INDICATIONS & IMPORTANT SAFETY INFORMATION FOR SOLIRIS® (eculizumab)

INDICATIONS

Generalized Myasthenia Gravis (gMG)

Soliris is indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

Neuromyelitis Optica Spectrum Disorder (NMOSD)

Soliris is indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS

Life-threatening and fatal meningococcal infections have occurred in patients treated with Soliris and may become rapidly life-threatening or fatal if not recognized and treated early.

- **Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccination in patients with complement deficiencies.**
- **Immunize patients with meningococcal vaccines at least 2 weeks prior to administering the first dose of Soliris, unless the risks of delaying Soliris therapy outweigh the risk of developing a meningococcal infection. (See *Serious Meningococcal Infections* for additional guidance on the management of the risk of meningococcal infection).**
- **Vaccination reduces, but does not eliminate, the risk of meningococcal infections. Monitor patients for early signs of meningococcal infections and evaluate immediately if infection is suspected.**

Soliris is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS). Under the Soliris REMS, prescribers must enroll in the program. Enrollment in the Soliris REMS program and additional information are available by telephone: 1-888-SOLIRIS (1-888-765-4747) or at www.solirisrems.com.

Contraindications

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

Please see Important Safety Information continued on page 2 and accompanying full Prescribing Information for SOLIRIS, including Boxed WARNING regarding serious meningococcal infections.

IMPORTANT SAFETY INFORMATION FOR SOLIRIS® (eculizumab) (cont'd)

Warnings and Precautions

Serious Meningococcal Infections
Risk and Prevention

The use of Soliris increases a patient's susceptibility to serious meningococcal infections (septicemia and/or meningitis).

Vaccinate or revaccinate for meningococcal disease according to the most current ACIP recommendations for patients with complement deficiencies. Immunize patients without a history of meningococcal vaccination at least 2 weeks prior to receiving the first dose of Soliris. If Soliris must be initiated immediately in an unvaccinated patient, administer meningococcal vaccine(s) as soon as possible and provide 2 weeks of antibacterial drug prophylaxis. Discontinue Soliris in patients who are undergoing treatment for serious meningococcal infections.

REMS

Prescribers must counsel patients about the risk of meningococcal infection, provide the patients with the REMS educational materials, and ensure patients are vaccinated with meningococcal vaccine(s).

Other Infections

Serious infections with *Neisseria* species (other than *N. meningitidis*), including disseminated gonococcal infections, have been reported.

Patients may have increased susceptibility to infections, especially with encapsulated bacteria. Additionally, *Aspergillus* infections have occurred in immunocompromised and neutropenic patients. Use caution when administering Soliris to patients with any systemic infection.

Infusion-Related Reactions

Administration of Soliris may result in infusion-related reactions, including anaphylaxis or other hypersensitivity reactions. Interrupt Soliris infusion and institute appropriate supportive measures if signs of cardiovascular instability or respiratory compromise occur.

Adverse Reactions

The most frequently reported adverse reaction in the gMG placebo-controlled clinical trial (≥10%) is: musculoskeletal pain.

The most frequently reported adverse reactions in the NMOSD placebo-controlled trial (≥10%) are: upper respiratory infection, nasopharyngitis, diarrhea, back pain, dizziness, influenza, arthralgia, pharyngitis, and contusion.

New patient checklist

ONESOURCE® Personalized Patient Support from Alexion

SOLIRIS® (eculizumab) Injection for Intravenous Use 300 mg/30 mL vial

This checklist contains suggested steps to initiate a patient on SOLIRIS® (eculizumab) after the treatment decision has been made. This checklist is not required for SOLIRIS treatment.

☐ **Enroll in our REMS program**

Due to the risk of meningococcal infections, prescribers must enroll in our Risk Evaluation and Mitigation Strategy (REMS) program to obtain SOLIRIS. Prescribers must counsel patients about the risk of meningococcal infection, provide the patients with the REMS educational materials, and ensure patients are vaccinated with meningococcal vaccine(s). Call Customer Operations at **888-SOLIRIS (888-765-4747)** or visit **SOLIRISREMS.com** to learn more and enroll.

