curative

Hemlibra Prior Authorization

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

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