

# Sample Appeal Letter for SOLIRIS® (eculizumab)

## In Anti-Aquaporin-4 (AQP4) Antibody- Positive Neuromyelitis Optica Spectrum Disorder (NMOSD) in Adults

### INDICATION

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

SOLIRIS, a complement inhibitor, increases the risk of serious infections caused by *Neisseria meningitidis* [see *Warnings and Precautions* (5.1)]. Life-threatening and fatal meningococcal infections have occurred in patients treated with complement inhibitors. These infections may become rapidly life-threatening or fatal if not recognized and treated early.

- Complete or update vaccination for meningococcal bacteria (for serogroups A, C, W, Y, and B) at least 2 weeks prior to the first dose of SOLIRIS, unless the risks of delaying SOLIRIS therapy outweigh the risk of developing a serious infection. Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against meningococcal bacteria in patients receiving a complement inhibitor. See *Warnings and Precautions* (5.1) for additional guidance on the management of the risk of serious infections caused by meningococcal bacteria.
- Patients receiving SOLIRIS are at increased risk for invasive disease caused by *Neisseria meningitidis*, even if they develop antibodies following vaccination. Monitor patients for early signs and symptoms of serious meningococcal infections and evaluate immediately if infection is suspected.

Because of the risk of serious meningococcal infections, SOLIRIS is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called ULTOMIRIS and SOLIRIS REMS [see *Warnings and Precautions* (5.2)].

Please see Important Safety Information on pages [1](#) and [9-10](#) and full [Prescribing Information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

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

# Introduction

When a payer (health plan or pharmacy benefit manager [PBM]) denies a prior authorization (PA), precertification, or reauthorization request for SOLIRIS prescribed for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive, your patient has the right to appeal the decision. If your patient wishes to appeal, you and your staff may assist by submitting an appeal letter and supporting documentation.

As part of the appeals process, payers may request additional documentation from you to support coverage of SOLIRIS when approval for its use has been denied. Your letter should explain why SOLIRIS is medically necessary for the specific patient and may include supporting documentation. The letter may be submitted in response to the denial letter or a payer’s request for additional documentation. The letter should include patient-specific information, address the reason for denial, be presented on the prescriber’s letterhead, and be signed by the prescriber. The provided sample appeal letter gives you a framework for composing an appeal.

This sample appeal letter is provided for informational purposes only and is not legal advice or official guidance from payers. It is not intended to increase or maximize reimbursement by any payer. Alexion does not warrant, promise, guarantee, or make any statement that the use of this information will result in coverage or payment for SOLIRIS or that any payment received will cover providers’ costs.

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Please see Important Safety Information on pages [1](#) and [9-10](#) and full [Prescribing Information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.



## General Tips for Completing an Appeal Letter

**Understand the appeals process for the specific payer.** It's important to follow the payer's guidelines when submitting an appeal. Payers may have their own appeal request forms, which are usually available on their website. If a form is required, include it with your own letter. Be sure to contact the payer with any questions and obtain written instructions for their appeals process.



**When submitting an appeal, timing is critical.** Refer to the denial letter to find the timelines for submitting the appeal and any payer-specific guidelines.



**In cases of medical urgency,** your patient may request an expedited review and can expect to receive a decision within 72 hours. For more information, please visit [HealthCare.gov](https://www.hhs.gov/healthcare).



**Understand the reason for denial.** It's important to read the denial letter carefully to understand the reason(s) provided. You may also call the payer to discuss a denial with them; this may help inform you about ways to resolve it in a timely manner.

- **If the denial is due to inaccurate or incomplete information,** carefully review the PA or reauthorization request that you submitted to identify information that is incorrect or was omitted. Resubmit the PA or reauthorization request when all the required information is accurate and complete.
- **If there is a medical reason for the denial,** ensure that your appeal letter includes specific and relevant medical information to support SOLIRIS use according to the payer's criteria. Your letter should clearly explain why you believe SOLIRIS is the most appropriate option for this patient.



