

## eculizumab (SOLIRIS) for Paroxysmal Nocturnal Hemoglobinuria (PNH) [3558]

Ordering restrictions for eculizumab (Soliris®):

1. Eculizumab (Soliris®) is restricted to attending-level physicians registered with the eculizumab (Soliris®) REMS Program
2. Patient must be registered with the manufacturer, Alexion Pharmaceuticals, Inc. to receive patient-specific doses for treatment
3. Indication must be FDA-approved (PNH or aHUS) or for transplant patients who meet criteria according to the solid organ transplant clinical practice guideline
4. Outpatient use when financial approval is obtained
5. Inpatient use for emergent care of newly diagnosed disease or continuation of maintenance therapy that is medically necessary

## Medications

Has patient received vaccination against meningococcal infection? (Single Response)

Yes, immunized more than two weeks prior to first dose of eculizumab (no additional antimicrobial prophylaxis required per REMS program)

Dosing of eculizumab (Soliris®) for paroxysmal nocturnal hemoglobinuria (PNH)

Treatment Week 1 - 600 mg (Single Response)

- First Dose - eculizumab (SOLIRIS) infusion - Week 1      600 mg, intravenous, once, For 1 Doses  
Given as first dose for PNH on Week 1  
This medication is restricted to attending-level physicians enrolled in the Soliris® REMS program. Are you an attending-level provider enrolled in the Soliris® REMS program or ordering on behalf of one?

Treatment Week 2 - 600 mg (Single Response)

- Second Dose - eculizumab (SOLIRIS) infusion - Week 2      600 mg, intravenous, once, For 1 Doses  
Given as second dose for PNH on Week 2  
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Treatment Week 3 - 600 mg

- Third Dose - eculizumab (SOLIRIS) infusion - Week 3      600 mg, intravenous, once, For 1 Doses  
Given as third dose for PNH on Week 3  
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Treatment Week 4 - 600 mg

- Fourth Dose - eculizumab (SOLIRIS) infusion - Week 4      600 mg, intravenous, once, For 1 Doses  
Given as fourth dose for PNH on Week 4  
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Treatment Week 5 and thereafter - 900 mg

- Fifth Dose - eculizumab (SOLIRIS) infusion - Week 5 and thereafter      900 mg, intravenous, every 14 days  
Given as fifth or subsequent dose for PNH on Week 5 and thereafter  
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Yes, immunized less than two weeks prior to first dose of eculizumab and risks of delaying eculizumab therapy outweigh the risk of meningococcal infection (antimicrobial prophylaxis)

Dosing of eculizumab (Soliris®) for paroxysmal nocturnal hemoglobinuria (PNH)

Treatment Week 1 - 600 mg (Single Response)

<input type="checkbox"/> First Dose - eculizumab (SOLIRIS) infusion - Week 1	600 mg, intravenous, once, For 1 Doses Given as first dose for PNH on Week 1 This medication is restricted to attending-level physicians enrolled in the Soliris® REMS program. Are you an attending-level provider enrolled in the Soliris® REMS program or ordering on behalf of one?
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<input type="checkbox"/> Antimicrobial Prophylaxis Against Meningococcal Infection (Single Response)	
If eculizumab (Soliris) is scheduled to be given LESS than two weeks after being vaccinated for meningococcal infection, please select antimicrobial prophylaxis to be administered in conjunction with vaccination.	
<input type="checkbox"/> ciprofloxacin HCl (CIPRO) tablet	500 mg, oral, 2 times daily Type of Therapy: New Anti-Infective Order Reason for Therapy: Medical Prophylaxis
<input type="checkbox"/> ciprofloxacin (CIPRO) IV	400 mg, intravenous, for 60 Minutes, 2 times daily For eligible patients, this intravenous antimicrobial can be changed by pharmacists to oral ciprofloxacin per hospital policy. Type of Therapy: New Anti-Infective Order Reason for Therapy: Medical Prophylaxis
<input type="checkbox"/> penicillin v potassium (VEETID) tablet	500 mg, oral, 2 times daily Type of Therapy: New Anti-Infective Order Reason for Therapy: Medical Prophylaxis
<input type="checkbox"/> No vaccination has been given and risks of delaying eculizumab therapy outweigh the risk of meningococcal infection (antimicrobial prophylaxis AND vaccination against meningococcal infection REQUIRED per REMS program and mandated through this order set)	
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<input type="checkbox"/> Treatment Week 2 - 600 mg (Single Response)	

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<input type="checkbox"/> Meningococcal infection vaccination	
<input type="checkbox"/> meningococcal polysaccharide (MENACTRA) injection	0.5 mL, intramuscular, once, For 1 Doses Inject into deltoid muscle.
<input type="checkbox"/> Meningococcal Group B vaccine (BEXSERO) 2-dose series	0.5 mL, intramuscular, once, For 1 Doses Give as a 2-dose series, with doses administered at least 1 month apart Bexsero (meningococcal group B vaccine) is given as a series of two vaccinations administered one month apart. Which dose is this? Indication for Therapy: Receiving eculizumab (Soliris)