



Prior Authorization Approval Criteria
Department of Pharmacy Services

Generic Name: Eculizumab

Brand Name: Soliris™

Medication Class: Monoclonal antibody

FDA Approved Uses: Paroxysmal nocturnal hemoglobinuria (PNH)

Available Dosage Forms: IV solution 10mg/mL

Usual Dose:

- 600 mg IV over 35 minutes every 7 days for the first 4 weeks
- 900 mg IV for the fifth dose 7 days later
- 900 mg IV every 14 days thereafter

Duration of Therapy: Indefinite

Approximate Monthly Cost (based on AWP 03/26/07):

- Therapy initiation \$68,640.00 (5 doses; 1 per week x 5 weeks)
- Monthly maintenance \$37,440.00 (2 doses; 1 every 14 days)

Criteria for Use: *(bullet points below are all inclusive unless otherwise noted)*

- Diagnosed with PNH using the HAM test or flow cytometry
- Must have a meningitis vaccine at least 2 weeks prior to start of therapy
- Must be transfusion-dependent, receiving at least 12 transfusions per year or one per month
- Baseline hemoglobin in patients with symptoms must be <9g/dl, or <7g/dl in patients without symptoms.
- Must have thromboses, pulmonary hypertension, transfusion dependency, renal insufficiency, or other end organ complications from PNH.

Criteria for Continuation of Therapy:

- Patient is tolerant to therapy
- Patient must maintain meningitis vaccine according to current recommendations
- Hemoglobin levels must be above baseline
- No longer a need for transfusions

Cautions:

- Patients are at an increased risk of meningococcal infections
- Serious hemolysis may occur after interruption or discontinuation of therapy
- Increased risk of systemic infections especially from encapsulated bacteria



Monitoring:

- Serum LDH levels
- Ferritin levels
- Signs and symptoms of infusion reactions for at least 1 hour post-infusion
- Early signs and symptoms of meningococcal infection
- Symptoms of hemolysis for at least 8 weeks after therapy discontinuation

Contraindications:

- Not currently vaccinated against Neisseria meningitidis
- Unresolved, serious Neisseria meningitidis infection

Not Approved if:

- Above criteria not met

P&T Approval: _____ Date: _____