**Provide all supporting documentation at the same time and in the requested order,** as shown in the individual payer's appeal instructions. This might include:

- The payer's appeal form (if required)
- Your appeal letter
- A copy of the payer's denial letter
- Supporting documentation, such as clinical notes, lab results, etc

For more information on the overall appeals process, please refer to the **Alexion SOLIRIS Access and Reimbursement Guide**.



**Our dedicated Field Reimbursement Managers (FRMs) can work with you.** In the event of a PA denial, FRMs can provide you or your office staff with educational support and guidance. FRMs can help with:

- Payer options for PA resubmission, including details about the resubmission process, peer-to-peer review, appeals process, and associated timelines
- Review of the redacted denial letter or Explanation of Benefits (EOB) letter to provide specific guidance on next steps and best practices



[John Doe, MD]  
[Address]  
[City, State ZIP Code]  
[(888) 555-5555]

# SAMPLE ONLY

Please copy onto your letterhead.

[Date]  
[Contact Name] [Title]  
[Name of Health Insurance Company]  
[Address] [City, State Zip Code]

RE: Insured: [Name]; Policy Number: [Number]; Group Number: [Number]  
Date(s) of service: [Date(s) of administration]; Claim number: [Claim number]

Dear [Name of Contact],

I am writing to appeal the coverage determination for my patient [patient name] with anti-aquaporin-4 (AQP4) antibody-positive neuromyelitis optica spectrum disorder (NMOSD).

- NMOSD relapses are unpredictable and tend to be severe and recurrent.<sup>1-3</sup> Over time, relapses have been shown to be inevitable for the majority of patients with NMOSD<sup>1,2,4</sup>;
- Severe disability can result after even a single relapse<sup>5</sup> and up to 76% of patients may not fully recover<sup>1</sup>;
- Complement activation is an important cause of anti-AQP4 antibody-positive NMOSD pathophysiology.<sup>6</sup>

[Insert reason for denial and why you disagree.]

This letter provides information about my patient's medical history and treatment rationale.

## 1 DISEASE SUMMARY (Reference page 5 for examples):

[Provide a brief discussion of patient's symptoms and treatments for anti-AQP4 antibody-positive NMOSD, including any relevant patient-specific clinical scenarios supportive of your treatment selection.]

## 2 TREATMENT RATIONALE (Reference page 6 for examples):

In my medical opinion, SOLIRIS is the most appropriate treatment for [name of patient]'s anti-AQP4 antibody-positive NMOSD based on the clinical efficacy and safety data.

[Based on your medical judgment, insert additional treatment rationale to support this appeal.]

Based on the above facts, I am confident you will agree that SOLIRIS is indicated and medically necessary for this patient, and I request that you reverse the coverage determination.

For your convenience, I am enclosing [list enclosures such as a paper copy of original claim form, a copy of the summary of benefits showing the denial, supporting clinical documentation, etc]. If you have any further questions, please feel free to call me at [physician's telephone number] to discuss.

Thank you in advance for your immediate attention to this request.

Sincerely,

[Physician's name], MD  
[Physician's practice name] [Phone number]

Enclosures

[At the bottom of your letter, list the items you have enclosed. Be sure to include every article that you referenced or any new documentation.]

