**Prior Authorization Criteria**

**Hemlibra (emicizumab-kxwh) Prior Authorization Criteria:**

Hemlibra (emicizumab-kxwh) is a bispecific factor IXa and factor X directed antibody.

**FDA Approved Indication(s):**

Hemlibra is 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.

**Hemlibra will be considered when all of the following criteria are met:**

1. **Initial Approval Criteria: up to 52 weeks**

   **A. Congenital Hemophilia A With Inhibitors (must meet all):**
   - Yes □ No  Prescribed for routine prophylaxis of bleeding episodes in patients with congenital hemophilia A (factor VIII deficiency) -AND-
   - Yes □ No  Prescribed by or in consultation with a hematologist -AND-
   - Yes □ No  Patient has an elevated inhibitor level. -AND-
   - Yes □ No  Provider confirms that patient will discontinue any use of bypassing agents or factor VIII products as prophylactic therapy while on Hemlibra (on-demand usage may be continued) -AND-
   - Yes □ No  Dose does not exceed 3 mg/kg per week during the first four weeks of therapy, followed by either 1.5 mg/kg per week, 3 mg/kg once every two weeks, or 6 mg/kg once every four weeks thereafter.
   -OR-

   **B. Congenital Hemophilia A Without Inhibitors (must meet all):**
   - Yes □ No  Prescribed for routine prophylaxis of bleeding episodes in patients with congenital hemophilia A (factor VIII deficiency); -AND-
   - Yes □ No  Prescribed by or in consultation with a hematologist; -AND-
   - Yes □ No  Patient has moderate to severe hemophilia A-defined as pre-treatment factor VIII level of:
     - 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)
     - Severe: Documentation of endogenous factor VIII levels less than 1% of normal factor VIII (< 0.01 IU/mL)
   -AND-
   - Yes □ No  Patient meets one of the following (a or b): next page
a. Failure of a factor VIII product used for routine prophylaxis as assessed and documented by prescriber unless contraindicated or clinically significant adverse effects are experienced

-OR-

b. Patient has poor venous access, does not tolerate frequent venous access, or has central line or port placement;

-AND-

☐ Yes ☐ No  Provider confirms that patient will discontinue any use of factor VIII products as prophylactic therapy while on Hemlibra (on-demand usage may be continued); -AND-

☐ Yes ☐ No  Dose does not exceed 3 mg/kg per week during the first four weeks of therapy, followed by either 1.5 mg/kg per week, 3 mg/kg once every two weeks, or 6 mg/kg once every four weeks thereafter.

2. Reauthorization Approval Criteria: up to 52 weeks

☐ Yes ☐ No  Provider confirms that patient continues to meet initial authorization criteria.