Sample Letter of Medical Necessity for SOLIRIS® (eculizumab) in Anti-Acetylcholine Receptor (AChR) Antibody-Positive Generalized Myasthenia Gravis (gMG)

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 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

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.

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.

Please see Important Safety Information on pages 1 and 3 and the full Prescribing Information for SOLIRIS® (eculizumab), including Boxed WARNING regarding serious meningococcal infections.

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

US/SOL-g/0390 07/21

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, [name of patient], to request that [name of health insurance company] approve coverage and appropriate reimbursement associated with [name of patient]'s treatment with SOLIRIS® (eculizumab). SOLIRIS is indicated for the treatment of adult patients with generalized Myasthenia Gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody-positive.

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-AChR antibody-positive gMG on [date of diagnosis MM-DD-YEAR].

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

- Labs confirming presence of anti-AChR antibodies
- Status based on the Myasthenia Gravis Foundation of America disease scale (I-V; note, only class II-IV assessed in the REGAIN clinical trial population)
- Score on the Myasthenia Gravis-Activities of Daily Living scale (0–24; note, only score of ≥6 assessed in the REGAIN clinical trial population)
- Score on the Quantitative Myasthenia Gravis scale (scale 0–39)
- List names of previous treatments including dosage, frequency, duration including dates, and the respective clinical responses
- Contraindications, if any, to any agents used in treatment of gMG
- Additional documentation of your clinical rationale to initiate SOLIRIS for this patient, such as clinical presentation, disease-related complications, recent medical history, or visits related to gMG
- 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
- Previous experience, if any, with receiving SOLIRIS, including any changes in the Myasthenia-Gravis-Activities of Daily Living (scale 0-24) and Quantitative Myasthenia Gravis total score (scale 0-39)

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

Dosing

For patients with gMG, 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 every 2 weeks thereafter.[1]

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 [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 [Supporting clinical documentation, Prescribing Information, FDA approval letter for SOLIRIS in anti-AChR antibody-positive gMG, etc]

Please copy language above the line for sample letter.

Please see Important Safety Information on pages 1 and 3 and the full Prescribing Information for SOLIRIS® (eculizumab), including Boxed WARNING regarding serious meningococcal infections.

Reference: 1. SOLIRIS. Prescribing information. Alexion Pharmaceuticals, Inc.; 2020.

US/SOL-g/0390 07/21

SELECT IMPORTANT SAFETY INFORMATION (cont.)

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

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.

Please see Important Safety Information on pages 1 and 3 and the full Prescribing Information for SOLIRIS® (eculizumab), including Boxed WARNING regarding serious meningococcal infections.

US/SOL-g/0390 07/21