



# BEGINNING TREATMENT CHECKLIST FOR THE INPATIENT SETTING

Use this checklist of suggested steps to help initiate a patient on SOLIRIS® (eculizumab) after deciding on it as a treatment option for adults with anti-aquaporin-4 (AQP4) antibody-positive neuromyelitis optica spectrum disorder (NMOSD).<sup>1</sup>

## SOME POSSIBLE PATIENT SITUATIONS MAY INCLUDE:

- Newly diagnosed with NMOSD—Patients hospitalized for a clinical event that led to their NMOSD diagnosis
- Currently being treated for NMOSD—Patients already receiving therapy or treatment for NMOSD
- Diagnosed with NMOSD after initial misdiagnosis of multiple sclerosis (MS)—Patients previously misdiagnosed with or currently being treated for MS but now receiving a new diagnosis of NMOSD

## 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 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](http://www.solirisrems.com).

Please see additional Important Safety Information throughout and full [Prescribing Information](#) for SOLIRIS, including Boxed WARNING regarding serious meningococcal infections.

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

**Anti-AQP4 antibody test**  
Confirm that the patient is positive for anti-AQP4 antibodies. If a test has not been conducted, choose a cell-based assay, the preferred testing method. False negatives are possible.<sup>1-3</sup>

**Meningococcal vaccinations**  
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. **Please see Important Safety Information throughout and the full [Prescribing Information](#) for SOLIRIS for additional details.**<sup>1</sup>

**Enroll in the SOLIRIS 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). To learn more and enroll, call 1-888-SOLIRIS (1-888-765-4747) or visit [SOLIRISREMS.com](http://SOLIRISREMS.com).<sup>1</sup>

**Order SOLIRIS**  
To place an order, call 1-888-SOLIRIS (1-888-765-4747). An Alexion Customer Operations Representative will identify an authorized distributor to coordinate delivery. NDC: 25682-001-01

**Transition of care**  
Discuss with the discharge team the need to advise the patient about the transition of care, including home infusion options.\*

\*Please note that the option for in-home infusion may be limited based on a patient's insurance and availability in their location.

## SELECT IMPORTANT SAFETY INFORMATION

### 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

## RESOURCES

### Medical information request form

[Alexion.com/Contact-Alexion/Medical-Information](http://Alexion.com/Contact-Alexion/Medical-Information)

### SOLIRIS REMS program enrollment

[SOLIRISREMS.com](http://SOLIRISREMS.com)

### Alexion OneSource™ patient enrollment

[AlexionOneSource.com/SOLIRIS](http://AlexionOneSource.com/SOLIRIS)

### SOLIRIS Initiation Guide

[SOLIRISNMOSD-HCP.com/SOLIRIS\\_NMOSD\\_HCP.com/Documents/Dosing-Admin-Web](http://SOLIRISNMOSD-HCP.com/SOLIRIS_NMOSD_HCP.com/Documents/Dosing-Admin-Web)

### SOLIRIS Prescribing Information and Medication Guide

[SOLIRISPro.com/pdf/SOLIRIS\\_USPI.pdf](http://SOLIRISPro.com/pdf/SOLIRIS_USPI.pdf)



Please see additional Important Safety Information throughout and full [Prescribing Information](#) for SOLIRIS, including Boxed WARNING regarding serious meningococcal infections.



Learn more at  
[SOLIRISNMOSD-HCP.com](https://www.solirisnmosd-hcp.com)

## SELECT IMPORTANT SAFETY INFORMATION

### 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 reactions in the NMOSD placebo-controlled trial ( $\geq 10\%$ ) are: upper respiratory infection, nasopharyngitis, diarrhea, back pain, dizziness, influenza, arthralgia, pharyngitis, and contusion.

**Please see additional Important Safety Information throughout and full Prescribing Information for SOLIRIS, including Boxed WARNING regarding serious meningococcal infections.**

**References:** 1. SOLIRIS. Package insert. Alexion Pharmaceuticals, Inc. 2. Wingerchuk DM, Banwell B, Bennett JL, et al. International consensus diagnostic criteria for neuromyelitis optica spectrum disorders. *Neurology*. 2015;85(2):177-189. doi:10.1212/WNL.0000000000001729 3. Waters PJ, Pittcock SJ, Bennett JL, Jarius S, Weinschenker BG, Wingerchuk DM. Evaluation of aquaporin-4 antibody assays. *Clin Exp Neuroimmunol*. 2014;5(3):290-303. doi:10.1111/cen3.12107



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