MetroPlus Health

Policy and Procedure

Title: UM-PT006 Hemlibra (emicizumab-kxwh)	**Division: Medical Management** **Department: Pharmacy**
Approval Date: 4/28/2023	**LOB: Medicaid, HIV SNP, HARP, CHP, QHP, EP, Gold, Goldcare**
Effective Date: 4/28/2023	**Policy Number: UM-PT006**
Review Date: 3/4/2026	**Cross Reference Number:**
Retired Date:	**Page 1 of 6**

I. POLICY DESCRIPTION:

Hematology – Antihemophilic Agent, Bispecific Antibody, Blood Modifier Agent, Hemlibra (Emicizumab-kxwh)

II. RESPONSIBLE PARTIES:

Medical Management Administration, Pharmacy Department, Utilization Management, Integrated Care Management, Claims Department

III. DEFINITIONS:

Hemlibra (Emicizumab-kxwh) is a humanized monoclonal modified immunoglobulin G4 (IgG4) antibody that binds to activated factor IXa and factor X to restore function of factor VIII which is needed to promote hemostasis. Hemlibra is FDA approved for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients ages newborn and older who have hemophilia A (congenital factor VIII deficiency) with or without factor VIII inhibitors.

IV. POLICY:

Hemlibra will be considered medically necessary once the following coverage criteria is met and may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Chart notes must be submitted to confirm diagnosis and previous treatment(s).

INITIAL REQUEST:

1. Hemophilia A with or without Factor VIII Inhibitors:

A. Member has ONE of the following diagnoses of hemophilia A:

a. Hemophilia A with factor VIII inhibitors defined as ONE of the following:

i. Positive Factor VIII inhibitor titer > 5 Bethesda Units (BU)**;**

OR

ii. Positive Factor VIII inhibitor titer ≤ 5 Bethesda Units (BU) and the member has had an anamnestic or an inadequeate clinical response to Factor VIII products;

OR

b. Hemophilia A without factor VIII inhibitors defined as ONE of the following:

i. Pretreatment Factor VIII levels ≤ 2% of normal;

OR

ii. Pretreatment Factor VIII levels > 2% and < 40% of normal plus ONE of the following scenarios:

1. Member has experienced a severe, traumatic, or spontaneous bleeding episode(s);

OR

2. Member has experienced a joint bleed, hemophilia-related joint damage or has a joint that is at risk of recurrent bleeding

OR

iii. Member is in a clinical situation that poses a bleeding risk in which the prescriber determines Hemlibra necessary;

AND

B. Member will be prescribed Hemlibra for prophylaxis therapy to prevent or reduce frequency of bleeding episodes;

AND

C. Hemlibra will be prescribed through the consultation of a hematologist;

AND

D. Prescriber attests to one of the following:

a. If member is currently receiving a bypassing agent (e.g., Feiba, NovoSeven RT, Sevenfact) for prophylatic use, therapy will be discontinued the day before starting Hemlibra

OR

b. If member is currently receiving a Factor VIII product (e.g., Advate, Adynovate, Eloctate, Nuwiq, Recombinate, Xyntha) for prophylatic use, therapy will be discontinued within the first week of Hemlibra.

AND

E. Prophylatic use of bypassing agents and Factor VIII products will not occur while using Hemlibra but the use of bypassing agents and Factor VIII products for breakthrough bleeding is permitted.

AND

F. If the member is receiving Feiba [activated prothrombin complex concentrate (aPCC)] for breakthrough bleeding, then ALL of the following must be considered:

a. Dose of aPCC will not exceed 100 U/kg/24 hours

AND

b. Monitoring will be conducted for thromboembolism and thromotic microangiopathy (TMA);

AND

G. Hemlibra will be prescribed based on the approved FDA dosing schedule;

AND

H. Authorization is for no more than 6 months

RENEWAL REQUEST:

1. **Hemophilia A with or without Factor VIII inhibitors:**
   - **A.** Initial conditions of coverage have been met;

   AND

   - **B.** Member has experienced a positive clinical response to Hemlibra as defined as reduction in frequency of breathrough bleeds;

   AND

   - **C.** Member is not using Hemlibra in combination with ANY of the following products prophylactically;
     - **a.** Bypassing agent (e.g., Feiba, NovoSeven RT, Sevenfact)

