

Hemlibra (emicizumab-kxwh)
Effective 01/01/2024

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Medical and Specialty Medications		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	N/A		

Overview

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.

Coverage Guidelines

Authorization may be granted for members new to the plan who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

OR

Authorization may be granted when the following criteria is met:

1. Member must be using the requested medication for routine prophylaxis to prevent or reduce the frequency of bleeding episodes.
2. Member meets ONE of the following criteria:
 - a. Member has a 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).
 - b. Member has moderate or severe disease (See Appendix A).
3. 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.
4. 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.
5. The requested medication must be prescribed by or in consultation with a hematologist.

Continuation of Therapy

Reauthorization may be granted for continued treatment in members requesting reauthorization when the following criteria are met:

1. Submission of documents supporting that member is experiencing benefit from therapy (e.g., reduced frequency or severity of bleeds).
2. Member is not using the requested medication in combination with factor VIII products (e.g., Advate, Adynovate, Eloctate, etc.) for prophylactic use.
3. 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.

Limitations

1. Initial approvals and reauthorizations will be granted for 12 months.

Appendix

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)

References

1. Hemlibra [package insert]. South San Francisco, CA: Genentech, Inc.; June 2022.



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 other bleeding disorders. Revised March 2022. MASAC Document #272. https://www.hemophilia.org/sites/default/files/document/files/272_Treatment.pdf. Accessed December 2, 2022.
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 2, 2022.
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 2, 2022.
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.

Review History

12/13/2023: Reviewed at Dec P&T, switched from SGM to Custom. Effective 1/1/2024

