Generic Name:
Eculizumab
Trade Name:
Soliris
Company:
Alexion Pharmaceuticals
Notes:

Eculizumab injection for I.V. use has gained a new indication as the first treatment for neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are positive for the anti-aquaporin-4 (AQP4) antibody. NMOSD is a CNS autoimmune disease that mainly affects the optic nerves and spinal cord.

Effectiveness of eculizumab for treatment of NMOSD was demonstrated in a clinical study of 143 patients with NMOSD who had antibodies against AQP4 (anti-AQP4 positive) and were randomized to receive either eculizumab treatment or placebo. The study showed that compared with placebo, treatment with eculizumab reduced the number of NMOSD relapses by 94% over the 48-week course of the trial. The agent also reduced the need for hospitalizations and for treatment of acute attacks with corticosteroids and plasma exchange.

Eculizumab has a boxed warning cautioning that life-threatening and fatal meningococcal infections have occurred and that such infections may become rapidly life-threatening or fatal if not recognized and treated early. Patients should be monitored for early signs of meningococcal infections and evaluated immediately if infection is suspected. Use should be discontinued in patients who are being treated for serious meningococcal infections. Health professionals should use caution when administering eculizumab to patients with any other infection. In the NMOSD clinical trial, no cases of meningococcal infection were observed.

Eculizumab is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS). Prescribers must enroll in the REMS program and counsel patients about the risk of meningococcal infection, give patients the REMS educational materials, and ensure patients are vaccinated with meningococcal vaccine(s).

The most frequently reported adverse reactions are upper respiratory infection, common cold, diarrhea, back pain, dizziness, influenza, joint pain, sore throat, and contusion.

The agent was first approved by FDA in 2007 for treatment of adults with paroxysmal nocturnal hemoglobinuria; for treatment of adults and children with atypical hemolytic uremic syndrome to inhibit complement-mediated thrombotic microangiopathy; and for treatment of adults with myasthenia gravis who are positive for the anti-acetylcholine receptor antibody.

Medication Monitor Categories:
Supplemental Approvals