Prior Authorization Criteria

MISSISSIPPI DIVISION OF MEDICAID

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 <u>With Inhibitors</u> (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 <u>Without Inhibitors</u> (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.