg once weekly for the first 4 weeks
<b>Maintenance</b>	<ul style="list-style-type: none"><li>• 1.5 mg/kg once every week, or</li><li>• 3 mg/kg once every two weeks, or</li><li>• 6 mg/kg once every four weeks.</li></ul>

### **Limitations:**

<b>Length of Authorization (if above criteria met)</b>	
Initial Authorization	<ul style="list-style-type: none"><li>• Up to 3 months</li></ul>
Reauthorization	<ul style="list-style-type: none"><li>• Up to 1 year</li></ul>

### **Codes:**

<b>Code</b>	<b>Description</b>
J7170	Injection, emicizumab-kxwh, 0.5 mg

### **REFERENCES**

1. Hemlibra (emicizumab-kxwh) [prescribing information]. South San Francisco, CA: Genentech Inc; March 2023

### **REVIEW HISTORY**

<b>DESCRIPTION OF REVIEW / REVISION</b>	<b>DATE APPROVED</b>
<i>Update to change platelet count labs from 60 days to 120 days for renewal requests and clarified Factor VIII use for prophylaxis in renewal pathway</i>	12/2025
<i>New Policy</i>	10/2024