## 1 Disease Summary May Include the Following:

- o [Name of patient] is a[n] [age]-year-old [male/female] born [MM-DD-YEAR] who requires treatment with SOLIRIS after being diagnosed with anti-AQP4 antibody-positive NMOSD on [date of diagnosis MM-DD-YEAR];
- o Clinical, imaging, and antibody findings including serology results confirming anti-AQP4 antibody status;
- o Past medical history including if the patient has experienced optic neuritis, longitudinally extensive transverse myelitis, area postrema syndrome (episode of otherwise unexplained hiccups or nausea and vomiting), acute brainstem syndrome, symptomatic narcolepsy or acute diencephalic clinical syndrome with anti-AQP4 antibody-positive NMOSD—typical diencephalic magnetic resonance imaging lesions, symptomatic cerebral syndrome with anti-AQP4 antibody-positive NMOSD—typical brain lesions and pertinent negative findings for other diagnoses such as multiple sclerosis (MS), sarcoidosis, or neoplasm;
- o Detailed relapse history including at least 2 relapses in the year prior to request for initiating SOLIRIS or at least 3 relapses in the past 2 years with at least 1 relapse within the past year prior to request for initiating SOLIRIS;
- o Status based on the Expanded Disability Status Scale (EDSS) score (required to be  $\leq 7$ , consistent with the presence of at least limited ambulation with aid);
- o Previous and/or current treatment on intravenous corticosteroids at a dose of  $\leq 20$  mg/day or immunosuppressants at a stable dosage, including name of treatments, dosage, frequency, and duration including dates and impact, if any, on patient's symptoms;
- o Treatments the patient will NOT be receiving in combination with SOLIRIS including disease-modifying therapies for MS or anti-interleukin-6 therapy;
- o Has not received rituximab or mitoxantrone within 3 months or intravenous immunoglobulin within 3 weeks prior to initiation;
- o Contraindications, if any, to any agents used in treatment of anti-AQP4 antibody-positive NMOSD;
- o Disease-related complications leading to emergency treatment, hospital admissions, and/or other interventions;
- o Description of how anti-AQP4 antibody-positive NMOSD has impacted the patient's level of function physically, visually, and neurologically;
- o Record of receiving the meningococcal vaccine at least 2 weeks prior to the first proposed treatment with SOLIRIS. If the patient was not vaccinated, they were provided with 2 weeks of antibacterial drug prophylaxis;
- o Previous experience, if any, with receiving SOLIRIS including submission of medical records demonstrating a positive clinical response from baseline.

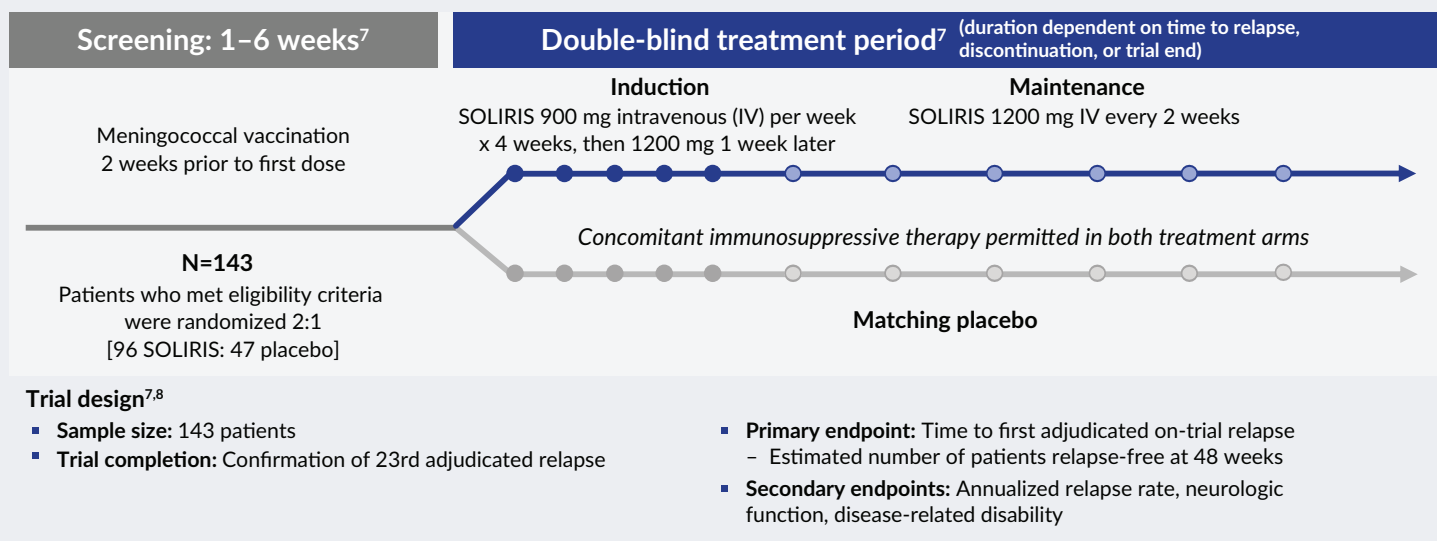
Please see Important Safety Information on pages [1](#) and [9-10](#) and full [Prescribing Information](#) for SOLIRIS, including **Boxed WARNING** regarding serious and life-threatening or fatal meningococcal infections.

