DATE: June 20, 2025

TO: Commonwealth of Kentucky Medicaid Prescriber Network

FROM: MedImpact Healthcare Systems

Subject: **Hemlibra Prior Authorization Criteria Changes**

Status: Effective July 1, 2025, the Commonwealth of Kentucky Department for Medicaid Services (DMS) will implement criteria for **Hemlibra (emicizumab-kxwh).** The new prior authorization (PA) criteria are defined below.

Any members with at least one paid Hemlibra claim within the 90 days prior to July 1, 2025 (April 2, 2025 through June 30, 2025) will be provided a grandfathered authorization until October 1, 2025 to allow time to obtain a PA and/or transition to a different therapy if applicable. For any members who are new starts or fall outside the 90 day window, a PA will be required starting July 1, 2025.

Agent(s) Subject to Criteria	Criteria for Approval

HEMLIBRA (emicizumab-kxwh)	**Approval Duration**: 1 year (initial), 1 year (renewal)
	
	Initial Approval Criteria
	
	*Hemophilia A **WITH** Factor VIII inhibitors*
	• Prescribed for prophylactic treatment to prevent or reduce bleeding episodes in patients with Hemophilia A; **AND**
	• Prescriber provides documentation (e.g., lab result within the past year) confirming the presence of Factor VIII inhibitors; **AND**
	• Prescriber provides documentation (e.g., chart notes or summary) of patient's current body weight (within last 6 months); **AND**
	• Provider attests to therapy transition protocol:
	  ○ During the transition to Hemlibra, short-term overlap with prophylactic bypassing agents or Factor VIII may occur to ensure continuous bleed protection. After the transition period, Hemlibra will not be used in combination with prophylactic Factor VIII or bypassing agents.
	  ▪ Prophylactic use of bypassing agents will be discontinued at least 24 hours prior to starting Hemlibra; **AND**
	  ▪ Prophylactic Factor VIII replacement products will be discontinued within 7 days after starting Hemlibra; **AND**
	• Provider attests to the following breakthrough bleed protocol:
	  ○ Hemlibra will not be used in combination with prophylactic Factor VIII or bypassing agents.
	  ▪ On-demand use of Factor VIII products for acute bleeds is permitted
	  ▪ If on-demand bypassing agents are used, dosing will not exceed aPCC ≤ 100 U/kg per 24 hours, and platelet

Agent(s) Subject to Criteria	Criteria for Approval

	counts will be monitored for signs of thrombotic microangiopathy (TMA) or thromboembolism; **AND**
	• The requested dose does not exceed the maximum FDA-approved dose for this condition
	
	*Hemophilia A **WITHOUT** Factor VIII inhibitors*
	• Prescribed for prophylactic treatment to prevent or reduce bleeding episodes in patients with Hemophilia A; **AND**
	• Prescriber provides documentation (e.g., lab result within the past year) of absence of Factor VIII inhibitors; **AND**
	• Prescriber provides documentation (e.g. chart notes or summary) of patient's current body weight (within last 6 months); **AND**
	• Provider attests to therapy transition protocol:
	  ○ During the transition to Hemlibra, short-term overlap with prophylactic Factor VIII may occur to ensure continuous bleed protection. After the transition period, Hemlibra will not be used in combination with prophylactic Factor VIII or bypassing agents.
	  ▪ Prophylactic Factor VIII products will be discontinued within 7 days after starting Hemlibra; **AND**
	  ▪ On-demand use of Factor VIII products for acute bleeds is permitted; **AND**
	• The requested dose does not exceed the maximum FDA-approved dose for this condition
	
	Renewal Criteria
	• Prescriber attests patient has experienced clinical benefit compared to baseline (e.g., reduced bleeding frequency/severity); **AND**
	• Prescriber provides documentation (e.g., lab result within the past year) of the patient's current Factor VIII inhibitor status (present or absent); **AND**
	• Prescriber provides documentation (e.g., chart notes or summary) of patient's current body weight (within last 6 months); **AND**
	• Prescriber attests that patient is not using Hemlibra in combination with Factor VIII products for prophylactic use. On-demand use for acute bleeds is permitted; **AND**
	• The requested dose does not exceed the maximum FDA-approved dose for this condition

Quantity limits and PA criteria for drugs on the preferred drug list can be found on the Kentucky Medicaid Provider Portal (https://kyportal.medimpact.com/provider-documents/drug-information).

KY MCO Contact Information

Program Questions	KYMCOPBM@MedImpact.com
Pharmacy Help Desk	(800) 210-7628 [24 hours per day/ 7 days per week]
Prior Authorizations	Phone (844) 336-2676 [8:00AM - 7:00PM EST/ 7 days per week];Fax (858) 357-2612
Pharmacy Portal	https://kyportal.medimpact.com/
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KY FFS Contact Information

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