

# Hemlibra® (emicizumab-kxwh)

Date of Origin: 01/22/2020

Last Review Date: 10/22/2021

Effective Date: 10/22/2021

Dates Reviewed: 10/2021; 01/22/2020

Developed By: Medical Criteria Committee

## I. Length of Authorization

- Initial: 6 months
- Renewal: 12 months

## II. Dosing Limits Max Units (per dose and over time) [HCPCS Unit]:

Product Name	Dosage Form	Indication
Hemlibra, emicizumab- kxwh	30 mg	Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients ages newborn and older with hemophilia A with or without factor VIII inhibitors
	60 mg	
	105 mg	
	150 mg	
<b>Quantity Limit**</b>		
<b>Loading Dose:</b> <ul style="list-style-type: none"><li>• 690 billable units weekly x4 doses</li></ul>		
<b>Maintenance Dose:</b> <ul style="list-style-type: none"><li>• 1.5 mg/kg weekly dosing = 360 BU weekly</li><li>• 3 mg/kg every 2 week dosing = 690 BU every 2 weeks</li><li>• 6 mg/kg every 4 week dosing = 1380 BU every 4 weeks</li></ul>		

\* Max dose based on 115kg person

\* Members must be dosed at a frequency that will produce the least wastage per dose based on available vial sizes

## III. Initial Approval Criteria

- I. Emicizumab-kxwh (Hemlibra) may be considered medically necessary when the following criteria below are met:
  - A. Member has a confirmed diagnosis of **hemophilia A *with* inhibitors** and the following are met:
    1. Treatment is prescribed by or in consultation with a hematologist; **AND**
    2. Clinical documentation confirming of a history of inhibitors [i.e. high anti-FVIII titer ( $\geq 5$  Bethesda units)]; **AND**
    3. Emicizumab-kxwh (Hemlibra) will be used as routine prophylaxis to reduce the frequency of bleeding episodes; **AND**

4. Emicizumab-kxwh (Hemlibra) will not be used in combination with Immune Tolerance Induction (ITI); **AND**
  5. At least one of the following is met:
    - i. Member has at least two documented episodes of spontaneous bleeding into joints; **OR**
    - ii. Member has had an inadequate response to ITI; **OR**
    - iii. Member is currently on, or has had an inadequate response to routine prophylaxis with a bypassing agent (e.g. NovoSeven, FEIBA); **OR**
- B. Member has a confirmed diagnosis of **hemophilia A without inhibitors** and the following are met:
1. Treatment is prescribed by or in consultation with a hematologist; **AND**
  2. Clinical documentation confirming that the member does not have a history of inhibitors [i.e. high anti-FVIII titer ( $\geq 5$  Bethesda units)]; **AND**
  3. Emicizumab-kxwh (Hemlibra) will be used as routine prophylaxis to reduce the frequency of bleeding episodes when one of the following is met:
    - i. Member has severe hemophilia A (defined as factor VIII level of  $<1\%$ ); **OR**
    - ii. Member has had more than one documented episode of spontaneous bleeding; **AND**
  4. Clinical documentation that prior prophylaxis with factor VIII was ineffective for the prevention of bleeding episodes

II. Emicizumab-kxwh (Hemlibra) is considered investigational when used for all other conditions.

### III. Renewal Criteria

- I. Documentation of clinical benefit, including decreased incidence of bleeding episodes or stability of bleeding episodes relative to baseline

### VI. Billing Code/Availability Information

**HCPCS Code:**

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

**NDC:**

Drug	Manufacturer	J-Code	1 Billable Unit Equiv.	Vial Size	NDC
Hemlibra 30mg	Genentech	J7199	1 mL	30 mg/mL	50242-920
Hemlibra 60mg			0.4 mL	150 mg/mL	50242-921
Hemlibra 105mg			0.7 mL	150 mg/mL	50242-922
Hemlibra 150mg			1 mL	150 mg/mL	50242-923

### VII. References

1. Hemlibra [Prescribing Information]. South San Francisco, CA: Genentech October 2018
2. National Hemophilia Foundation. Hemophilia A. Available from: <https://www.hemophilia.org/Bleeding-Disorders/Types-of-Bleeding-Disorders/Hemophilia-A>. Accessed July 5, 2019.

3. National Hemophilia Foundation. MASAC Recommendations Concerning products Licensed for the Treatment of Hemophilia and Other Bleeding Disorders. Available from: <https://www.hemophilia.org/Researchers-Healthcare-Providers/Medical-and-Scientific-Advisory-Council-MASAC/MASAC-Recommendations>. Accessed July 5, 2019.
4. Recommendation on the Use and Management of Emicizumab-kxwh (Hemlibra®) for Hemophilia A with and without Inhibitors. Available from: <https://www.hemophilia.org/Researchers-Healthcare-Providers/Medical-and-Scientific-Advisory-Council-MASAC/MASAC-Recommendations/Recommendation-on-the-Use-and-Management-of-Emicizumab-kxwh-Hemlibra-for-Hemophilia-A-with-and-without-Inhibitors> Accessed August 19, 2019
5. UpToDate, Inc. Hemophilia A and B: Routine management including prophylaxis Hemophilia A and B: Routine management including prophylaxis. UpToDate [database online]. Last updated February 11, 2019.

## Appendix 1 – Covered Diagnosis Codes

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

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corporation (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corporation (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Cahaba Government Benefit Administrators, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC

L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC