Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 179.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Hemlibra (emicizumab-kxwh)

Applicable line of business:

Commercial	X	Medicaid	
Medicare	X	ACA	X
CHIP	X		

I. Policy:
Hemlibra (emicizumab-kxwh)

II. Purpose/Objective:
To provide a policy of coverage regarding Hemlibra (emicizumab-kxwh)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:
a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

DESCRIPTION:
Hemlibra (emicizumab-kxwh) is a humanized monoclonal modified immunoglobulin G4 (IgG4) antibody with a bispecific factor IXa- and factor X-directed antibody, bridges activated factor IX and factor X to restore the function of missing activated factor VIII that is needed for effective hemostasis. Emicizumab-kxwh has no structural relationship or sequence homology to FVIII and, therefore, does not induce or enhance the development of direct inhibitors to FVIII. Hemlibra is indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in patients with hemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Hemlibra (emicizumab-kxwh) will be considered medically necessary for the commercial, exchange, CHIP and Medicare lines of business when ALL of the following criteria are met:

- Medical record documentation of a diagnosis of hemophilia A (a documented Factor VIII deficiency) **AND**
- Medical record documentation that Hemlibra is being used for routine prophylaxis

LIMITATIONS:
Hemlibra is not indicated for on-demand/perioperative control of bleeding episodes associated with a diagnosis of hemophilia A. Hemlibra is formulated to allow self-administration. Requests for routine prophylaxis in which Hemlibra will be self-administered should be submitted under the members Pharmacy Benefit for Prior Authorization. In the event a member is unable to self-administer, Hemlibra will be covered under the Medical Benefit if above Prior Authorization criteria are met, and it is documented that a health care professional will be administering weekly doses for routine prophylaxis. Hemlibra will not be covered for on-demand and perioperative control of bleeding episodes.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:
1. Hemlibra [prescribing information]. South San Francisco, CA: Genentech Inc; March 2023.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 7/17/18

Revised: 3/19/19 (removed clotting factor inhibitors), 1/16/23 (LOB carve out), 12/29/23 (references added), 1/8/24 (Medicaid business segment), 1/7/25 (LOB table, taglines, removed Medicaid business segment)

Reviewed: 2/1/20, 1/19/21, 1/18/22

MA UM Committee approval: 12/31/23, 12/31/24