AETNA BETTER HEALTH® Coverage Policy/Guideline					
Name:	Hemlibra			Page:	1 of 3
Effective Date:	4/25/2025			Last Review Date:	4/4/2025
Applies to:	☒Illinois ☒Maryland	☒Florida Kids ☒Pennsylvania Kids		☒New Jersey ☒Kentucky PRMD	

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Hemlibra under the patient's prescription drug benefit.

Description:

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Hemlibra is 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.

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Hemlibra

Policy/Guideline:

Documentation:

Submission of the following information is necessary to initiate the prior authorization review: For continuation requests: Chart notes documenting benefit from therapy (e.g., reduced frequency or severity of bleeds).

Prescriber Specialty:

Must be prescribed by or in consultation with a hematologist.

Criteria for Initial Approval:

Hemophilia A (congenital factor VIII deficiency)

Authorization of 12 months may be granted for treatment of hemophilia A (congenital factor VIII deficiency) when ALL the following criteria is met:

A. Member must be using the requested medication for routine prophylaxis to prevent or reduce the frequency of bleeding episodes.
B. Member meets ONE of the following criteria:
    1. Member has mild disease (See Appendix A) and has had an insufficient response to desmopressin or a documented clinical reason for not using desmopressin (See Appendix B).

2. Member has moderate or severe disease (See Appendix A).

C. Member will not use the requested medication in combination with Alhemo or Hympavzi.
D. Member has not previously received treatment with a gene therapy product (e.g., Roctavian) for the treatment of hemophilia A
E. Prophylactic use of factor VIII products (e.g., Advate, Adynovate, Eloctate) will be discontinued after the first week of starting therapy with the requested medication.

Continuation of Therapy:

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in criteria for initial approval when the member is experiencing benefit from therapy (e.g., reduced frequency or severity of bleeds) and member is not using the requested medication in combination with factor VIII products (e.g., Advate, Adynovate, Eloctate, etc.) for prophylactic use.

Dosage and Administration:

For initial and continuation requests, dosing does not exceed the following:

A. Induction: 3mg/kg subcutaneously once weekly for the first 4 weeks.
B. Maintenance: 1.5mg/kg once weekly, or 3mg/kg once every 2 weeks, or 6mg/kg once every 4 weeks.

Appendices:

Appendix A: Classification of Hemophilia by Clotting Factor Level (% Activity) and Bleeding Episodes

Severity	Clotting Factor Level % activity*	Bleeding Episodes
Severe	<1%	Spontaneous bleeding episodes, predominantly into joints and muscles Severe bleeding with trauma, injury or surgery
Moderate	1% to 5%	Occasional spontaneous bleeding episodes Severe bleeding with trauma, injury or surgery
Mild	6% to 40%	Severe bleeding with serious injury, trauma or surgery

Appendix B: Clinical Reasons For Not Utilizing Desmopressin in Patients with Hemophilia A

a. Age < 2 years
b. Pregnancy
c. Fluid/electrolyte imbalance
d. High risk for cardiovascular or cerebrovascular disease (especially the elderly)
e. Predisposition to thrombus formation
f. Trauma requiring surgery

g. Life-threatening bleed
h. Contraindication or intolerance to desmopressin
i. Stimate Nasal Spray is unavailable due to backorder/shortage issues (where applicable)

Approval Duration and Quantity Restrictions:

Approval: 12 months

References:

1. Hemlibra [package insert]. South San Francisco, CA: Genentech, Inc.; January 2024.
2. Srivastava A, Santagostino E, Dougall A, et al. WFH Guidelines for the Management of Hemophilia, 3rd edition. Haemophilia. 2020;26 Suppl 6:1-158. doi:10.1111/hae.14046.
3. National Hemophilia Foundation. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Selected Disorders of the Coagulation System. Revised October 2024. MASAC Document #290. https://www.hemophilia.org/sites/default/files/document/files/MASAC-Products-Licensed.pdf. Accessed December 9, 2024.
4. National Hemophilia Foundation. Hemophilia A (Factor VIII Deficiency). Available at: http://www.hemophilia.org/NHFWeb/MainPgs/MainNHF.aspx?menuid=180&contentid=45&rptname=bleeding. Accessed December 9, 2024.
5. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed December 9, 2024.
6. Leissinger C, Carcao M, Gill JC, et al. Desmopressin (DDAVP) in the management of patients with congenital bleeding disorders. Haemophilia. 2014;20:158-167.