

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

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I. Length of Authorization

- Initial and renewal authorization periods vary by specific covered indication
- Unless otherwise specified, the initial authorization will be provided for 3 months and may be renewed.

The cumulative amount of medication(s) the patient has on-hand will be taken into account when authorizing.

II. Dosing Limits

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

<p><u>Loading Dose:</u></p> <ul style="list-style-type: none"> • 3mg/kg weekly for the first 4 weeks=1,380mg per 28 day supply
<p><u>Maintenance Dose:</u></p> <ul style="list-style-type: none"> • 1.5mg/kg weekly = 690mg per 28 day supply • 3mg/kg every 2 weeks = 690mg per 28 day supply • 6mg/kg every 4 weeks = 690mg per 28 day supply

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

<p><u>Loading Dose:</u></p> <ul style="list-style-type: none"> • 3mg/kg weekly for the first 4 weeks=1,380mg per 28 day supply
<p><u>Maintenance Dose:</u></p> <ul style="list-style-type: none"> • 1.5mg/kg weekly = 690mg per 28 day supply • 3mg/kg every 2 weeks = 690mg per 28 day supply • 6mg/kg every 4 weeks = 690mg per 28 day supply

It is required to dose the patient at a frequency that will product the least wastage per dose based on available vials of 30mg, 60mg, 105, and 150mg.

III. Initial Approval Criteria

A. Hemlibra

Hemophilia A (congenital factor VIII deficiency) with inhibitors†

- Diagnosis of congenital factor VIII deficiency has been confirmed by blood coagulation testing; **AND**
- Confirmation the patient has inhibitors to Factor VIII ; **AND**
- 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 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).

Hemophilia A (congenital factor VIII deficiency) without inhibitors†

- Diagnosis of congenital factor VIII deficiency has been confirmed by blood coagulation testing; **AND**
- Used for routine prophylaxis: **AND**
 - Patient must have severe hemophilia A (factor VIII level of <1%); **OR**
 - Patient has 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. 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 the following: symptoms of allergic-anaphylactic reactions (anaphylaxis, dyspnea, rash); thromboembolic events (thromboembolism, pulmonary embolism); and development of neutralizing antibodies (inhibitors); **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.).
- The cumulative amount of medication(s) the patient has on-hand will be taken into account when authorizing.
- Patient meets the disease specific criteria below:

Routine prophylaxis to prevent or reduce the frequency of bleeding episode

- Renewals will be approved for a 6 month authorization period

Dosage/Administration

Indication	Dose
Routine Prophylaxis 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, 3mg/kg every two weeks, or 6mg/kg every four weeks

VI. Billing Code/Availability Information

Jcode & NDC:

Drug	Manufacturer	J-Code	Nominal Volume	Concentration	NDC
Hemlibra 30mg	Genentech	J7170	1 mL	30 mg/mL	50242-0920-01
Hemlibra 60mg			0.4 mL	150 mg/mL	50242-0921-01
Hemlibra 105mg			0.7 mL	150 mg/mL	50242-0922-01
Hemlibra 150mg			1mL	150 mg/mL	50242-0923-01

VII. References

1. Hemlibra [package insert]. South San Francisco, CA; Genentech, Inc. October 2018. Accessed October 2018

2. MASAC RECOMMENDATIONS CONCERNING PRODUCTS LICENSED FOR THE TREATMENT OF HEMOPHILIA AND OTHER BLEEDING DISORDERS. 2016 National Hemophilia Foundation. MASAC Document #249; October 2016. Available at: <http://www.hemophilia.org>. Accessed June 2017.
3. Guidelines for the Management of Hemophilia. 2nd Edition. World Federation of Hemophilia. 2013. Available at: <https://www1.wfh.org/publication/files/pdf-1472.pdf>. Accessed June 2017.
4. First Coast Service Options, Inc. Local Coverage Determination (LCD): Hemophilia Clotting Factors (L33684). Centers for Medicare & Medicaid Services, Inc. Updated on 01/03/2017 with effective date 01/01/2017. Accessed June 2017.
5. Novitas Solutions, Inc. Local Coverage Determination (LCD): Hemophilia Clotting Factors (L35111). Centers for Medicare & Medicaid Services, Inc. Updated on 01/06/2017 with effective date 01/01/2017. Accessed June 2017.
6. Annual Review of Factor Replacement Products. Oklahoma Health Care Authority Review Board. Updated April 2016. Access June 2016.
7. Graham A1, Jaworski K. Pharmacokinetic analysis of anti-hemophilic factor in the obese patient. Haemophilia. 2014 Mar;20(2):226-9.
8. Croteau SE1, Neufeld EJ. Transition considerations for extended half-life factor products. Haemophilia. 2015 May;21(3):285-8.
9. Mingot-Castellano, et al. Application of Pharmacokinetics Programs in Optimization of Haemostatic Treatment in Severe Hemophilia a Patients: Changes in Consumption, Clinical Outcomes and Quality of Life. Blood. 2014 December; 124 (21).
10. MASAC RECOMMENDATION CONCERNING PROPHYLAXIS. 2016 National Hemophilia Foundation. MASAC Document #241; February 2016. Available at: <http://www.hemophilia.org>. Accessed August 2017.
11. UKHCDO protocol for first line immune tolerance induction for children with severe haemophilia A: A protocol from the UKHCDO Inhibitor and Paediatric Working Parties. 2017. Available at: <http://www.ukhcdo.org/guidelines>. Accessed December 2017

Appendix 1 – Covered Diagnosis Codes

Hemlibra

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):

Jurisdiction(s): H,L	NCD/LCD Document (s): L35111
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L35111&bc=gAAAAAAAAAAAAA ==	

Jurisdiction(s): N	NCD/LCD Document (s): L33684
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L33684&bc=gAAAAAAAAAAAAA ==	

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	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