# Sample Letter of Medical Necessity for SOLIRIS® (eculizumab)

## In Anti-Acetylcholine Receptor (AChR) Antibody-Positive Generalized Myasthenia Gravis (gMG)

### INDICATION

SOLIRIS is indicated for the treatment of generalized myasthenia gravis (gMG) in adult and pediatric patients six years of age and older who are anti-acetylcholine receptor (AChR) 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 7-8 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

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.

## Table of Contents

[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 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 and pediatric patients six years of age and older 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].

1 **Medical History (including Clinical Signs, Symptoms, and Laboratory Results)** [see page 5 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, eculizumab-aagh, or eculizumab-aeeb]. In my medical opinion, [rituximab, efgartigimod, eculizumab-aagh, or eculizumab-aeeb] 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**
For patients 18 years of age and older 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.[1]

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



For patients 6 years of age and older with AChR antibody-positive gMG, the recommended dosing regimen for SOLIRIS is based on body weight according to the following schedule[1]:

| Patient Body Weight | Induction | Maintenance |
|---|---|---|
| 40 kg and over | 900 mg weekly x 4 doses | 1200 mg at week 5; then 1200 mg every 2 weeks |
| 30 kg to less than 40 kg | 600 mg weekly x 2 doses | 900 mg at week 3; then 900 mg every 2 weeks |
| 20 kg to less than 30 kg | 600 mg weekly x 2 doses | 600 mg at week 3; then 600 mg every 2 weeks |
| 10 kg to less than 20 kg | 600 mg weekly x 1 dose | 300 mg at week 2; then 300 mg every 2 weeks |
| 5 kg to less than 10 kg | 300 mg weekly x 1 dose | 300 mg at week 2; then 300 mg every 3 weeks |

**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]

# 1 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

If there is a requirement for prior use of rituximab, efgartigimod, eculizumab-aagh, and/or eculizumab-aeeb 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.

# 1 Medical History (including Clinical Signs, Symptoms, and Laboratory Results) (cont'd)

☐ **Clinical Signs and Symptoms** to help describe the patient's current clinical presentation[2a]:

- 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

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

**For additional access resources, please visit:**

**Explore Alexion Access Navigator**

ALEXION ACCESS 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

# SELECT IMPORTANT SAFETY INFORMATION FOR SOLIRIS® (eculizumab) (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 or 1-888-765-4747.

# SELECT IMPORTANT SAFETY INFORMATION FOR SOLIRIS® (eculizumab) (cont'd)

## WARNINGS AND PRECAUTIONS (cont'd)

**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. Children treated with SOLIRIS may be at increased risk of developing serious infections due to *Streptococcus pneumoniae* and *Haemophilus influenzae* type b (Hib). Administer vaccinations for the prevention of *Streptococcus pneumoniae* and *Haemophilus influenzae* type b (Hib) infections according to ACIP recommendations. 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 reaction in the adult gMG placebo-controlled clinical trial (≥10%) was: musculoskeletal pain.

## DRUG INTERACTIONS

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

Concomitant use of SOLIRIS with plasma exchange (PE), plasmapheresis (PP), fresh frozen plasma infusion (PE/PI), or in patients with gMG on concomitant IVIg 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.**

**Please see accompanying full Prescribing Information for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.**

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



ALEXION® AstraZeneca Rare Disease