



## Prior Authorization Approval Criteria *antihemophilic factor VIII (recombinant)*

<b>Generic name:</b>	Antihemophilic factor VIII (recombinant)
<b>Brand name:</b>	Advate; Helixate FS; Kogenate FS; Recombinate; ReFacto
<b>Medication class:</b>	Antihemophilic agent
<b>FDA-approved uses:</b>	Treatment of classic hemophilia (hemophilia A) for patients in whom a deficiency in factor VIII has been demonstrated Prevention and control of bleeding episodes Perioperative management of patients with hemophilia Significant therapeutic value in patients with acquired factor VIII inhibitors not exceeding 10 Bethesda units per mL (< 10 BU/mL)
<b>Available dosage form:</b>	Sterile powder for reconstitution for IV infusion
<b>Usual dose range:</b>	Dosage based on desired factor VIII increase (%): Int. units factor VIII = (desired factor VIII increased %) x 0.5 x (body weight)  Recommended dose: <ul style="list-style-type: none"><li>○ Average normal antihemophilic factor plasma activity ranges: 50-150%</li><li>○ Level to prevent spontaneous hemorrhage: 5%</li><li>○ Minor hemorrhage: 20-40%</li><li>○ Moderate to major hemorrhage and minor surgery: 30-60%</li><li>○ Life threatening hemorrhage, fracture, and head trauma: 80-100%</li><li>○ Major surgery: 100%</li></ul> Dose can be repeated every 6-24 hours based on the circulating AHF levels.
<b>Duration of therapy:</b>	Usually 1 to 3 days, or until pain and disability are resolved, or until threat is resolved, or until healing complete (10-14 days).
<b>Criteria for use</b> <i>(bullet points below are all inclusive unless otherwise noted):</i>	<ul style="list-style-type: none"><li>• Patients with hemophilia A with a deficiency in factor VIII</li><li>• Patients with bleeding episodes</li><li>• Patients with acquired factor VIII inhibitors not exceeding 10 Bethesda units/mL</li></ul>
<b>Criteria for continuation of therapy:</b>	May be used until pain and disability are resolved or healing is achieved.
<b>Caution:</b>	<ul style="list-style-type: none"><li>• Products may potentially contain infectious agents</li><li>• Factor VIII deficiency should be proven prior to the administration of medications</li><li>• Possibility of the development of circulating neutralizing antibodies to Factor VIII</li><li>• Possibility of hypersensitivity reactions</li><li>• Pregnancy and lactation</li></ul>

**Monitoring:**

- Heart rate and blood pressure before and during I.V. administration
- AHF levels prior to and during treatment
- Development of factor VIII inhibitors
- Signs and symptoms of bleeding

**Contraindications:**

- Hypersensitivity to any component of the formulation
- Hypersensitivity to mouse or hamster protein

**Not approved if:**

- Patients have von Willebrand's disease
- Patients with acquired factor VIII inhibitors exceeding 10 Bethesda units/mL
- Being used for long-term routine prophylaxis to reduce bleeding episodes
- Current or planned treatment with immunomodulatory drugs
- Severe hepatic impairment

FCHP Pharmacy and Therapeutics Committee approval: \_\_\_\_\_

Date: \_\_\_\_\_

Adopted: 03/15/06