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

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 additional Important Safety Information on pages 4 and 5 and full Prescribing Information for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

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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 do 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.

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

Relevant Lab Results for gMG

- Because SOLIRIS is approved only for anti-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 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 risk evaluation and mitigation strategy (REMS). Under the ULTOMIRIS and SOLIRIS REMS, prescribers must enroll in the program. Proof of the 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

J1299 Injection, eculizumab, 2 mg
for date of service beginning April 1, 2025

J1300 Injection, eculizumab, 10 mg
for date of service through March 31, 2025

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

*Check payer policy reporting requirements.

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 Centers for Disease Control and Prevention (CDC) Recommended Adult Immunization Schedule 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 laboratory 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 myasthenia gravis on oral cholinesterase inhibitors
- Physician assessment of the baseline Quantitative Myasthenia Gravis (QMG) score, MG-ADL total score, and Myasthenia Gravis Foundation of America (MGFA) Clinical Classification

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.

Important Reminder

Healthcare providers may need to obtain a new PA for SOLIRIS when using HCPCS J1299, the HCPCS code effective for dates of service on/after April 1, 2025.

Check with individual payers whether a new PA is needed even if the current PA that was obtained with J1300 is still valid.

CPT, Current Procedural Terminology; **HCPCS,** Healthcare Common Procedure Coding System; **ICD-10-CM,** International Classification of Diseases, 10th Revision, Clinical Modification; **US,** United States.

Source: Information is based on a review of 2025 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) (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.

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.

Please see additional Important Safety Information on pages 1 and 5 and full Prescribing Information for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

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

WARNINGS AND PRECAUTIONS (cont'd)

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.

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This resource is provided for informational purposes only and is not medical advice or guidance. It is not inclusive of all payer prior authorization or precertification criteria for SOLIRIS for gMG. 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.

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US/SOL-g/0346 V5 03/2025