Subject: Eculizumab (Soliris) for Paroxysmal Nocturnal Hemoglobinuria (PNH)*

Effective Date: September 11, 2007

Department(s): Utilization Management

Policy: Eculizumab (Soliris) (HCPCS J1300) is reimbursable under Plans administered by QualCare, Inc., for the treatment of PNH (ICD-9 283.2), under the circumstances enumerated in this Policy.

Objective: To assure proper and consistent reimbursement and to delineate criteria for coverage of a specific therapeutic agent.

Procedure:

A. The physician ordering Soliris must document the following information:

1. The data supporting the diagnosis of PNH, including Sucrose Lysis test with confirmation by Ham acid hemolysis test OR flow cytometry documentation of PNH AND at least one of the following:
   a. Evidence of acquired hemolysis (negative direct Coombs test)
   b. Evidence of intravascular hemolysis, including at least one of the following:
      i. Hemoglobinemia
      ii. Hemoglobinuria
      iii. Hemosiderinuria
   c. Granulcytopenia and/or thrombocytopenia in the presence of an elevation in the reticulocyte count
   d. Venous thrombosis
   e. Aplastic anemia
   f. Myelodysplastic syndrome (refractory anemia variant)
   g. Episodic dysphagia or abdominal pain with evidence of intravascular hemolysis

2. Complications of PNH experienced by this patient
3. The patient’s transfusion requirement (if any)
4. All prior therapy
5. The reasons why this specific patient should receive Soliris, apart from the fact that he/she has PNH

B. Soliris is **not** reimbursable for any indication other than PNH, as for any other condition it is considered experimental, investigational, or unproven.

C. All requests for Soliris must be reviewed by the medical director before this preparation can be authorized.

References


Davis J. Eculizumab. *Am J Health Syst Pharm* 2008;65(17):1609-1615 (Sep 1)


Rosse WF. Diagnosis and treatment of paroxysmal nocturnal hemoglobinuria. *UpToDate* 15.1 October 19, 2006. Available at [www.utdol.com/utd/content/topic.do?topicKey=red_cell/8579&view=print](http://www.utdol.com/utd/content/topic.do?topicKey=red_cell/8579&view=print) Access 07/13/07


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*Consistent with Summary Plan Description (SPD). If there is discordance with the SPD, provisions of the SPD take precedence.*