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## 2 Treatment Rationale to Support Appeal

PREVENT (Prevention of Relapses in Neuromyelitis Optica) is a phase 3, randomized, double-blind, placebo-controlled, time-to-event study evaluating the efficacy and safety of SOLIRIS in 143 adult patients with anti-AQP4 antibody-positive NMOSD who received SOLIRIS (n=96) or placebo (n=47).

### THE FOLLOWING EFFICACY AND SAFETY DATA ARE BASED ON THE TRIAL DESIGN BELOW.



- o SOLIRIS is a complement inhibitor that is approved by the Food and Drug Administration for treatment of NMOSD in adult patients who are anti-AQP4 antibody positive
- o In the SOLIRIS PREVENT study of patients with anti-AQP4 antibody-positive NMOSD, SOLIRIS was superior to placebo based on time to first adjudicated on-trial relapse (primary endpoint). The time to first adjudicated on-trial relapse was significantly longer in SOLIRIS-treated patients compared to patients on placebo (relative risk reduction 94%; hazard ratio=0.058; 95% confidence interval: 0.017, 0.197;  $P<0.0001$ )<sup>9</sup>
- o 98% of patients treated with SOLIRIS were relapse-free at 48 weeks vs 63% with placebo log-rank  $P$ -value  $<0.0001$ <sup>8,9</sup>
- o SOLIRIS has an established safety profile<sup>7,9</sup>
- o SOLIRIS has a black box warning regarding serious and life-threatening or fatal meningococcal infections. 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<sup>9</sup>
- o SOLIRIS is a monoclonal antibody that specifically binds to the complement protein C5 with high affinity, thereby inhibiting its cleavage to C5a and C5b and preventing the generation of the terminal complement complex C5b-9. The precise mechanism by which eculizumab exerts its therapeutic effect in NMOSD is unknown but is presumed to involve inhibition of aquaporin-4-antibody–induced terminal complement C5b-9 deposition<sup>9</sup>

Please see Important Safety Information on pages [1](#) and [9-10](#) and full [Prescribing Information](#) for SOLIRIS, including **Boxed WARNING** regarding serious and life-threatening or fatal meningococcal infections.



