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

A Guide to

Common Prior Authorization Criteria for SOLIRIS® (eculizumab)

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

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 FOR SOLIRIS

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 additional Important Safety Information on page 4 and full Prescribing Information for SOLIRIS, including Boxed WARNING regarding serious meningococcal infections.

ALEXION®

Common Prior Authorization Criteria for SOLIRIS® (eculizumab) for the Treatment of Anti-AChR Antibody-Positive gMG

Many commercial, Medicare Advantage, and Managed Medicaid plans require prior authorization (PA) or precertification for use of SOLIRIS in anti-AChR antibody-positive gMG. Although requirements vary by plan, there are common criteria that may be used for SOLIRIS. Please verify current requirements for SOLIRIS for anti-AChR antibody-positive gMG, including whether a PA is required, with each individual plan.

PA Process Tips

Contact your Alexion Field Reimbursement Manager for information about plan-specific PA requirements or general questions about submitting PA requests.

For personalized support on behalf of a specific patient, the patient must enroll in OneSource™ and provide consent for these optional services. Your Field Reimbursement Manager will be able to provide educational support for the above services once the enrollment form is submitted and approved.

When a Plan Member is a Candidate for SOLIRIS for Anti-AChR Antibody-Positive gMG Based on Payer Criteria

Medicare Part A and Medicare Part B Plans

Medicare Part A and Part B may not require PA for beneficiaries to receive SOLIRIS. However, you should always verify benefits before ordering SOLIRIS and initiating treatment.

Commercial, Medicare Advantage, and Managed Medicaid Plans

Below are common criteria that are required by many commercial, Medicare Advantage, and Managed Medicaid plans.

Date of Birth

- Only adult patients are eligible to receive SOLIRIS

Relevant Lab Results for gMG

- Because SOLIRIS is approved only for anti-acetylcholine receptor (AChR) antibody-positive gMG, a positive serologic test for anti-AChR antibodies must be documented

Clinical Findings (both required)

- Member meets Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV criteria
- Member has a Myasthenia Gravis-Specific Activities of Daily Living (MG-ADL) total score ≥6

Prior Treatment Failure, Intolerance, or Contraindications

Medical record documentation of therapeutic failure, intolerance, or contraindication:

- 2 or more immunosuppressive agents used alone or in combination (eg, azathioprine, cyclophosphamide, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus) for 12 months, OR
- 1 or more immunosuppressive agents as either monotherapy or combination therapy and required chronic plasmapheresis or plasma exchange over the preceding 12 months
- Some plans may also require medical record documentation of therapeutic failure, intolerance, or contraindication to monotherapy or combination therapy with corticosteroids, cholinesterase inhibitors, rituximab, or intravenous immunoglobulin (IVIg)

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Who May Prescribe?

- Some plans require that SOLIRIS® (eculizumab) be prescribed by or in consultation with a neurologist, neuromuscular specialist, or other specialist for the treatment of anti-AChR antibody-positive gMG
- SOLIRIS is available only through a restricted program under a REMS. Under the SOLIRIS REMS, prescribers must enroll in the program. Proof of prescriber's REMS certification for SOLIRIS for anti-AChR antibody-positive gMG may be required

Coding for SOLIRIS in Anti-AChR Antibody-Positive gMG

ICD-10-CM diagnosis codes

G70.00 Myasthenia gravis without (acute) exacerbation

G70.01 Myasthenia gravis with (acute) exacerbation

HCPCS code

J1300 Injection, eculizumab, 10 mg

CPT codes for drug administration

96365 Intravenous infusion, for therapy, prophylaxis, or diagnosis; initial, up to one hour

96413 Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug

For comprehensive Coding & Billing guidance, please refer to the CODING AND BILLING GUIDE FOR THE USE OF SOLIRIS® (eculizumab) In Adult Patients With Anti-Acetylcholine Receptor (AChR) Antibody Positive Generalized Myasthenia Gravis (gMG).

Additional Information That May Be Required

- Documentation, including attestation and dates, that the member has received meningococcal vaccinations at least 2 weeks prior to treatment if not previously vaccinated
  - Refer to the most current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccinations in patients with persistent complement component deficiencies or in patients receiving complement inhibitors, including patients receiving SOLIRIS
- Physician statement documenting that the patient does not have an active meningococcal infection
- Other lab results or clinical findings, including history of abnormal neuromuscular transmission test demonstrated by single-fiber electromyography (SFEMG) or repetitive nerve stimulation, history of positive anticholinesterase test (eg, edrophonium chloride test), demonstrated signs of improvement in MG on oral cholinesterase inhibitors
- Physician assessment of the baseline Quantitative Myasthenia Gravis (QMG) score

Important Reminder

In order to facilitate a timely review of the PA request when one is required, be sure to submit all requisite documentation together with the fully completed PA/precertification form.

Providers are responsible for timely and accurate submission of PA requests. Alexion Pharmaceuticals does not make any representation or guarantee concerning reimbursement or coverage for any service or item.

Source: Information is based on a review of 2020 Medicare Part A coverage and PA criteria for national and large regional US commercial, Medicare Part B, and Medicare Advantage plans. Please check with the individual payer for specific coverage information because coverage policies change, and information can vary.

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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.

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