Initiating patients

A GUIDE TO SOLIRIS® (eculizumab) ORDERING, DOSING, AND ADMINISTRATION FOR ADULT PATIENTS WITH NMOSD WHO ARE ANTI-AQP4 ANTIBODY POSITIVE

INDICATION & IMPORTANT SAFETY INFORMATION FOR SOLIRIS® (eculizumab)

INDICATION

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.

SELECT IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS

Life-threatening and fatal meningococcal infections have occurred in patients treated with Soliris. Meningococcal infection 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.

Please see additional Important Safety Information throughout and accompanying full prescribing information for Soliris, including Boxed WARNING regarding serious meningococcal infections.

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

WHEN YOU RUN OUT OF CHECKLISTS, ASK YOUR SOLIRIS REPRESENTATIVE TO PROVIDE YOU WITH MORE

Prior to initiating Soliris treatment in adult patients with anti-AQP4 antibody-positive NMOSD, consult this new patient checklist. It may help ensure an efficient start.

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Ordering Soliris® (eculizumab)

STEP 1

Enroll in our REMS

Due to the risk of meningococcal infections, prescribers must enroll in our Risk Evaluation and Mitigation Strategy (REMS) program to obtain Soliris. Call Customer Operations at **888-SOLIRIS (888-765-4747)** or visit **SolirisREMS.com** to learn more and enroll.

STEP 2

Provide information about the patient's insurance benefits

Customer Operations Representatives will work with your designated distributor or the supplier required by your patient's insurance to ensure delivery of Soliris.

STEP 3

Place your order with an authorized specialty distributor, OR send your completed prescription to the payer-designated specialty pharmacy

An Alexion Customer Operations Representative will work with either party to facilitate order processing and delivery.

THE FOLLOWING INFORMATION IS REQUIRED TO ORDER SOLIRIS:
NDC 25682-001-01 SINGLE-UNIT, 300 mg/30 mL (10 mg/mL) SINGLE-DOSE VIAL PER CARTON

SELECT IMPORTANT SAFETY INFORMATION

Contraindications

Soliris is contraindicated in:

- 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

Warnings and Precautions

Serious Meningococcal Infections

Risk and Prevention

*See **Boxed WARNING** for additional information on serious meningococcal infections.*

Life-threatening and fatal meningococcal infections have occurred in patients treated with Soliris. The use of Soliris increases a patient's susceptibility to serious meningococcal infections (septicemia and/or meningitis).

Vaccinate for meningococcal disease according to the most current ACIP recommendations for patients with complement deficiencies. Revaccinate patients in accordance with ACIP recommendations, considering the duration of Soliris therapy.

(continued on next page)

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Prescribing Soliris® (eculizumab)

Recommended vaccination and prophylaxis

- Vaccinate patients according to current ACIP guidelines to reduce the risk of serious infection
- Provide 2 weeks of antibacterial drug prophylaxis to patients if Soliris must be initiated immediately and vaccines are administered less than 2 weeks before starting Soliris therapy
- Healthcare professionals who prescribe Soliris must enroll in the Soliris REMS

Treatment with Soliris begins with an induction phase, followed by a maintenance phase

DOSING FOR ADULT PATIENTS WITH ANTI-AQP4 ANTIBODY-POSITIVE NMOSD*

INDUCTION PHASE		MAINTENANCE PHASE†
900 mg given as IV infusion once weekly for 4 weeks	1200 mg given as IV infusion once at week 5	1200 mg given as IV infusion every 2 weeks thereafter

Abbreviation: IV, intravenous.

*Administer Soliris at the recommended dosage regimen time points or within 2 days of these time points.
†This assumes that the patient has completed the 5-week induction phase.

Supplemental dosing of Soliris is required in patients receiving concomitant plasmapheresis, plasma exchange, or fresh frozen plasma infusion

TYPE OF PLASMA INTERVENTION	MOST RECENT SOLIRIS DOSE	SUPPLEMENTAL SOLIRIS DOSE WITH EACH PLASMA INTERVENTION	TIMING OF SUPPLEMENTAL SOLIRIS DOSE
Plasmapheresis or plasma exchange	300 mg	300 mg per each plasmapheresis or plasma exchange session	Within 60 minutes after each plasmapheresis or plasma exchange session
	≥600 mg	600 mg per each plasmapheresis or plasma exchange session	
Fresh frozen plasma infusion	≥300 mg	300 mg per infusion of fresh frozen plasma	60 minutes prior to each infusion of fresh frozen plasma

SELECT IMPORTANT SAFETY INFORMATION

Risk and Prevention (continued)

Immunize patients without a history of meningococcal vaccination at least 2 weeks prior to receiving the first dose of Soliris. If urgent Soliris therapy is indicated in an unvaccinated patient, administer meningococcal vaccine(s) as soon as possible and provide patients with 2 weeks of antibacterial drug prophylaxis.

The benefits and risks of antibiotic prophylaxis for prevention of meningococcal infections in patients receiving Soliris have not been established.

Monitoring patients

Monitor patients for early signs and symptoms of meningococcal infection

Vaccination reduces, but does not eliminate, the risk of meningococcal infections. Advise patients to seek immediate medical attention if these signs or symptoms occur. Meningococcal infection may become rapidly life-threatening or fatal if not recognized and treated early.