## 2 Treatment Rationale to Support Appeal (cont'd)

- o **Denial due to required use of biosimilar [eculizumab-aagh or eculizumab-aeeb]<sup>a</sup>:** In my medical opinion, [eculizumab-aagh or eculizumab-aeeb] is not an appropriate step for my patient based on the following relevant clinical criteria [below is a list of potential considerations why eculizumab-aagh or eculizumab-aeeb may not be appropriate for your patient given their case or specific clinical presentation. One or more of these reasons may apply to your patient's individual case].
  - **Non-medical switching**  
 [Name of patient] is currently being treated for anti-AQP4 antibody-positive NMOSD with SOLIRIS. While non-medical switching is a practice becoming more common as biosimilars enter the market, study results regarding similarities in efficacy and safety from different originator-biosimilar combinations cannot be generalized.<sup>12</sup> Based on my medical experience, a non-medical switch could result in potential interrupted therapy due to treatment logistics, side effects, and medication abandonment by the patient. Since [Name of patient] is currently clinically stable on SOLIRIS as shown with [relapse history; neurologic function; visual acuity; disability assessments],<sup>13</sup> the patient and I have a strong preference to continue using SOLIRIS in treating [his/her/their] anti-AQP4 antibody-positive NMOSD.
  - **Patient is allergic, intolerant, or has a medical condition that is not compatible with excipients present in [eculizumab-aagh or eculizumab-aeeb]**  
 The patient is unable to take [eculizumab-aagh or eculizumab-aeeb] due to an [allergic reaction, intolerance, or incompatible medical condition (eg, diabetes)] to [trehalose in eculizumab-aagh<sup>10</sup> or sorbitol, edetate disodium (EDTA), and/or sodium hydroxide in eculizumab-aeeb<sup>11</sup>]. Due to this [allergic reaction, intolerance, or incompatible medical condition (eg, diabetes)], it would be in the patient's best interest to continue using SOLIRIS as [he is/she is/they are] currently stable as shown with [relapse history; neurologic function; visual acuity; disability assessments].<sup>13</sup>
  - **[eculizumab-aagh or eculizumab-aeeb] lacks real-world evidence**  
 As [eculizumab-aagh<sup>14</sup> or eculizumab-aeeb<sup>15</sup>] was recently approved in 2024 for the treatment of PNH, aHUS, and gMG, [eculizumab-aagh or eculizumab-aeeb] lacks real-world evidence. [Name of patient] and I prefer to use a therapy, such as SOLIRIS, with real-world evidence, 6 years of approved use, and demonstrated substantial and established safety and efficacy to patients.<sup>16</sup>

a. Bkemy™ (eculizumab-aeeb) and Epysqli® (eculizumab-aagh) are only approved as biosimilars to SOLIRIS® (eculizumab) and indicated for paroxysmal nocturnal hemoglobinuria (PNH), atypical uremic syndrome (aHUS), and generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine (AChR) antibody positive.<sup>10,11</sup>

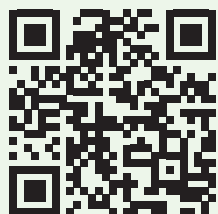
Please see Important Safety Information on pages [1](#) and [9-10](#) and full [Prescribing Information](#) for SOLIRIS, including **Boxed WARNING** regarding serious and life-threatening or fatal meningococcal infections.

### 3 Attachments and Supporting Documentation

In the appeal, you only need to include the original appeal letter and new supporting documentation. If you referred to any specific articles or obtained any photographs or attestations, be sure to attach them to the appeal.

Additional resources that may be used in submitting your letter of appeal may include the SOLIRIS Prescribing Information, the original denial letter, the SOLIRIS Letter of Medical Necessity, and the SOLIRIS Access and Reimbursement Guide.

For additional access resources, please visit:



Explore Alexion  
Access Navigator

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NAVIGATOR

Alexion Access Navigator is a dedicated resource website for US Healthcare Professionals and their offices that contains downloadable access and reimbursement materials for SOLIRIS® (eculizumab).

