

Pharmacy Management Drug Policy

SUBJECT: Hemlibra (emicizumab-kxwh)

POLICY NUMBER: PHARMACY-94

EFFECTIVE DATE: 10/01/2020

LAST REVIEW DATE: 06/24/2024

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. This drug policy applies to the following line/s of business:

Policy Application

Category:	<input checked="" type="checkbox"/> Commercial Group (e.g., EPO, HMO, POS, PPO)	<input checked="" type="checkbox"/> Medicare Advantage
	<input checked="" type="checkbox"/> On Exchange Qualified Health Plans (QHP)	<input type="checkbox"/> Medicare Part D
	<input checked="" type="checkbox"/> Off Exchange Direct Pay	<input checked="" type="checkbox"/> Essential Plan (EP)
	<input checked="" type="checkbox"/> Medicaid & Health and Recovery Plans (MMC/HARP)	<input checked="" type="checkbox"/> Child Health Plus (CHP)
	<input type="checkbox"/> Federal Employee Program (FEP)	<input type="checkbox"/> Ancillary Services
	<input checked="" type="checkbox"/> Dual Eligible Special Needs Plan (D-SNP)	

DESCRIPTION:

Hemophilia is an inherited, lifelong bleeding disorder caused by deficiency of coagulation factors. The blood fails to clot which can result in bleeding into soft tissue, joints, and internal organs. It can also cause severe bleeding and death in trauma from intracranial bleeding. Hemophilia is an X-linked recessive disease that presents almost exclusively in male children of female carriers. The two most common types of hemophilia are Hemophilia A, which is a lack of Factor VIII and Hemophilia B, which is a lack of Factor IX.

There are varying severities of both hemophilia A and B depending upon the level of factor produced by the patient. Patients with severe hemophilia frequently experience bleeding even in the absence of trauma. Patients with moderate hemophilia experience less bleeding, and mild hemophilia patients usually experience bleeding only after obvious trauma. The severity classification system is based on the patient's factor activity level:

Disease Severity	Clotting Factor Level
Severe	< 1 IU/dl or < 1% of normal
Moderate	1-5 IU/dl or 1-5% of normal
Mild	5-40 IU/dl or 5 to < 40% of normal

The current treatment for both hemophilia A and B is to replace the deficient coagulation factor either through episodic (on demand) treatment which is replacement factor given at the time of bleeding or through continuous prophylaxis which is replacement factor given to prevent bleeding. Patients can develop antibodies to the factor, known as inhibitors, that will render the factor inactive (infused factor is seen as a foreign protein). Inhibitor development (both low and high titer inhibitors) can greatly interfere with the ability to treat bleeding and achieve adequate hemostasis. High titer inhibitors bind to exogenously administered replacement factor and prevent it from achieving hemostasis.

Hemlibra (emicizumab-kxwh) is a monoclonal antibody used for routine prophylaxis to prevent or decrease the frequency of bleeding episodes for patients with hemophilia A with or without factor VIII inhibitors. It is a bispecific factor IXa and factor-X directed antibody that works by bridging factor IXa and factor X to activate the natural coagulation cascade to restore the blood clotting process in hemophilia A, bypassing the need of FVIII.

Pharmacy Management Drug Policy

Hemlibra (emicizumab – kxwh)

POLICY:

