Prior Authorization Approval Criteria

Thrombate III® (Antithrombin III (Human))

Generic Name:  Antithrombin III (Human)

Brand Name:  Thrombate III®

Medication Class:  Anticoagulant Agent

FDA Approved Uses:
- Hereditary antithrombin III (AT-III) deficiency in connection with surgical or obstetrical procedures, or thromboembolism in these patients

Available Dosage Forms:  Sterile, nonpyrogenic powder for reconstitution for IV administration only

Usual Dose:  must be individualized based on pretherapy AT-III
- The initial dose should raise AT-III levels to 120% and may be calculated based on the following formula:
  Initial dosage (int. units) = [desired AT-III level % - baseline AT-III level %] x body weight (kg) divided by 1.4%/int. units/kg
  [Desired % - baseline %] x Wt
  Int. units = _________
  1.4
- Maintenance dose should keep levels between 80% to 120%: Administering 60% of the initial dose q24 hrs

Duration of Therapy:  Usually 2-8 days depending on type of surgery or procedure

Criteria for Use:  (bullet points below are all inclusive unless otherwise noted)
- Must be diagnosed with hereditary AT-III deficiency via both testing and family history
- Acquired deficiency must be excluded

Criteria for Continuation of Therapy:  may be used until healing is achieved

Cautions:
- Products may potentially contain infectious agents
- Reduce heparin dose during concurrent therapy
- The AT-III level in neonates of parents with hereditary AT-III deficiency should be measured immediately after birth
- Testing and treatment in neonates, particularly premature infants, should be discussed with a coagulation specialist before initiating treatment
- Pregnancy

Monitoring:
- Monitor AT-III levels at least every 12 hrs and before the next infusion to maintain plasma AT-III levels at greater than 80%

Contraindications:  Hypersensitivity to any component of formulation

Not Approved if:  Patient has acquired AT-III deficiency rather than hereditary

Special Considerations:  Low plasma AT-III levels in neonates, particularly premature infants, do not necessarily indicate hereditary deficiency

The criteria listed above applies to Fallon Health Plan and its subsidiaries.
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