Reference number(s)
2417-A

SPECIALTY GUIDELINE MANAGEMENT

HEMLIBRA (emicizumab-kxwh)

POLICY

I. INDICATIONS

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 with hemophilia A (congenital factor VIII deficiency) with or without factor VIII inhibitors

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

Authorization of 6 months may be granted for the treatment of:

- Hemophilia A (congenital factor VIII deficiency) with inhibitors, when member has a history of one of the following:
  - High-inhibitor titer (i.e., ≥ 5 Bethesda units per milliliter [BU/mL]) as confirmed by laboratory testing
  - Inadequate response to Immune Tolerance Therapy (ITT)
  - Utilization of bypassing agents (e.g. Feiba, NovoSeven)
- Hemophilia A without inhibitors if severe (i.e., endogenous factor VIII level less than 1%) and either there is evidence of:
  - Significant bleeds, such as at least one episode of a central nervous system, large joint (e.g., ankle, knee, elbow, shoulder, hip), or life-threatening bleed
  - Arthropathy

III. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for all members (including new members) who meet all initial authorization criteria and achieve or maintain reduction in the frequency of bleeding episodes

IV. REFERENCES

1. Hemlibra [package insert]. South San Francisco, CA: Genentech, Inc.; October 2018.
2. Oldenburg J, Mahlangu JN, Kim B, et al. Emicizumab Prophylaxis in Hemophilia A with Inhibitors. N Engl J Med. 2017; 377:809-818.
3. A Study of Emicizumab Administered Subcutaneously (SC) in Pediatric Participants With Hemophilia A and Factor VIII (FVIII) Inhibitors (HAVEN 2). ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). June 10, 2016. Identifier: NCT02795767. Available at https://clinicaltrials.gov/ct2/show/NCT02795767. Accessed November 20, 2017.

4. Srivastava A, Brewer A, Street A, et al. Guidelines for the management of hemophilia. Haemophilia. January 2013;19(1):e1-e47. Available at https://www.wfh.org/en/resources/wfh-treatment-guidelines. Accessed November 20, 2017.
5. Kruse-Jarres R, Kempton CL, Baudo F, et al. Acquired hemophilia A: Updated review of evidence and treatment guidance. Am J Hematol. 2017;92:695–705.
6. National Hemophilia Foundation. MASAC recommendations concerning products licensed for the treatment of hemophilia and other bleeding disorders. Revised April 2018. MASAC Document #253. Available at https://www.wfh.org/en/resources/wfh-treatment-guidelines. Accessed October 15, 2018.
7. J. Mahlangu, J. Oldenburg, et al. Emicizumab Prophylaxis in Patients who have Hemophilia A without Inhibitors (HAVEN 3). N Engl J Med. 2018; 379:811-822.