Hemlibra (emicizumab-kxwh) – Rx or Medical benefit

1. Must be prescribed by a hematologist **AND**
2. Must be used for routine prophylaxis or to prevent or reduce frequency of bleeding episodes **AND**
3. Patient has a history of two or more episodes of spontaneous bleeding into joints or muscles **AND**
4. Must have a diagnosis of hemophilia A with inhibitors **OR**
5. Must have a diagnosis of hemophilia A without inhibitors
 - a. Patient must have severe hemophilia with a factor VIII <1% as confirmed by laboratory testing **AND**
 - b. Prescriber must attest that prophylactic use of bypassing agent will not occur while using Hemlibra **AND**
 - c. In addition to documentation of the patient's baseline annualized bleeding rate, the prescriber must provide documentation of continuation of spontaneous bleeds and/or inability to achieve appropriate trough level after a trial of prophylactic factor VIII replacement products
 - d. Use of Hemlibra due to convenience will not be considered medically necessary and will not be authorized
6. Approval will be for 2 years.
7. Recertification will require documentation that the patient has had a beneficial response (ex: reduction in bleeding events and/or severity, reduction in number of bleeding events requiring treatment and/or number of spontaneous bleeding events) to current therapy with Hemlibra
8. The recommended dosage is:
 - a. Initial dosage: 3mg/kg SC once weekly for 4 weeks
 - b. Maintenance dosage: 1.5 mg/kg once weekly **or** 3 mg/kg once every 2 weeks **or** 6 mg/kg once every 4 weeks

APPROVAL TIME PERIODS:

Line of Business	Initial approval	Recertification
Managed Medicaid (MMC) / Essential Plan (EP) / Child Health Plus (CHP) / Health and Recovery Program (HARP)	6 months	12 months
Commercial/Exchange/Medicare Part B	2 years	2 years

POLICY GUIDELINES:

1. Prior authorization is contract dependent.
2. Not all benefits allow coverage of healthcare professional administered drugs as part of their pharmacy benefit
3. This policy does not apply to Medicare Part D and D-SNP pharmacy benefits. The drugs in this policy may apply to all other lines of business including Medicare Advantage.
4. For members with Medicare Advantage, medications with a National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) will be covered pursuant to the criteria outlined by the NCD and/or LCD. NCDs/LCDs for applicable medications can be found on the CMS website at <https://www.cms.gov/medicare-coverage-database/search.aspx>. Indications that have not been addressed by the applicable medication's LCD/NCD will be covered in accordance with criteria determined by the Health Plan (which may include review per the Health Plan's Off-Label Use of FDA Approved Drugs policy). Step therapy requirements may be imposed in addition to LCD/NCD requirements.
5. Continued approval at time of recertification will require documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition. Such

Pharmacy Management Drug Policy

Hemlibra (emicizumab – kxwh)

documentation may include progress notes, imaging or laboratory findings, and other objective or subjective measures of benefit which support that continued use of the requested product is medically necessary. Also, ongoing use of the requested product must continue to reflect the current policy's preferred formulary.

6. All non-FDA approved indications for Hemlibra will be evaluated using off label policy criteria.
7. Dose and frequency should be in accordance with the FDA label or recognized compendia (for off-label uses). When services are performed in excess of established parameters, they may be subject to review for medical necessity.
8. Not all contracts cover all Medical Infusible drugs. Refer to specific contract/benefit plan language for exclusions of Injectable Medications.

CODES:

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

Codes may not be covered under all circumstances. Please read the policy and guideline statements carefully.

Codes may not all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I). Not medically necessary/appropriate = (NMN).
Copyright © 2006 American Medical Association, Chicago, IL

HCPCS:

Description (Number): Hemlibra (J7170)

UPDATES:

Date	Revision
06/24/2024	Revised
05/09/2024	P&T Committee Approval
04/19/2024	Revised
03/14/2023	Revised
12/15/2022	Revised
05/5/2022	P&T Committee Approval
05/6/2021	P&T Committee Approval
03/02/21	Revised
02/15/21	Revised
10/2020	Policy Effective
02/2020	Policy Created/P & T Approval

REFERENCES:

1. IPD Analytics. Hemophilia – Update on Treatment Management. Feb 2019. Accessed: Feb 1, 2020.
2. IPD Analytics. Hemlibra for use in Hemophilia. Nov 2018. Accessed: Feb 1, 2020.
3. Recommendation on the Use and Management of Emicizumab-kxwh (Hemlibra®) for Hemophilia A with and without Inhibitors. National Hemophilia Foundation, Medical and Scientific Advisory Council. Accessed: Feb 1, 2020.