

Clinical Pharmacy Program Guidelines for Hemlibra

Program	Prior Authorization
Medication	Hemlibra [®] (emicizumab-kxwh)
Markets in Scope	Arizona, California, Florida-CHIP, Hawaii, Maryland, Nevada, New Mexico, New York, New York EPP, Ohio, Rhode Island
Issue Date	2/2018
Pharmacy and Therapeutics Approval Date	2/2018
Effective Date	4/2018

1. Background:

Hemlibra (emicizumab-kxwh) is a bispecific factor IXa- and factor X-directed antibody indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients with hemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors.¹

2. Coverage Criteria:

<p>A. Hemophilia A</p> <p>1. <u>Initial Authorization</u></p> <p>a. Hemlibra will be approved based on both of the following criteria</p> <p>(1) Diagnosis of hemophilia A</p> <p style="text-align: center;">-AND-</p> <p>(2) Patient has developed high-titer factor VIII inhibitors (≥ 5 Bethesda units [BU])</p> <p style="text-align: center;">-AND-</p> <p>(3) Prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis)</p> <p>Authorization will be issued for 12 months.</p> <p>2. <u>Reauthorization</u></p>

a. Documentation of positive clinical response to Hemlibra therapy

Authorization will be issued for 12 months.

3. References:

1. Hemlibra[®] [package insert]. South San Francisco, CA: Genentech, Inc., November 2017.
2. Oldenburg, J, Mahlangu JN, Kim, B, et al. Emicizumab Prophylaxis in Hemophilia A with Inhibitors. N Engl J Med 2017; 377:809-818.

Program	Prior Authorization –Hemlibra (emicizumab-kxwh)
Change Control	
Date	Change
2/2018	New Program