Prior Authorization Approval Criteria

Albumin: Plasbumin®-25 (25%), Plasbumin®-5 (5%)
Plasma protein fraction: Plasmanate® (5%)
(Albumin (Human); Plasma Protein Fraction (Human))

Generic Name: Albumin (Human); Plasma Protein Fraction (Human)

Brand Name:
- Albumin: Plasbumin®-25 (25%), Plasbumin®-5 (5%)
- Plasma protein fraction: Plasmanate® (5%)

Medication Class: Plasma Volume Expander, Colloid

FDA Approved Uses:
- Emergency treatment of hypovolemic shock due predominantly to plasma fluid loss and not red blood cells
- In addition, albumin is also used for: burn patients and cardiopulmonary bypass

Available Dosage Forms: Sterile solution for injection

Usual Dose:
- Albumin: 0.5-1.0 g/kg/dose IV based on different situations, maintenance: 6 g/kg/day
- Plasma protein fraction: 250-500 mL IV, repeat as needed

Duration of Therapy: variable depending on different situations

Criteria for Use: (bullet points below are all inclusive unless otherwise noted)
- Patients need expansion and maintenance of plasma volume
- Patients without severe dysfunction of heart, liver and kidney, and without severe anemia and dehydration
- Patients receiving additional therapy to maintain normal fluid balance

Cautions:
- Products may potentially contain infectious agents
- Plasbumin®-5 should be used in patients with volume deficit such as hypovolemic patients or intravascularly-depleted patients
- Plasbumin®-25 should be used in patients with oncotic deficit such as maintaining the plasma colloid osmotic pressure in whom fluid and sodium intake must be minimized
- Patients with chronic renal insufficiency, hepatic impairment, or chronic anemia
- Possibility of hypotension or circulatory overload
- Possibility of hypersensitivity reactions
- Pregnancy and lactation, children

Monitoring:
- Monitor carefully for signs and symptoms of circulatory overload
- Blood pressure

Contraindications:
- Hypersensitivity to any component of formulation
- Patients with severe anemia, congestive cardiac failure, or increased blood volume
- Plasmanate® is also contraindicated in cardiopulmonary bypass and severe hypotension
Not Approved if:

- Patients with hepatic dysfunction, renal dysfunction, severe anemia, congestive heart failure, and cardiopulmonary bypass
- Patients with chronic cirrhosis, chronic nephrosis, malabsorption, protein losing enteropathies, pancreatic insufficiency, and undernutrition
- Supplementation of albumin only

P&T Approval: ________________________________ Date: __________________________