

Eculizumab (Soliris®) Procedure for Use in Patients Age ≥ 18 Years

Jackson Memorial Hospital

Eculizumab Prescribing Procedure:

- **All prescribers must be enrolled in the Soliris REMS (Risk Evaluation and Mitigation Strategy) Program**
 - Additional REMS information and enrollment instructions can be found at www.solirisrems.com
- **Approval must be obtained** from the following services prior to eculizumab being given:
 - (1) Hematology
 - (2) Infectious Diseases
 - Consult the ID Immunocompromised host service at 305-996-0007 and discuss with an attending OR
 - Contact the JMH Antimicrobial Stewardship Program at 786-586-0607

Indications:

- Treatment of paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis
 - Dosing: 600 mg weekly for the first 4 weeks, followed by 900 mg for the 5th dose 1 week later, then 900 mg every 2 weeks
- Treatment of atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy
 - Dosing: 900 mg weekly for the first 4 weeks, followed by 1200 mg for the 5th dose 1 week later, then 1200 mg every 2 weeks

Vaccination Recommendations:

- **Life-threatening and fatal meningococcal infections have occurred in patients treated with eculizumab and may become rapidly life-threatening or fatal if not recognized and treated early**
- **Meningococcal Vaccination:**
 - Administer Menveo (MenACWY) and either Bexsero or Trumenba (MenB) at least 2 weeks prior to administering the first dose of eculizumab
 - Prophylactic antibiotics may be administered in addition to vaccination for the duration of the eculizumab treatment at the discretion of the Infectious Diseases service
 - If unable to vaccinate 2 weeks prior to the first dose of eculizumab because the risk of delaying treatment outweighs the risks of developing a meningococcal infection the prescriber must consult infectious diseases at 305-996-0007
 - Administer meningococcal vaccine as soon as possible and administer prophylactic medications for at least two weeks after vaccination
 - **Consultation with Infectious Diseases is needed to determine best antimicrobial prophylaxis**
 - Prophylactic antibiotic recommendations:
 - Ciprofloxacin 400 mg IV or 500 mg PO BID x 14 days
 - After 14 days of ciprofloxacin, give Penicillin 250 mg PO BID while on eculizumab therapy
 - Monitor patients for early signs of meningococcal infections, and evaluate immediately if infection is suspected

Additional Recommended Vaccinations:

- In addition to meningococcal immunizations, patients should be vaccinated against other encapsulated organisms due to high risk of infections. If not previously immunized:
 - At least 2 weeks prior to the first dose of eculizumab
 - Administer Prevnar 13
 - Administer Haemophilus influenza B (HiB) x 1 dose
 - If unable to vaccinate 2 weeks prior to the first dose of eculizumab because the risk of delaying treatment, the prescriber must consult Infectious Diseases at 305-996-0007
 - Administer HiB and pneumococcal vaccines as soon as possible
 - No sooner than 8 weeks after Prevnar 13
 - Administer Pneumovax 23

Contraindications to eculizumab:

- Patients with unresolved serious *Neisseria meningitidis* infection
- Patients who are not currently vaccinated against *Neisseria meningitidis*, unless the risks of delaying eculizumab treatment outweigh the risks of developing a meningococcal infection