

Origination Date: 10/07	Revision Date(s): 10/08, 3/11
Developed By: Medical Criteria Committee	

Approved: Robert Neal Mills

Date: 03/16/09

ODS Rx <sup>1.0</sup> <input type="checkbox"/>	ODS Rx <sup>2.0</sup> <input checked="" type="checkbox"/>	OEBB <input checked="" type="checkbox"/>	OHP <input type="checkbox"/>
NON-SPECIALTY <input type="checkbox"/>	SPECIALTY <input checked="" type="checkbox"/>		
PA <input checked="" type="checkbox"/>	QLL <input type="checkbox"/>	STEP THERAPY <input type="checkbox"/>	

## ***Ecuzumab (Soliris®)***

**PURPOSE:** To ensure the appropriate use of Soliris® for treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis.

### **QUANTITY LIMITS:**

- Ecuzumab (Soliris®):
  - Initiation (weeks 1-4): 540 mL (8 vials) per 30 days
  - Maintenance: 180 mL (6 vials) per 30 days

### **DESCRIPTION:**

Ecuzumab is a recombinant humanized monoclonal antibody that is indicated for the reduction of hemolysis in patients with paroxysmal nocturnal hemoglobinuria, a rare form of hemolytic anemia. Ecuzumab works by binding to complement protein C5, inhibiting its enzymatic cleavage, blocking formation of the terminal complement complex, and preventing red cell lysis. PNH is a clonal disorder in which red blood cells lack terminal complement inhibitors, resulting in increased sensitivity to complement-mediated intravascular hemolysis. Historically, only supportive care measures have been used to treat PNH, including hydration, anticoagulation, folic acid supplementation, and red blood cell transfusion. Allogenic stem cell transplantation can be curative but is associated with significant morbidity and mortality.

Soliris® has a black box warning due to the drug's propensity to increase the risk of meningococcal infection. The manufacturer recommends patients receive a meningococcal vaccine at least 2 weeks prior to receiving the first dose of Soliris® if the patient does not have prior documented vaccination.

### **FDA APPROVED DOSING:**

- **Initial:** 600 mg intravenous injection once weekly for 4 weeks, followed by 900 mg intravenous injection 1 week later
- **Maintenance:** 900 mg every 2 weeks

### **PRODUCT AVAILABILITY:**

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- Soliris<sup>®</sup>:
  - How Supplied: 30mL vial
  - Concentration: 10 mg/mL

**INDICATIONS:**

- Soliris<sup>®</sup> is indicated for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis.

**GUIDELINES FOR USE:**

- 1) Does the patient have paroxysmal nocturnal hemoglobinuria (PNH), diagnosed through a negative Coombs' test or by using the HAM test or flow cytometry?
  - a) If yes, go to #2
  - b) If no, forward to clinical
- 2) Will the patient receive a meningococcal vaccine at least 2 weeks prior to treatment initiation or has the patient been revaccinated according to the CDC guidelines?
  - a) If yes, go to #3
  - b) If no, forward to clinical
- 3) Is the member up to date with all immunizations?
  - a) If yes, go to #4
  - b) If no, forward to clinical
- 4) Has the patient experienced any **one** of the following
  - i) Transfusion dependency
  - ii) Thrombotic event attributable to PNH
  - iii) Pulmonary hypertension
  - iv) Renal insufficiency
  - v) End organ complications from PNH
  - b) If yes, go to #5
  - c) If no, forward to clinical
- 5) Is the patient symptomatic with a baseline hemoglobin < 9 g/dl?
  - a) If yes, go to #7
  - b) If no, go to #6
- 6) Is the patient without symptoms with baseline hemoglobin of < 7 g/dl?
  - a) If yes, go to #7
  - b) If no, forward to clinical
- 7) Approve for 3 months

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**RENEWAL**

- 1) Have hemoglobin levels improved over baseline?
  - a) If yes, go to #2
  - b) If no, forward to clinical
  
- 2) Is the patient no longer in need of transfusions?
  - a) If yes, go to #3
  - b) If no, forward to clinical
  
- 3) Will the patient maintain meningococcal vaccine according to CDC recommendations?
  - a) If yes, go to #4
  - b) If no, forward to clinical
  
- 4) Approve for 12 months

**REFERENCES**

- 1) Soliris (eculizumab) [package insert]. Cheshire, CT: Alexion Pharmaceuticals, Inc.; June 2009.
- 2) Kim J, et al. The use of the complement inhibitor eculizumab (Soliris<sup>®</sup>) for treating Korean patients with paroxysmal nocturnal hemoglobinuria. Korean J Hematol 2010;45:269-74.
- 3) Kanakura Y, et al. AEGIS Clinical Trial. Int J Hematol (2011) 93:36–46.