

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

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Description:

Paroxysmal nocturnal hemoglobinuria (PNH) is a rare, disabling and life threatening blood disorder. It usually develops in adults and is characterized by red blood cells that have developed abnormally. Naturally occurring proteins (the complement system) that destroy bacteria and other infection causing organisms break down these cells. Depending on the severity of PNH, patients may have pain, fatigue and debilitating weakness, the need for frequent blood transfusions, blood clots, strokes, heart attacks, and intestinal disease.

Soliris (eculizumab), an intravenous medication used for the treatment of PNH, received FDA approval on March 16, 2007. It is a monoclonal antibody that works by blocking part of the immune system. While Soliris does not cure PNH, it treats the breakdown of the blood cells thereby lessening symptoms and the need for blood transfusions. Since Soliris affects the immune system, patients who are undergoing treatment with Soliris are at a higher risk of infection.

Soliris therapy is administered as an IV infusion over 35 minutes based on the following recommended dosage regimen:

- 600 mg every 7 days for the first 4 weeks (doses 1- 4), followed by
- 900 mg for the fifth dose 7 days later (dose 5), then
- 900 mg every 14 days thereafter

Criteria:

ODS will allow IV Soliris therapy up to plan limitations when **all** of the following criteria are met:

1. The patient has a diagnosis of paroxysmal nocturnal hemoglobinuria; and
2. The patient has received at least four red cell transfusions during the previous 12 months; and
3. Soliris has been prescribed by a hematologist; and
4. The patient has had a meningococcal vaccine at least 2 week prior to the start of Solaris therapy (if the patient has previously received a meningococcal vaccine, the vaccine must be maintained according to current recommendations); and
5. The patient is enrolled in the Soliris OneSource Program 1-888-Soliris (1-888-765-4747)

Contraindications:

Soliris is contraindicated and will not be covered for the following situations:

1. Patient has an active bacterial infection
2. Patient is pregnant, breast-feeding, or intending to conceive
3. Patient with unresolved of Neisseria meningitidis infection
4. Patient is not currently vaccinated against Neisseria meningitidis

Information to be Submitted with Pre-Authorization Request:

Chart notes from treating physician documenting diagnosis, past transfusion requirements, and history of PNH along with verification of meningococcal vaccination.

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References:

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