

Factor VIIa Prior Authorization

Drug(s) Applied:	SevenFact (coagulation factor VIIa recombinant-jncw)
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Criteria:

Drug 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** as indicated by chart notes within past 90 days

1. Patient is ≥ 12 years of age **and**
2. Patient has inhibitors to Factor VII **and**
3. Requested agent is being used for ONE of the following:
 - a) On-demand use for bleeds **or**
 - b) Peri-operative management of bleeding **or**
 - c) Prophylaxis AND the following:
 - (1) The patient will NOT be using the requested agent in combination with another Factor VIIa agent or Feiba (exception: on-demand use of Feiba is acceptable) **and**
4. 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

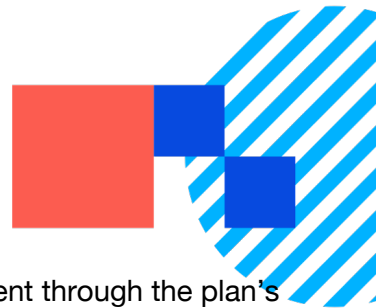
B. **Hemophilia B** as indicated by chart notes within past 90 days

1. Patient is ≥ 12 years of age **and**
2. The patient has inhibitors to Factor IX **and**
3. The requested agent is being used for ONE of the following:
 - a) On-demand use for bleeds **or**
 - b) Prophylaxis AND the following:
 - (1) The patient will NOT be using the requested agent in combination with another Factor VIIa agent or Feiba (exception: on-demand use of Feiba is acceptable) **or**
 - c) Peri-operative management of bleeding **and**
4. 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 or B with 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 for breakthrough bleeds, 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**
5. Patient will NOT be using the requested agent in combination with another prophylaxis agent 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