Online: <https://alexionaccessnavigator.com>

**References:** 1. Jarius S, Ruprecht K, Wildemann B, et al. Contrasting disease patterns in seropositive and seronegative neuromyelitis optica: a multicentre study of 175 patients. *J Neuroinflammation*. 2012;9:14. 2. Wingerchuk DM, Hogancamp WF, O'Brien PC, et al. The clinical course of neuromyelitis optica (Devic's syndrome). *Neurology*. 1999;53(5):1107-1114. 3. Kitley J, Leite MI, Nakashima I, et al. Prognostic factors and disease course in aquaporin-4 antibody-positive patients with neuromyelitis optica spectrum disorder from the United Kingdom and Japan. *Brain*. 2012;135(Pt 6):1834-1849. 4. Mealy MA, Newsome S, Greenberg BM, et al. Low serum vitamin D levels and recurrent inflammatory spinal cord disease. *Arch Neurol*. 2012;69(3):352-356. 5. Flanagan EP, Cabre P, Weinshenker BG, et al. Epidemiology of aquaporin-4 autoimmunity and neuromyelitis optica spectrum. *Ann Neurol*. 2016;79(5):775-783. 6. Dutra BG, da Rocha AJ, Nunes RH, et al. Neuromyelitis optica spectrum disorders: spectrum of MR imaging findings and their differential diagnosis. *Radiographics*. 2018;38(1):169-193. 7. Data on file. Alexion Pharmaceuticals, Inc. 8. Pittock SJ, Berthele A, Fujihara K, et al. Eculizumab in aquaporin-4-positive neuromyelitis optica spectrum disorder. *N Engl J Med*. 2019;381(7):614-625. 9. SOLIRIS. Prescribing Information. Alexion Pharmaceuticals, Inc. 10. EPYSQLI. Prescribing Information. Samsung Bioepis Co., Ltd. 11. BKEMV. Prescribing Information. Amgen Inc. 12. Feagan BG, Marabani M, Wu JJ, et al. The challenges of switching therapies in an evolving multiple biosimilars landscape: a narrative review of current evidence. *Adv Ther*. 2020;37(11):4491-4518. 13. Pittock SJ, Berthele A, Fujihara K, et al. Eculizumab in aquaporin-4-positive neuromyelitis optica spectrum disorder. *N Engl J Med*. 2019;381(7):614-625. 14. US Food and Drug Administration. Department of Health and Human Services. EPYSQLI BLA761340 approval letter. July 19, 2024. Accessed February 26, 2025. [https://www.accessdata.fda.gov/drugsatfda\\_docs/appletter/2024/761340Orig1s000ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/761340Orig1s000ltr.pdf) 15. US Food and Drug Administration. Department of Health and Human Services. Bkerv BLA 761333 approval letter. May 28, 2024. Accessed November 18, 2024. [https://www.accessdata.fda.gov/drugsatfda\\_docs/appletter/2024/761333Orig1s000ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/761333Orig1s000ltr.pdf) 16. US Food and Drug Administration. Department of Health and Human Services. Soliris BLA 125166/S-431 approval letter. June 27, 2019. Accessed March 5, 2025. [https://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2019/125166Orig1s431.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/125166Orig1s431.pdf)

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## SELECT IMPORTANT SAFETY INFORMATION (cont'd)

### CONTRAINDICATIONS

- SOLIRIS is contraindicated for initiation in patients with unresolved serious *Neisseria meningitidis* infection.

### WARNINGS AND PRECAUTIONS

#### Serious Meningococcal Infections

SOLIRIS, a complement inhibitor, increases a patient's susceptibility to serious, life-threatening, or fatal infections caused by meningococcal bacteria (septicemia and/or meningitis) in any serogroup, including non-groupable strains. Life-threatening and fatal meningococcal infections have occurred in both vaccinated and unvaccinated patients treated with complement inhibitors.

Revaccinate patients in accordance with ACIP recommendations considering the duration of therapy with SOLIRIS. Note that ACIP recommends an administration schedule in patients receiving complement inhibitors that differs from the administration schedule in the vaccine prescribing information.

If urgent SOLIRIS therapy is indicated in a patient who is not up to date with meningococcal vaccines according to ACIP recommendations, provide the patient with antibacterial drug prophylaxis and administer meningococcal vaccines as soon as possible. Various durations and regimens of antibacterial drug prophylaxis have been considered, but the optimal durations and drug regimens for prophylaxis and their efficacy have not been studied in unvaccinated or vaccinated patients receiving complement inhibitors, including SOLIRIS. The benefits and risks of treatment with SOLIRIS, as well as those associated with antibacterial drug prophylaxis in unvaccinated or vaccinated patients, must be considered against the known risks for serious infections caused by *Neisseria meningitidis*.

