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

Document Number: IC-0349

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I. Length of Authorization

The initial authorization will be provided for 3 months and may be renewed every 12 months thereafter.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC unit]:

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

B. Max Units (per dose and over time) [HCPCS Unit]:

Loading Dose: • 690 billable units (BU) weekly x 4 doses
Maintenance Dose: • 1.5 mg/kg weekly dosing = 360 BU weekly • 3 mg/kg every 2 week dosing = 690 BU every 2 weeks • 6 mg/kg every 4 week dosing = 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, and 150 mg.

III. Initial Approval Criteria [1,2,3,8,10,11]

Coverage is provided in the following conditions:

- Diagnosis of congenital factor VIII deficiency has been confirmed by blood coagulation testing; AND

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Hemophilia A (congenital factor VIII deficiency) with inhibitors †

- Patient has confirmed inhibitors to Factor VIII; **AND**
- Must be used as routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**
- Not used in combination with Immune Tolerance Induction (ITI); **AND**
    - Patient has had at least two documented episodes of spontaneous bleeding into joints; **OR**
    - Patient had a documented trial and failure of Immune Tolerance Induction (ITI); **OR**
    - Patient had a documented trial and failure of, or is currently on, routine prophylaxis with a bypassing agent (i.e., NovoSeven, Feiba).

Hemophilia A (congenital factor VIII deficiency) without inhibitors †

- Must be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**
    - Patient must have severe hemophilia A (factor VIII level of <1%); **OR**
    - Patient has had 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)

IV. Renewal Criteria [1,2,3,8]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: symptoms of allergic-anaphylactic reactions (anaphylaxis, dyspnea, rash); thromboembolic events (thromboembolism, pulmonary embolism); and development of neutralizing antibodies (inhibitors); **AND**
- Patient has demonstrated a beneficial response to therapy (i.e., the frequency of bleeding episodes has decreased from pre-treatment baseline)

Dosage/Administration[1,2,3]

Indication	Dose
Routine Prophylaxis Congenital	Loading Dose: 3 mg/kg by subcutaneous injection once weekly for the first 4 weeks

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Indication	Dose
Hemophilia A with or without inhibitors	Maintenance Dose: • 1.5 mg/kg once weekly; **OR** • 3 mg/kg every two weeks; **OR** • 6 mg/kg every four weeks

V. Billing Code/Availability Information

HCPCS

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

NDC:

Drug	Strength	Form	NDC
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

VI. References

1. Hemlibra [package insert]. South San Francisco, CA; Genentech, Inc. October 2018. Accessed January 2020.
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8. MASAC RECOMMENDATION CONCERNING PROPHYLAXIS. 2016 National Hemophilia Foundation. MASAC Document #241; February 2016. Available at: http://www.hemophilia.org. Accessed January 2019.

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10. Oldenburg J, Mahlangu JN, Kim B, et al. Emicizumab Prophylaxis in Hemophilia A with Inhibitors. N Engl J Med. 2017 Aug 31;377(9):809-818. doi: 10.1056/NEJMoa1703068. Epub 2017 Jul 10.
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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), Local Coverage Determinations (LCDs) and Articles 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/Articles): N/

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 Corp (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 Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, 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

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