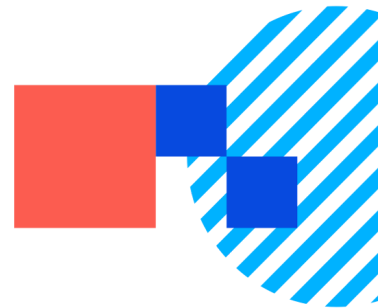




Hemlibra Prior Authorization

Drug(s) Applied:	Hemlibra (emicizumab-kxwh, subcutaneous solution)
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Criteria:

Drug(s) Applied will be approved when the requested medication is being used for an FDA approved indication and all of the following criteria are met:

I. Initial Approval Criteria

A. **Hemophilia A with Factor VIII inhibitors** as indicated by chart notes within past 90 days:

1. Patient's inhibitor level is greater than or equal to 5 Bethesda Units (lab records required) **and**
2. If the patient is receiving Feiba for breakthrough bleeds, BOTH of the following:
 - a) Patient will be monitored for thrombotic microangiopathy and thromboembolism **and**
 - b) Prescriber has counseled the patient on the maximum dosages of Feiba to be used (i.e., no more than 100 u/kg/24 hours) **and**
3. ALL of the following
 - a) Requested agent will be used as prophylaxis to prevent or reduce the frequency of bleeding episodes **and**
 - b) Beyond the first week of starting the requested agent, the patient will NOT be using the requested agent in combination with a Factor VIIa product (e.g., NovoSeven RT), a Factor VIII product (e.g., Advate, Adynovate, Eloctate, Nuwiq, Recombinate, Xyntha), or a bypassing agent (e.g., Feiba, NovoSeven. Sevenfact) used for prophylaxis treatment (exception: on-demand treatment is acceptable to continue) **and**
 - c) Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., hematology)

Approval Duration: 12 months

B. **Hemophilia A without Factor VIII inhibitors** or the patient has an inhibitor level < 5; as indicated by chart notes within past 90 days:

1. ONE of the following
 - a) Patient has severe hemophilia with residual Factor VIII level of less than 1% (medical records required) **or**
 - b) Patient is under 2 years of age **or**



- c) The patient has had at least two episodes of spontaneous bleeding into the joints **or**
- d) The patient has had 1 or more episodes of bleeding into the central nervous system or other serious life-threatening bleed **and**
- 2. ALL of the following
 - a) Requested agent will be used as prophylaxis to prevent or reduce the frequency of bleeding episodes **and**
 - b) Beyond the first week of starting the requested agent, the patient will NOT be using the requested agent in combination with a Factor VIIa product (e.g., NovoSeven RT), a Factor VIII product (e.g., Advate, Adynovate, Eloctate, Nuwiq, Recombinate, Xyntha), or a bypassing agent (e.g., Feiba, NovoSeven, Sevenfact) used for prophylaxis treatment (exception: on-demand treatment is acceptable to continue) **and**
 - c) Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., hematology)

Approval Duration: 12 months

II. Continued Therapy Approval

- A. **Hemophilia A with or without Factor VIII inhibitors** as indicated by chart notes within past 12 months
 - 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization process or meets the initial therapy criteria above **and**
 - 2. Patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **and**
 - 3. The patient has shown clinical benefit since starting the requested agent (i.e., less breakthrough bleeds) **and**
 - 4. If the patient is receiving Feiba [activated prothrombin complex concentrate (aPCC)] for breakthrough bleeds, the patient will be monitored for thrombotic microangiopathy and thromboembolism **and**
 - 5. The patient will NOT be using the requested agent in combination with a Factor VIIa product (e.g., NovoSeven RT), a Factor VIII product (e.g., Advate, Adynovate, Eloctate, Nuwiq, Recombinate, Xyntha) or a bypassing agent (e.g., Feiba, NovoSeven, Sevenfact) used for prophylaxis treatment (exception: on-demand treatment is acceptable to continue) **and**
 - 6. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., hematology)

Approval Duration: 12 months

Policy Owned by: Curative PBM team