

Blue Cross and Blue Shield of Vermont and the Vermont Health Plan Prior Authorization Guidelines Soliris® (Eculizumab)

Description: Eculizumab is a monoclonal antibody that specifically binds to the complement protein C5 with high affinity, thereby inhibiting its cleavage to C5a and C5b and preventing the generation of the terminal complement complex C5b-9. Eculizumab inhibits terminal complement mediated intravascular hemolysis in PNH patients.

Indications: 1) Treatment of paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis.

**Warnings/
Precautions:** Eculizumab can increase a patient's susceptibility to serious meningococcal infections, septicemia and/or meningitis. All patients without a history of prior meningococcal vaccination must receive the meningococcal vaccine at least 2 weeks prior to receiving the first dose of Soliris® and revaccinated according to medical guidelines.

**Reasons for
Prior
Authorization:** Cost Potential for misuse Toxicity

**Criteria for
Approval:**

- 1) For patients diagnosed with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis.
- 2) Given a meningococcal vaccine at least two weeks prior to initiation of therapy
- 3) 18 years of age or older
- 4) Patient has no contraindications to treatment (See Below)

**Reasons for
Denial of
Benefit:**

- 1) Patient has a history of hypersensitivity to eculizumab or its components.
- 2) Patient does not meet criteria

**Benefit
Approval:** If criteria are met, eculizumab therapy initial approval for 3 months, renewable for a 6 month period. Dispensed in 30 days supply only.

References: 1) Soliris® Product information, Alexion Pharmaceuticals, Inc. Cheshire, CT 2008