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.

Severity	Clotting Factor Level % Activity	Bleeding Episodes
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. <u>Initial Authorization Criteria:</u>

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 ≥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/μL (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
- Must provide documentation of a platelet count ≥ 100,000 cells/μL (within 60 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.

Dosing Table	
Initial	3 mg/kg once weekly for the first 4 weeks
Maintenance	• 1.5 mg/kg once every week, or • 3 mg/kg once every two weeks, or • 6 mg/kg once every four weeks.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	• Up to 3 months
Reauthorization	• Up to 1 year

Codes:

Code	Description
J7170	Injection, emicizumab-kxwh, 0.5 mg

REFERENCES

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

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
New Policy	*10/2024*