Vaccination does not eliminate the risk of serious meningococcal infections, despite development of antibodies following vaccination.

Closely monitor patients for early signs and symptoms of meningococcal infection and evaluate patients immediately if infection is suspected. Inform patients of these signs and symptoms and instruct patients to seek immediate medical care if these signs and symptoms

occur. Promptly treat known infections. Meningococcal infection may become rapidly life-threatening or fatal if not recognized and treated early. Consider interruption of SOLIRIS in patients who are undergoing treatment for serious meningococcal infection, depending on the risks of interrupting treatment in the disease being treated.

#### ULTOMIRIS and SOLIRIS REMS

Due to the risk of serious meningococcal infections, SOLIRIS is available only through a restricted program called ULTOMIRIS and SOLIRIS REMS.

Prescribers must enroll in the REMS, counsel patients about the risk of serious meningococcal infection, provide patients with REMS educational materials, assess patient vaccination status for meningococcal vaccines (against serogroups A, C, W, Y, and B) and vaccinate if needed according to current ACIP recommendations two weeks prior to the first dose of SOLIRIS. Antibacterial drug prophylaxis must be prescribed if treatment must be started urgently and the patient is not up to date with both meningococcal vaccines according to current ACIP recommendations at least two weeks prior to the first dose of SOLIRIS. Patients must receive counseling about the need to receive meningococcal vaccines and to take antibiotics as directed, the signs and symptoms of meningococcal infection, and be instructed to carry the Patient Safety Card with them at all times during and for 3 months following SOLIRIS treatment.

Further information is available at [www.UltSolREMS.com](http://www.UltSolREMS.com) or 1-888-765-4747.

#### Other Infections

Serious infections with *Neisseria* species (other than *Neisseria 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, such as infections with *Neisseria meningitidis* but also *Streptococcus pneumoniae*, *Haemophilus influenzae*, and to a lesser extent, *Neisseria gonorrhoeae*. Additionally, *Aspergillus* infections have occurred in immunocompromised and neutropenic patients. Patients receiving SOLIRIS are at increased risk for infections due to these organisms, even if they develop antibodies following vaccination.

Please see Important Safety Information on pages 1 and 9-10 and full Prescribing Information for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

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## SELECT IMPORTANT SAFETY INFORMATION (cont'd)

### WARNINGS AND PRECAUTIONS (cont'd)

#### Thrombosis Prevention and Management

The effect of withdrawal of anticoagulant therapy during SOLIRIS treatment has not been established. Therefore, treatment with SOLIRIS should not alter anticoagulant management.

#### Infusion-Related Reactions

Administration of SOLIRIS may result in infusion-related reactions, including anaphylaxis or other hypersensitivity reactions. In clinical trials, no patients experienced an infusion-related reaction which 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 ( $\geq 10\%$ ) were: upper respiratory infection, nasopharyngitis, diarrhea, back pain, dizziness, influenza, arthralgia, pharyngitis, and contusion.

### DRUG INTERACTIONS

#### Plasmapheresis, Plasma Exchange, or Fresh Frozen Plasma Infusion

Concomitant use of SOLIRIS with plasma exchange (PE), plasmapheresis (PP), or fresh frozen plasma infusion (PE/PI) treatment can reduce serum eculizumab concentrations and requires a supplemental dose of SOLIRIS.

#### Neonatal Fc Receptor Blockers

Concomitant use of SOLIRIS with neonatal Fc receptor (FcRn) blockers may lower systemic exposures and reduce effectiveness of SOLIRIS. Closely monitor for reduced effectiveness of SOLIRIS.

To report **SUSPECTED ADVERSE REACTIONS** contact Alexion Pharmaceuticals, Inc. at 1-844-259-6783 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

Please see full [Prescribing Information](#) for SOLIRIS, including **Boxed WARNING** regarding serious and life-threatening or fatal meningococcal infections.