     OR

     - b. Factor VIII products (e.g., Advate, Adynovate, Eloctate, Nuwiq, Recombinate, Xyntha);

   AND

   - **D.** If member is receiving Feiba [activated prothrombin complex concentrate (aPCC)] for breakthrough bleeding, prescriber will continue to monitor the member for thromboembolism and thrombotic microangiopathy (TMA);

   AND

   - **E.** Authorization is for no more than 12 months

V. LIMITATIONS/ EXCLUSIONS:

Hemlibra is considered to be experimental and investigational if prescribed for indications that have not been approved by the FDA.

VI. APPLICABLE PROCEDURE CODES:

CPT	Description
J7170	Injection, emicizumab-kxwh, 0.5 mg

VII. APPLICABLE DIAGNOSIS CODES:

CODE	Description
D66	Hereditary factor VIII deficiency
Z14.01	Asymptomatic hemophilia A carrier
Z14.02	Symptomatic hemophilia A carrier

VIII. REFERENCES:

1. Genentech, Inc. Hemlibra (emicizumab-kxwh) [package insert]. U.S Food and Drug Administration website. https://www.gene.com/download/pdf/hemlibra_prescribing.pdf January 2024
2. Hoffmann-La Roche, Chugai Pharmaceutical. A Randomized, Multicenter, Open-Label, Phase III Clinical Trial to Evaluate the Efficacy, Safety, and Pharmacokinetics of Prophylactic Emicizumab Versus no Prophylaxis in Hemophilia A Patients With Inhibitors. clinicaltrials.gov. Published May 26, 2021. Accessed March 14, 2023. https://clinicaltrials.gov/ct2/show/NCT02622321
3. Hoffmann-La Roche, Chugai Pharmaceutical. A Multicenter, Open-Label, Phase III Clinical Trial to Evaluate the Efficacy, Safety, and Pharmacokinetics of Subcutaneous Administration of Emicizumab in Hemophilia A Pediatric Patients With Inhibitors. clinicaltrials.gov. Published May 7, 2021. Accessed March 14, 2023. https://clinicaltrials.gov/ct2/show/NCT02795767
4. Hoffmann-La Roche, Chugai Pharmaceutical. A Randomized, Multicenter, Open-Label, Phase III Clinical Trial to Evaluate the Efficacy, Safety, and Pharmacokinetics of Prophylactic Emicizumab Versus no Prophylaxis in Hemophilia A Patients Without Inhibitors. clinicaltrials.gov. Published October 19, 2022. Accessed March 14, 2023. https://clinicaltrials.gov/ct2/show/NCT02847637
5. Hoffmann-La Roche, Chugai Pharmaceutical. A Multicenter, Open-Label, Phase III Study to Evaluate the Efficacy, Safety, Pharmacokinetics, and Pharmacodynamics of Emicizumab Given Every 4 Weeks (Q4W) in Patients With Hemophilia A. clinicaltrials.gov. Published January 31, 2022. https://clinicaltrials.gov/ct2/show/NCT03020160

REVISION LOG:

REVISIONS	INITIAL	DATE
Creation date	SC	4/28/2023
Annual review	JL	3/4/2026

Approved: **Date:**	**Approved:** **Date:**
Suzana Patel 3/12/26	03.12.2026
Suzana Patel, PharmD **Senior Director of Pharmacy**	**Sanjiv Shah, MD** **Chief Medical Officer**

Medical Guideline Disclaimer:

 The treating physician or primary care provider must submit MetroPlus Health Plan clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, Metroplus Health Plan will not be able to properly review the request for prior authorization. The clinical review criteria expressed in this policy reflects how MetroPlus Health Plan determines whether certain services or supplies are medically necessary. MetroPlus Health Plan established the clinical review criteria based upon a review of currently available clinical information(including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). MetroPlus Health Plan expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered andor paid for by MetroPlus Health Plan, as some programs exclude coverage for services or supplies that MetroPlus Health Plan considers medically necessary. If there is a discrepancy between this guidelines and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and website links are accurate at time of publication.

MetroPlus HealthPlan has adopted the herein policy in providing management, administrative and other services to our members, related to health benefit plans offered by our organization.