Sample Appeal Letter for SOLIRIS® (eculizumab) in Anti-Acetylcholine Receptor (AChR) Antibody-Positive generalized Myasthenia Gravis (gMG)

When a health plan denies a Prior Authorization (PA), pre-certification, or reauthorization request for SOLIRIS for anti-acetylcholine receptor (AChR) antibody-positive gMG, your patient has the right to appeal the decision. If your patient wishes to appeal, you and your staff may assist with submitting an appeal and accompanying materials.

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 to 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.

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 FOR SOLIRIS® (eculizumab)

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.

General Tips for Completing an Appeal Letter

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

When submitting an appeal, timing is critical. Refer to the denial letter to find the timelines for submitting the appeal, as well as any plan-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.

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 health plan 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® (eculizumab) use according to the health plan's criteria. Your letter should explain clearly why you believe SOLIRIS is the most appropriate option for this patient

Provide all supporting documentation at the same time and in the correct 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 health plan's denial letter
- Supporting documentation, such as clinical notes, lab results, etc.

[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: [First/Second]-Level Appeal for Coverage Denial of SOLIRIS® (eculizumab) J1300
[Request for Expedited Review Due to Medical Urgency]

Denial Letter Date: [MM/DD/YYYY]
Denial Reference #: [Denial Reference #]

Patient: [Name]
Date of Birth: [MM/DD/YYYY]
Member ID Number: [Insurance ID Number] Group Number: [Insurance Group Number]

Dear [Contact Name],

I am writing to appeal the coverage denial for [name of patient]'s treatment with SOLIRIS® (eculizumab) for anti-AChR antibody-positive gMG. In the letter referenced above, you stated that the reason for denial was [insert reason for denial]. This letter provides information about my patient's medical history and my treatment rationale.

1 MEDICAL HISTORY
[Provide a brief history of adult patient's symptoms and treatments for anti-AChR antibody-positive gMG, including any relevant patient-specific clinical scenarios demonstrating serious medical need. Refer to page 4 for examples of information you may want to include]

2 TREATMENT RATIONALE
Regarding the reason for denial in your letter: [Refer to common reasons for denial and sample responses on page 4].

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

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

Based on the above facts, and the clinical trials and FDA-approved indication for SOLIRIS in this disease, 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 additional information, I am enclosing [list enclosures, such as a copy of the denial letter, 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.

[Physician's Name, Degree Initials]
[Provider Identification Number]
[Physician's Practice Name]
[Physician's Phone Number]
[Physician's Fax Number]
[Physician's Email]

Attachments:
[Original denial letter]
[Relevant medical records]
[SOLIRIS Full Prescribing Information]
[SOLIRIS FDA Approval Letter for anti-AChR antibody-positive gMG]

1 Medical History May Include the Following:

- [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]
- Current symptoms, such as profound muscle weakness throughout the body, as demonstrated by slurred speech, impaired swallowing, double vision, upper and lower extremity weakness, disabling fatigue, and/or shortness of breath due to respiratory muscle weakness
- [Myasthenia Gravis Foundation of America Clinical Classification Class II to IV]
- Attestation the patient has tried and failed therapies the plan requires before use of SOLIRIS is permitted, such as 2 immunosuppressants, oral corticosteroids, intravenous immunoglobulin (IVIg), plasmapheresis, pyridostigmine, and/or rituximab in order to meet the plan's medical policy, pre-certification, or prior authorization criteria
- Documentation of your clinical rationale to initiate SOLIRIS for this patient, such as contraindications to other therapies, clinical presentation, recent medical history, or visits related to gMG, etc.

2 Treatment Rationale to Support Appeal

- **SOLIRIS indication:** SOLIRIS is indicated for the treatment of gMG in adult patients who are anti-AChR antibody positive
- **Previous treatments:** Upon diagnosis with anti-AChR antibody-positive gMG, [Patient Name] was treated with [list treatments and the respective clinical responses here]. My rationale for treatment with SOLIRIS at this time is [include rationale here]
- **Pyridostigmine:** Pyridostigmine treatment was tried with the following results: Describe clinical response and/or failure with pyridostigmine treatment. For this reason/these reasons, [include rationale for treatment with SOLIRIS]
- **Rituximab:** Rituximab does not have an FDA-approved indication for the treatment of gMG, and it is my clinical opinion [include rationale for treatment with SOLIRIS]
- **MG-ADL score:** Documentation of current score ≥6 on the Myasthenia Gravis-Specific Activities of Daily Living (MG-ADL) scale, 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)*
- **Antibody test:** Evidence of a positive anti-AChR antibody test (include laboratory results and date), and any other context you consider relevant around this laboratory result
- **Meningococcal vaccinations:** Provide documentation of initial series and/or most recent booster(s) for MenACWY and MenB vaccinations

Potential References and Resources to Support Appeal

- The *Common Prior Authorization Criteria* for SOLIRIS resource provides you with information about common criteria used by health plans to make prior authorization decisions for SOLIRIS for anti-AChR antibody-positive gMG
- The *Clinical Reference Library Overview* provides information about specific scientific data and publications that may provide additional evidence for your Appeal Letter

When preparing an Appeal Letter, ensure that you have provided specific and relevant medical information to support appropriate use according to the health plan's criteria. Include other documentation, as appropriate, such as clinical records, lab reports, and SOLIRIS full Prescribing Information.

SELECT IMPORTANT SAFETY INFORMATION FOR SOLIRIS® (eculizumab) - Continued

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 additional Important Safety Information on page 1 and the full Prescribing Information for SOLIRIS, including Boxed WARNING regarding serious meningococcal infections.

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