



Prior Authorization Criteria

Soliris® (eculizumab)

Coverage:

Commercial Enrollees: Soliris is administered by intravenous infusion and is therefore covered under the medical benefit for commercial enrollees.

Medicare Enrollees: Soliris is subject to the Part B vs Part D determination process.

Description/ Background^{1,2}:

Paroxysmal nocturnal hemoglobinuria (PNH) is a rare, life-threatening, and genetically acquired form of hemolytic anemia. A genetic mutation in PNH patients leads to the generation of abnormal red blood cells that are deficient in terminal complement inhibitors rendering them sensitive to persistent terminal complement-mediated destruction. Chronic hemolysis is central to the morbidities and mortality in PNH, including severe anemia, disabling fatigue, recurrent pain, dyspnea, smooth muscle dystonias, impaired quality of life and thrombotic events. Eculizumab is a monoclonal antibody that inhibits terminal complement mediated intravascular hemolysis in PNH patients by specifically binding to the complement protein C5 with high affinity; inhibiting its cleavage to C5a and C5b; and preventing the generation of the terminal complement complex C5b-9.

Indication¹:

Eculizumab is indicated to reduce hemolysis in patients with paroxysmal nocturnal hemoglobinuria (PNH).

Dosage and Administration^{1,2}:

- Soliris therapy should NOT be initiated in patients with unresolved serious *N. meningitidis* infection OR who are not currently vaccinated against *N. meningitidis*.
- Patients MUST be administered a meningococcal vaccine at least 2 weeks prior to initiation of Soliris® therapy and revaccinated according to current medical guidelines for vaccine use.
- The recommended dosage regimen is 600 mg via 35 minute IV infusion every 7 days for the first 4 weeks, followed by 900 mg for the fifth dose 7 days later, then 900 mg every 14 days thereafter. Soliris should not be administered by IV bolus.
- Safety and efficacy have not been established in children and adolescents.

Unlabeled Indication(s): None

Criteria for Approval:

1. Candidates for Soliris patient should have a medical records documented diagnosis of paroxysmal nocturnal hemoglobinuria (PNH).
2. Candidates for Soliris should receive a meningococcal vaccine at least 2 weeks prior to initiation of therapy with Soliris.
3. Documentation of continued efficacy of Soliris at the suggested maintenance dose of 900mg IV every 14 days as demonstrated by stabilized hemoglobin levels or decreased need for blood transfusions is necessary for authorization of continued therapy.

Question and Answer Guide:

1. Is the request for initial approval?
 Yes = Proceed to question # 2
 No = Proceed to question # 4

2. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)?
 Yes = Proceed to question # 3
 No = Deny – Soliris is only indicated for the treatment of paroxysmal nocturnal hemoglobinuria.

3. Will/has the patient receive/d a meningococcal vaccination at least 2 weeks prior to the initiation of therapy with Soliris®?
 Yes = Approve for 12 months based on appropriate diagnosis**
 No = Refer to pharmacist for review

4. Has continued efficacy of Soliris® been demonstrated as evidenced by the stabilization in hemoglobin concentration or a reduction in the need for blood transfusions?
 Yes = Approve for 12 months**
 No = Continued therapy with Soliris is indicated only in patients who have experienced a continued response to treatment as evidenced by a reduction in transfusion need or stabilization in hemoglobin levels.

**** If the member is a Medicare Enrollee, Determine Medicare Coverage (B vs. D):**

1. Coverage will be provided under Medicare Part B when the following apply:
 - The member meets criteria for approval (above).
 - The drug is being purchased by and administered in a physician's office or ambulatory center.
2. All others meeting criteria for approval (above) will be approved under Part D (including Long Term Care facilities).

If home health care is required for administration, refer back to SummaCare for approval and coordination of home health care: 1(888) 996-8710.

References:

1. Package Insert for Soliris. Alexion Pharmaceuticals. 2007.
2. <https://clinicalpharmacology.com/Forms/drugoptions.aspx?cpnum=3533>. Accessed 5/1/2008.