

Sample Letter of Medical Necessity for SOLIRIS® (eculizumab) in Anti-Aquaporin-4 (AQP4) Antibody-Positive Neuromyelitis Optica Spectrum Disorder (NMOSD) in Adults

Payers may request a letter of medical necessity to support coverage of SOLIRIS. The letter should explain why the drug is medically necessary for the specific patient and may include supporting documentation (eg, medical records, peer-reviewed literature, Prescribing Information, clinical treatment history, etc). The letter may be submitted as part of a prior authorization (PA) request, with the claim form, or in response to a payer's request for additional documentation. The letter should include patient-specific information, be on the prescriber's letterhead, be signed by the prescriber, and be submitted to a payer to support a PA request or claim for SOLIRIS.

This sample letter of medical necessity is provided for informational purposes only and is not based on 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.

INDICATION & IMPORTANT SAFETY INFORMATION FOR SOLIRIS

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



John Doe, [Credentials]

12345 West Main Street
City Name, FL 33223
(888) 555-5555

SAMPLE ONLY
Please copy onto your letterhead.

[Date]
[Contact Name] [Title]
[Name of Health Insurance Company]
[Address] [City, State Zip Code]
Insured: [Name]; Policy Number: [Number]; Group Number: [Number]
Date(s) of service: [Date(s)]

Dear [Name of Contact]:

I am writing on behalf of my patient, [First Name] [Last Name], to request that [name of health insurance company] approve coverage and appropriate reimbursement associated with [Mr/Ms/Mrs/other title] [Last Name]'s treatment with SOLIRIS® (eculizumab). SOLIRIS is indicated for the treatment of adult patients with anti-aquaporin-4 (AQP4) antibody-positive neuromyelitis optica spectrum disorder (NMOSD).

Patient History and Diagnosis

[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].

[Provide a brief discussion of patient's anti-AQP4 antibody-positive NMOSD symptoms and previous treatments for anti-AQP4 antibody-positive NMOSD. It may be helpful to include information on the patient, as applicable:

- Clinical, imaging, and laboratory findings including serology confirming anti-AQP4 antibody status, at least one core clinical characteristic, and exclusion of alternative diagnoses¹
- Detailed history of relapses
- Status based on the Expanded Disability Status Scale (0-10; note, required to be ≤7, consistent with the presence of at least limited ambulation with aid)
- List names of previous and/or current treatments including dosage, frequency, duration including dates, and impact, if any, on patient's symptoms
- Contraindications, if any, to any agents used in treatment of anti-AQP4 antibody-positive NMOSD
- Additional documentation of your clinical rationale to initiate SOLIRIS (eculizumab) for this patient, such as clinical presentation, disease-related complications, recent medical history, or visits related to anti-AQP4 antibody-positive NMOSD, etc
- Description on how anti-AQP4 antibody-positive NMOSD has impacted the patient's level of function physically, visually, and neurologically
- Meningococcal vaccinations: Provide documentation of initial series and/or most recent booster(s) for MenACWY and MenB vaccinations at least 2 weeks prior to the first proposed treatment with SOLIRIS (eculizumab) or antibiotics for prophylaxis of meningococcal infection until at least 2 weeks after meningococcal vaccinations
- Previous experience, if any, with receiving SOLIRIS (eculizumab)]

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

Dosing

For patients with anti-AQP4 antibody-positive NMOSD, the recommended dosing regimen with SOLIRIS consists of 900 mg weekly for the first 4 weeks, followed by 1200 mg for the fifth dose 1 week later, then 1200 mg once every 2 weeks thereafter.²

Based on the above facts, I am confident you will agree that SOLIRIS is indicated and medically necessary for this patient. If you have any further questions, please feel free to call me at [prescriber's telephone number] to discuss. Thank you in advance for your immediate attention to this request.

Sincerely,

[Prescriber's name], [Credentials]

[Prescriber's practice name] [Phone number]

Enclosures [Paper copy of original claim form, supporting clinical documentation, Prescribing Information, FDA approval letter for SOLIRIS in anti-AQP4 antibody-positive NMOSD, invoice, etc]

Please copy language above the line for sample letter.

Please see Important Safety Information on pages **1** and **3** and accompanying full [Prescribing Information](#) for SOLIRIS, including **Boxed WARNING** regarding serious and life-threatening or fatal meningococcal infections.

References: 1. Wingerchuk DM, Banwell B, Bennett JL, et al. International consensus diagnostic criteria for neuromyelitis optica spectrum disorders. *Neurology*. 2015;85(2):177-189. 2. SOLIRIS. Prescribing information. Alexion Pharmaceuticals, Inc.

SELECT IMPORTANT SAFETY INFORMATION (cont.)

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 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.

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.

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.

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