



Prior Authorization Approval Criteria

antihemophilic factor VIII (human)

Generic name:	Antihemophilic factor VIII (human)
Brand name:	Hemofil M; Monoclate P; Koāte DVI; Humate P; Alphanate
Medication class:	Antihemophilic agent
FDA-approved uses:	<p>Management of hemophilia A for patients in whom a deficiency in factor VIII has been demonstrated</p> <p>Significant therapeutic value in patients with acquired factor VIII inhibitors not exceeding 10 Bethesda units/mL</p> <p><i>Humate P®</i>: In addition, indicated as treatment of spontaneous bleeding in patients with severe von Willebrand disease and in mild and moderate von Willebrand disease where desmopressin is known or suspected to be inadequate</p>
Available dosage form:	Single dose dry concentrate for reconstitution for injection
Usual dose range:	<p>Dosage based on desired factor VIII increased (%): Int. units factor VIII = (desired factor VIII increased %) x 0.5 x (body weight).</p> <p>Recommended dose:</p> <ul style="list-style-type: none">○ Average normal antihemophilic factor plasma activity ranges: 50% to 150%.○ Level to prevent spontaneous hemorrhage: 5%○ Early hemarthrosis or muscle or oral bleed: 20-40%○ More extensive hemarthrosis, muscle bleed, or hematoma: 30-60%○ Life threatening bleeds: 60-100%○ Minor surgery: 60-80%○ Major surgery: 80-100% <p><i>Humate P for von Willebrand disease</i>: 40-80 int. units/kg, depends on different type of disease and the status of hemorrhage</p>
Duration of therapy:	<p>Usually 1 to 3 days or single dose based on bleeding status.</p> <p><i>Humate P® for von Willebrand disease</i>: 3 to 7 days</p>
Criteria for use (<i>bullet points below are all inclusive unless otherwise noted</i>):	<ul style="list-style-type: none">• Patients with hemorrhage due to factor VIII deficiency• Patients with hemophilia A with a deficiency in factor VIII• Patients with acquired factor VIII inhibitors not exceeding 10 Bethesda units/mL• Patients with type I, II, and III von Willebrand disease•
Criteria for continuation of therapy:	May be used until pain and disability are resolved or healing is achieved.

Caution:

- Products may potentially contain infectious agents
- It is important to identify the clotting defect as a Factor VIII deficiency before administration of drugs, and identify the von Willebrand Factor deficiency before administration of Humate P for von Willebrand disease.
- Thromboembolic events have been reported.
- Pregnancy and lactation

Monitoring:

- Careful control of the substitution therapy
- Laboratory tests including serial AHF assays: AHF levels prior to and during treatment; in patients with circulating inhibitors, the inhibitor level should be monitored; WBC and hematocrit
- Monitor for signs and symptoms of intravascular hemolysis, bleeding, heart rate and blood pressure

Contraindications:

- Hypersensitivity to any component of the formulation or to mouse protein (Monoclate P, Hemofil M)

Not approved if:

- Alphanate is being used for von Willebrand disease
- Acquired factor VIII inhibitors exceed 10 Bethesda units/mL

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 03/15/06