SIGNS AND SYMPTOMS OF MENINGOCOCCAL INFECTIONS INCLUDE:

- Headache with nausea or vomiting
- Headache with a stiff neck or stiff back
- Fever and a rash
- Muscle aches with flu-like symptoms
- Headache and fever
- Fever
- Confusion
- Eyes sensitive to light

Evaluate patients immediately if an infection is suspected

- Meningococcal infection may become rapidly life-threatening or fatal if not recognized and treated early
- Discontinue Soliris in patients who are undergoing treatment for serious meningococcal infections

See additional information on monitoring patients for infusion reactions on page 7.

SELECT IMPORTANT SAFETY INFORMATION

Risk and Prevention (continued)

Vaccination reduces, but does not eliminate, the risk of meningococcal infections.

Closely monitor patients for early signs and symptoms of meningococcal infection and evaluate patients immediately if an infection is suspected. Meningococcal infection may become rapidly life-threatening or fatal if not recognized and treated early. Discontinue Soliris in patients who are undergoing treatment for serious meningococcal infections.

REMS

Because of the risk of meningococcal infections, Soliris is available only through a restricted program under a REMS. Under the Soliris REMS, prescribers must enroll in the program.

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).

Please see additional Important Safety Information throughout and accompanying full prescribing information for Soliris, including Boxed WARNING regarding serious meningococcal infections.

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

Preparation and administration instructions

It is important to carefully adhere to the following preparation and administration instructions for Soliris® (eculizumab)

STEP 1 • INSPECT THE VIAL

Soliris is supplied in 300-mg, single-dose vials containing 30 mL (10 mg/mL) of sterile, preservative-free solution. Prior to administration, inspect Soliris vials for particulate matter and discoloration. Soliris should be clear and colorless.

STEP 2 • DILUTE THE SOLUTION

Prior to administration, dilute Soliris to a final concentration of 5 mg/mL. Choose one of the following diluents:

0.9%	Sodium Chloride Injection, USP	**5%**	Dextrose in Water Injection, USP
0.45%	Sodium Chloride Injection, USP		Ringer's Injection, USP

1. Withdraw the required amount of Soliris from the vial into a sterile syringe and transfer the recommended dose to an infusion bag.
2. Dilute Soliris to a final concentration of 5 mg/mL by adding the appropriate amount of diluent, using the table below as a guideline. The volume of diluent should be equivalent to the drug volume.

SOLIRIS DOSE	DILUENT VOLUME	FINAL VOLUME
900 mg	90 mL	180 mL
1200 mg	120 mL	240 mL

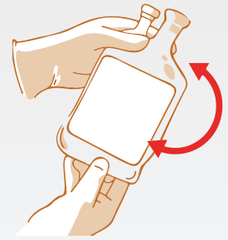
SELECT IMPORTANT SAFETY INFORMATION

Other Infections

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

Soliris blocks terminal complement activation; therefore 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.

STEP 3 • INVERT THE INFUSION BAG



- Gently invert the infusion bag containing the diluted Soliris solution to ensure thorough mixing of the product and the diluent. Discard any unused portion left in a vial, as the product contains no preservatives
- Allow the admixture to adjust to room temperature prior to administration (18°C to 25°C or 64°F to 77°F); it must not be heated in a microwave or with any heat source other than ambient air temperature
- Inspect visually for particulate matter and discoloration prior to administration
- The admixed solution of Soliris is stable for up to 24 hours at 2°C to 8°C (36°F to 46°F) and at room temperature prior to administration

STEP 4 • ADMINISTER THE IV INFUSION

- **Soliris should only be administered by IV infusion.** Administer over 35 minutes via gravity feed, a syringe-type pump, or an infusion pump. Do not administer as an IV push or bolus injection
- If an adverse reaction occurs during administration of Soliris:
  - The infusion may be slowed or stopped at the discretion of the physician
    - If the infusion is slowed, the total infusion time should not exceed 2 hours
- Monitor the patient during the infusion and for at least 1 hour following completion for signs or symptoms of an infusion reaction. These can include anaphylaxis or other hypersensitivity reactions
- Interrupt Soliris infusion and institute appropriate supportive measures if signs of cardiovascular instability or respiratory compromise occur

STORAGE AND HANDLING

- Store Soliris vials in the original carton to protect from light until time of use, refrigerated at 2°C to 8°C (36°F to 46°F)
- Soliris vials may be stored in the original carton at a controlled room temperature (not more than 25°C [77°F]) for only a single period up to 3 days. Do not use beyond the expiration date stamped on the carton
- Refer to the Prescribing Information (section 2 Dosage and Administration) for information on the stability and storage of diluted solutions of Soliris
- DO NOT FREEZE; DO NOT SHAKE

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Connect patients to OneSource™ for ongoing support

ONESOURCE™
Personalized Patient Support from Alexion

VISIT ALEXIONONESOURCE.COM TO ENROLL PATIENTS

Alexion Case Managers, all of whom have extensive training in insurance and clinical information, are available for each patient and their healthcare team. OneSource offers patients assistance with:

HEALTH INSURANCE NAVIGATION

DISEASE INFORMATION

CONTINUITY OF CARE

COMMUNITY CONNECTIONS

Contact OneSource at 888-SOLIRIS(888-765-4747) for support.

SELECT IMPORTANT SAFETY INFORMATION

Infusion Reactions

Administration of Soliris may result in infusion reactions, including anaphylaxis or other hypersensitivity reactions. In clinical trials, no patients experienced an infusion reaction that required discontinuation of Soliris. Interrupt Soliris infusion and institute appropriate supportive measures if signs of cardiovascular instability or respiratory compromise occur.

Adverse Reactions

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.

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Reference: Soliris [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc; 2019.

ALEXION®

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