Hemophilia Products – Anti-Inhibitor Antibody: Hemlibra (emicizumab-kxwh) (Subcutaneous)

Effective date: 01/01/2020

Review date: 12/18/19, 1/22/20, 2/25/2021, 06/24/2021, 6/16/2022, 6/22/2023, 12/07/2023, 01/04/2024, 05/15/2024, 08/14/2024

Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

I. Length of Authorization

Unless otherwise specified*, the initial authorization will be provided for 3 months and may be renewed every 12 months thereafter.

Note: The cumulative amount of medication the patient has on-hand will be taken into account for authorizations.

** Initial and renewal authorization periods may vary by specific covered indication*

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

Loading Dose: • 345mg weekly x 4 doses
Maintenance Dose: • 1.5mg/kg weekly = 180mg weekly • 3mg/kg every 2 weeks = 345mg every 2 weeks • 6mg/kg every 4 weeks = 690mg every 4 weeks

B. Max Units (per dose and over time) [Medical Benefit]:

Loading Dose: • 690 billable units (BU) weekly x 4 doses
Maintenance Dose: • 1.5mg/kg weekly = 360 BU weekly • 3mg/kg every 2 weeks = 690 BU every 2 weeks • 6mg/kg every 4 weeks = 1380 BU every 4 weeks

Note: Patient must be dosed at a frequency that will produce the least wastage per dose based on available vial sizes of 30 mg, 60 mg, 105 mg, 150 mg, and 300mg.

III. Initial Approval Criteria

Hemophilia A (congenital factor VIII deficiency) with inhibitors † Φ

- Diagnosis of congenital factor VIII deficiency has been confirmed by blood coagulation testing; **AND**
- Patient has inhibitors to Factor VIII with a current or historical titer of ≥ 5 Bethesda Units (BU)**** ; **AND**
- Must be used as routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**
    - Used as primary prophylaxis in patients with severe factor VIII deficiency (factor VIII level of <1%); **OR**
    - Used as secondary prophylaxis in patients with at least TWO documented episodes of spontaneous bleeding into joints; **AND**
- Not used in combination with Immune Tolerance Induction (ITI); **AND**
    - Patient has at least two documented episodes of spontaneous bleeding into joints; **OR**
    - Patient has documented trial and failure of Immune Tolerance Induction (ITI); **OR**
    - Patient has documented trial and failure of or is currently on routine prophylaxis with a bypassing agent (i.e., NovoSeven, FEIBA).

***Note:** Patients with inhibitor titer levels >0.6 BU to <5 BU who are not responding to or are not a candidate for standard factor replacement, will be evaluated on a case-by-case basis.*

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Hemophilia A (congenital factor VIII deficiency) without inhibitors † Φ

- Diagnosis of congenital factor VIII deficiency has been confirmed by blood coagulation testing; **AND**
- Used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**
- Used as treatment in one of the following:
    - Primary prophylaxis in patients with severe factor VIII deficiency (factor VIII level of <1%); **OR**
    - Secondary prophylaxis in patients with at least TWO documented episodes of spontaneous bleeding into joints; **AND**
- Patient is not a suitable candidate for treatment with shorter half-life Factor VIII (recombinant) products at a total weekly dose of 100 IU/kg or less (as attested by the prescribing physician with appropriate clinical rationale)

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); **Φ** Orphan Drug

IV. Dispensing Requirements for Rendering Providers (Hemophilia Management Program)

- Prescriptions cannot be filled without an expressed need from the patient, caregiver or prescribing practitioner. Auto-filling is not allowed.
- Monthly, rendering provider must submit for authorization of dispensing quantity before delivering factor product.
- The cumulative amount of medication(s) the patient has on-hand should be taken into account when dispensing factor product.
- Dispensing requirements for renderings providers are a part of the hemophilia management program. This information is not meant to replace clinical decision making when initiating or modifying medication therapy and should only be used as a guide.

V. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include thrombotic microangiopathy thromboembolic events (thromboembolism, pulmonary embolism), development of neutralizing antibodies (inhibitors), etc.; **AND**
- Any increases in dose must be supported by an acceptable clinical rationale (i.e. weight gain, half-life study results, increase in breakthrough bleeding when patient is fully adherent to therapy, etc.); **AND**
- Patient has demonstrated a beneficial response to therapy (i.e., the frequency of bleeding episodes has decreased from pre-treatment baseline); **AND**
- The cumulative amount of medication(s) the patient has on-hand will be taken into account when authorizing.

Routine prophylaxis to prevent or reduce the frequency of bleeding episode

- Renewals will be approved for a 12 month authorization period

Dosage/Administration

Indication	Dose
Routine Prophylaxis in Congenital Hemophilia A with or without inhibitors	3 mg/kg by subcutaneous injection once weekly for the first 4 weeks, followed by 1.5 mg/kg once weekly, 3 mg/kg every two weeks, or 6 mg/kg every four weeks

VI. Billing Code/Availability Information

HCPCS Code:

- J7170 - Injection, emicizumab-kxwh, 0.5 mg; 1 billable unit = 0.5 mg

NDC:

Drug	Strength	Form	NDC
	12mg/0.4 mL	SDV	50242-0927-xx
Hemlibra	30 mg/mL	SDV	50242-0920-xx
	60 mg/0.4 mL	SDV	50242-0921- xx
	105 mg/0.7 mL	SDV	50242-0922- xx
	150 mg/mL	SDV	50242-0923- xx
	300 mg/2 mL	SDV	50242-0930-xx

VII. References

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Appendix 1 – Covered Diagnosis Codes

Hemlibra

ICD-10	ICD-10 Description
D66	Hereditary factor VIII deficiency