ALASKA MEDICAID
Prior Authorization Criteria

Hemlibra®
(emicizumab-kxwh)

FDA INDICATIONS AND USAGE[1]

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 inhibitors.

APPROVAL CRITERIA[1,2]

1. Patient has been diagnosed with hemophilia A and has documented congenital factor VIII deficiency confirmed by blood coagulation testing **AND**;
2. Being prescribed by or in consultation with hemophilia specialist or hematologist **AND;**
3. Hemlibra® is not being used in combination with Immune Tolerance Induction (ITI) **AND;**
4. Medication will be used as routine prophylaxis to prevent or reduce bleeds **AND;**
5. Patient agrees to maintain a log of bleeds

DENIAL CRITERIA[1,2]

1. Patient has not been diagnosed with hemophilia A and has no documentation of congenital factor VIII deficiency confirmed by blood coagulation testing **OR**;
2. Has not been prescribed by or in consultation with hemophilia specialist or hematologist **OR;**
3. Hemlibra® is being used in combination with Immune Tolerance Induction (ITI) **OR;**
4. Medication will not be used as routine prophylaxis to prevent or reduce bleeds **OR;**
5. Patient does not agree to maintain a log of bleeds

CAUTIONS[1]

- Thrombotic events have been reported and should be monitored for thromboembolism, thrombocytopenia, microangiopathic hemolytic anemia, and acute kidney injury.
- Injection site reactions, pyrexia, headache, diarrhea, and arthralgia were the most common reactions.

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to 12 months with documentation that the patient has responded positively reducing spontaneous bleeds verified by the provider ~~and that the patient has not developed neutralizing antibodies to the drug.~~

QUANTITY LIMITS

- Loading dose is 3 mg/kg subcutaneously injection once a week for the first 4 weeks

Maintenance dosing as follows:

- 1.5 mg/kg once every week, or
- 3 mg/kg once every two weeks, or
- 6 mg/kg once every four weeks.

REFERENCES / FOOTNOTES:

1. Hemlibra [package insert]. South San Francisco, CA; Genentech, Inc. October 2018. Accessed March 2019.
2. Mahlanggu, J; Oldenburg, J; et all. Emicizumab Prophylaxis in Patients Who Have Hemophilia A without Inhibitors. New England Journal of Medicine 2018; 379:811-822 DOI: 10.1056/NEJMoa1803550. Accessed March 14, 2019.