Sample Letter of Medical Necessity for SOLIRIS® (eculizumab)

In Adult Patients Who Have 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 your 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

Soliris is indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

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 4 and 5 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 02/22

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

[Date]
[Contact Name], [Title] [Name of Health Insurance Plan or PBM]
[Address]
[City, State ZIP Code]

Letter of Medical Necessity for SOLIRIS® (eculizumab)
[Request for Expedited Review Due to Medical Urgency]
Insured: [Name]; Policy Number: [Number]; Group Number: [Number]
Date(s) of service: [Date(s)]

Dear [Contact Name],

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. SOLIRIS is indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody-positive.

Patient Medical Overview
[Name of patient] is a[n] [age]-year-old [gender] born [MM-DD-YYYY] who requires treatment with SOLIRIS after being diagnosed with AChR antibody-positive gMG on [date of diagnosis MM-DD-YYYY].

Medical History (including Clinical Signs, Symptoms, and Laboratory Results) [see page 3 for reference]
[Provide relevant gMG clinical signs and symptoms and describe the severity of disease of your patient's current presentation and disease progression (eg, patient's medical history of myasthenic crises) based on your medical opinion. Include specific clinical presentations, relevant patient-specific clinical scenarios demonstrating serious medical need, and previous treatments for gMG.]

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

IF POLICY REQUIRES STEP THERAPY (OPTIONAL)
Your policy requires a step edit through [rituximab / efgartigimod]. In my medical opinion, [rituximab / efgartigimod] is not an appropriate step for my patient because [insert rationale – see 'Treatment Rationale to Support Appeal' section in the Sample Appeal Letter for SOLIRIS].

Treatment Plan
In adult patients with AChR antibody-positive gMG, the recommended dosing regimen with SOLIRIS is 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.

Summary
Based on the above facts, I am confident you will agree that SOLIRIS, a complement inhibitor, is indicated and medically necessary for this patient. For your convenience, I am enclosing [list enclosures such as paper copy of original claim form, supporting clinical documentation, Prescribing Information, FDA approval letter for SOLIRIS in gMG, invoice, 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 Identification Number]
[Physician's Practice Name]
[Physician's Phone Number]
[Physician's Fax Number]
[Physician's Email]

Enclosures
[Supporting clinical documentation, Prescribing Information, FDA press release for SOLIRIS in gMG, etc]

Medical History (including Clinical Signs, Symptoms, and Laboratory Results)

- ☐ Evidence of a positive serological test for **AChR antibodies** (include laboratory results and date) and any other context you consider relevant to the laboratory result
- ☐ Status based on the **Myasthenia Gravis Foundation of America (MGFA) Clinical Classification** Class I to V (MGFA Class II-IV assessed in REGAIN clinical trial population)[1]
- ☐ Score on the **Myasthenia Gravis-Activities of Daily Living (MG-ADL)** scale 0–24; MG-ADL score of ≥6 assessed in REGAIN clinical trial population),1 including case notes and other clinical impressions. If patient or caregiver has tracked changes in their MG-ADL score, include the score history; payers may require the MG-ADL scores for initial approval and reauthorizations of treatment
- ☐ Previous experience, if any, with receiving SOLIRIS, including any changes in the **Quantitative Myasthenia Gravis (QMG)** total score (scale 0–39)
- ☐ **Previous treatment** on corticosteroids, immunosuppressants, intravenous immune globulin, chronic plasmapheresis, and/or plasma exchange, [such as name of treatments, dosage, frequency, duration including dates, and impact, if any, on patient's symptoms]
- ☐ **Contraindications,** if any, to any agents used in treatment of gMG
- ☐ **History of complications, exacerbations, or myasthenic crises** leading to emergency room visits, hospital admissions, and/or intensive care unit stays
- ☐ Record of receiving the **meningococcal vaccine** at least 2 weeks prior to the first proposed treatment with SOLIRIS
- ☐ **Clinical Signs and Symptoms** to help describe the patient's current clinical presentation:*[2]
  - o Ocular muscle weakness: Ptosis and diplopia, or sometimes blurry vision
  - o Axial muscle weakness: Neck flexor or extensor weakness
  - o Oropharyngeal muscle weakness: Chewing difficulties, dysarthria, dysphagia, facial muscles frequently involving eyelid closure, drooling
  - o Limb muscle weakness: Proximal limb weakness with arms more affected than legs
  - o Respiratory muscle weakness: orthopnea, tachypnea, exertional dyspnea-poor inspiratory sniff, cough

*List is not all inclusive of gMG clinical signs and symptoms.

If there is a requirement for prior use of rituximab and/or efgartigimod before SOLIRIS, you are encouraged to proactively address why these treatments may not be suitable for your patient(s). Please refer to the appropriate section in the **Sample Appeal Letter for SOLIRIS** for treatment rationale.

References: 1. SOLIRIS. Prescribing information. Alexion Pharmaceuticals, Inc. 2. Meriggioli MN, et al. *Lancet Neurol*. 2009;8(5): 475-490.

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INDICATION & IMPORTANT SAFETY INFORMATION FOR SOLIRIS® (eculizumab)

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IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS

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- **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).**
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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).

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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.

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ALEXION®
AstraZeneca Rare Disease