☐ **Complete the Neurology SOLIRIS Patient & Prescriber START Form to get your patient started**
PATIENT SIGNATURE REQUIRED

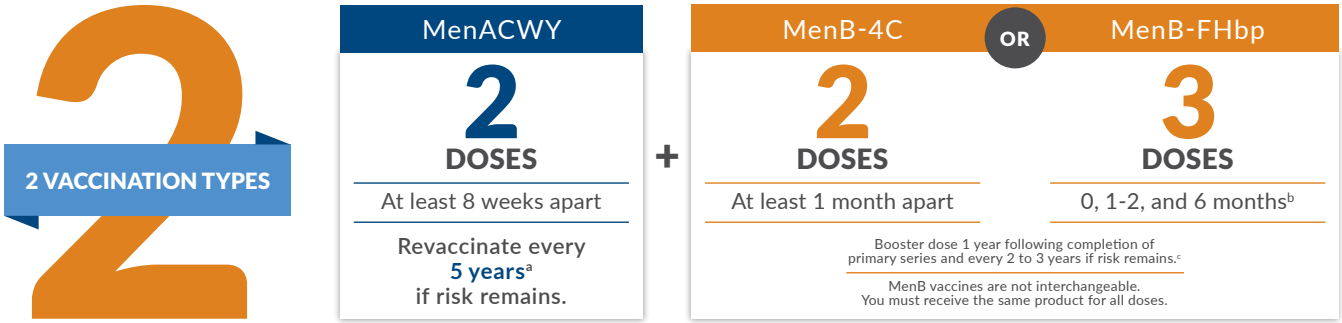
OneSource™ may be able to assist your patient with vaccination support

☐ **Confirm patient has prescriptions for required meningococcal vaccinations**

a. Patient can be vaccinated at
   i. Primary care office
   ii. Local pharmacy
   iii. Local hospital
   iv. Health department
   v. Travel clinic

Immunize patients with both types of meningococcal vaccines at least 2 weeks before starting treatment with SOLIRIS[1,2]

The 2021 Advisory Committee on Immunization Practices (ACIP) recommends the following meningococcal vaccination regimens for patients with persistent complement component deficiency or in patients receiving complement inhibitors, including patients receiving SOLIRIS[3]*



[a]The Centers for Disease Control and Prevention ACIP guidelines recommend all patients undergoing complement inhibition receive the MenACWY booster every 5 years.[3]
[b]For MenB-FHbp, if dose 2 was administered at least 6 months after dose 1, dose 3 is not needed.[3]
[c]Special situations for MenB include those receiving a complement inhibitor (eg, SOLIRIS). ACIP recommends a MenB booster dose 1 year following completion of a MenB primary series followed by MenB booster doses every 2 to 3 years if risk remains.[3]

* **Please refer to the most up-to-date ACIP recommendations for the most current and complete information for meningococcal vaccination in persons with persistent complement component deficiencies and patients treated with complement inhibitors, such as SOLIRIS.**

Please see Important Safety Information on pages 1 and 2 and accompanying full Prescribing Information for SOLIRIS, including Boxed WARNING regarding serious meningococcal infections.

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- ☐ **Identify preferred site of care for infusion on START Form**
  a. Prescriber's office
  b. Home infusion
  c. Infusion center

- ☐ **Encourage completion of gMG assessment tools[4]**
  a. Patient-reported
     i. MG-ADL
  b. Physician-reported
     i. QMG

- ☐ **Confirm SOLIRIS order has been placed**
  An Alexion Customer Operations Representative will facilitate order processing and delivery.

- ☐ **Refer to sample letter of medical necessity should a payer request one**

Alexion Patient Services is here to help you and your patients.

OneSource™ is a complimentary, personalized patient support program tailored to the specific needs of adults living with anti-AChR antibody-positive gMG and anti-AQP4 antibody-positive NMOSD.

For more information, please visit AlexionOneSource.com, or contact us at

☎ **1-888-765-4747**

✉ **OneSource@alexion.com**

Please see Important Safety Information on pages 1 and 2 and accompanying full Prescribing Information for SOLIRIS, including Boxed WARNING regarding serious meningococcal infections.

AChR, acetylcholine receptor; AQP4, aquaporin-4; gMG, generalized myasthenia gravis; MG-ADL, Myasthenia Gravis Activities of Daily Living; NMOSD, neuromyelitis optica spectrum disorder; QMG, Quantitative Myasthenia Gravis.

References: 1. SOLIRIS [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc.; November 2020. **2.** Meningococcal vaccination: what everyone should know. Centers for Disease Control and Prevention website. Accessed June 11, 2021. https://www.cdc.gov/vaccines/vpd/mening/public **3.** Recommended Adult Immunization Schedule for Ages 19 Years or Older. Centers for Disease Control and Prevention. February 11, 2021. Accessed June 11, 2021. https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf **4.** Resources for professionals. Myasthenia Gravis Foundation of America website. Accessed June 11, 2021. https://myasthenia.org/professionals/resources-for-professionals

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