Sample Appeal Letter for SOLIRIS® (eculizumab)

for Atypical Hemolytic Uremic Syndrome (aHUS)

INDICATION & SELECT IMPORTANT SAFETY INFORMATION FOR SOLIRIS® (eculizumab)

INDICATION

SOLIRIS is indicated for the treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy.

Limitation of Use

SOLIRIS is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).

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 10-11 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

When a payer (health plan or pharmacy benefit manager [PBM]) denies a prior authorization (PA), precertification, or reauthorization request for SOLIRIS prescribed for the treatment of atypical hemolytic uremic syndrome (aHUS), your patient has the right to appeal the decision. If your patient wishes to appeal, you and your staff may assist by submitting an appeal letter and supporting documentation.

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.

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General Tips for Completing an Appeal Letter

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

When submitting an appeal, timing is critical. Refer to the denial letter to find the timelines for submitting the appeal and any payer-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 payer 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 use according to the payer's criteria. Your letter should clearly explain why you believe SOLIRIS is the most appropriate option for this patient.

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

For more information on the overall appeals process, please refer to the **Alexion SOLIRIS Access and Reimbursement Guide**.

Our dedicated Field Reimbursement Managers (FRMs) can work with you. In the event of a PA denial, FRMs can provide you or your office staff with educational support and guidance. FRMs can help with:

- Payer options for PA resubmission, including details about the resubmission process, peer-to-peer review, appeals process, and associated timelines
- Review of the redacted denial letter or explanation of benefits (EOB) letter to provide specific guidance on next steps and best practices

Contact form: Connect with a Field Reimbursement Manager

Please see Important Safety Information on pages 1 and 10-11 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

[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]

Re: [First/Second]-Level Appeal for Coverage Denial of SOLIRIS® (eculizumab)
[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]
Rx Bin: [Rx Bin Number] Rx PCN: [Rx PCN Number] Rx Group: [Rx Group Number]

Dear [Contact Name],

I am writing to appeal the coverage denial for [Name of patient]'s treatment with SOLIRIS® (eculizumab) for atypical hemolytic uremic syndrome (aHUS). In the letter referenced above, the denial reason was stated as follows: [insert reason for denial: eg, a requirement of a history of trial/failure of or intolerance to eculizumab-aagh or eculizumab-aeeb therapy]. This letter provides information about my patient's medical history and my treatment rationale.

1 REASON(S) FOR DENIAL AND TREATMENT RATIONALE

In the appeal letter, you will need to address every denial reason(s) stated in the denial letter from the insurance plan. Provide a clear rationale and explain why you disagree with the denial reason. Refer to "Treatment Rationale to Support Appeal" on pages 6 and 7.

If applicable, describe your patient's treatment goals and your rationale why a step therapy through eculizumab-aagh or eculizumab-aeeb is not optimal for meeting these goals. Clearly explain why you have concerns regarding the requirement that your patient must have a history of trial/failure of or intolerance to eculizumab-aagh or eculizumab-aeeb. Refer to "Treatment Rationale to Support Appeal" on pages 6 and 7.

In my medical opinion, SOLIRIS remains the most appropriate treatment for [Name of patient]. The stated reason(s) for denial was [insert each denial reason and address each reason point by point, referring to "Treatment Rationale to Support Appeal," "Rationale for Reauthorization for Patients Currently Receiving SOLIRIS," and "Attachments and Supporting Documentation" on pages 6-9; provide any laboratory results if applicable].

2 SUMMARY AND OPTIONAL MEDICAL HISTORY

After addressing each stated reason for denial, you may wish to summarize your appeal and restate your patient's relevant medical history and laboratory results.

As stated in my initial authorization request, [Name of patient] is currently [treatment-naïve or stable on the current eculizumab regimen].

Based on my assessment of their current clinical symptoms and labs, they require [insert recommendations for addressing patient's current therapeutic needs (eg, effective long-term control of aHUS drastic manifestations including reduction of dialysis and/or maintenance of stable regimen)] for which SOLIRIS treatment is medically necessary.

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

SAMPLE ONLY

Please copy onto your letterhead.

[Note: Payer policies may require physician attestation regarding the discussion of alternative treatment options and shared decision-making of an aHUS treatment plan with patients previously or currently treated with SOLIRIS. To fulfill these requirements for continued used of SOLIRIS, the following text must be included in the appeal.]

I have counseled the patient on alternative treatment options with aHUS. My patient has shared in the decision-making process regarding their aHUS therapy plan. Collectively, we have determined that SOLIRIS is the most clinically appropriate treatment choice for managing their aHUS at this time.

For the above reasons, I request that you approve SOLIRIS for the treatment for this patient.

3 ATTACHMENTS AND SUPPORTING DOCUMENTATION

For your additional information, I am enclosing [list enclosures, such as copy of the denial letter, supporting clinical documentation, etc]. If you have any further questions, please feel free to call me at [physician's phone 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
[At the bottom of your letter, list the items you have enclosed. Be sure to include every article that you referenced or any new documentation.]

1 Treatment Rationale to Support Appeal

In your appeal letter, you may choose to include some of the reasons below for justification. Be sure to attach the supporting references and any additional documentation in your reply.

- **Denial due to indication:** SOLIRIS® (eculizumab) is indicated for the treatment of patients with aHUS to inhibit complement-mediated thrombotic microangiopathy (TMA). Limitation of use: SOLIRIS is not indicated for the treatment of patients with Shiga toxin *Escherichia coli* related hemolytic uremic syndrome (STEC-HUS).[1]
- **Denial due to underlying etiology:** Provide documentation to confirm diagnosis of aHUS in a patient with signs of TMA by ruling out thrombocytopenic purpura (TTP) and STEC-HUS.[2]
  - o Evidence of thrombocytopenia: Platelet count <150 x 10^9/L or >25% decrease from baseline.

  AND

  - o Evidence of microangiopathic hemolytic anemia: schistocytes and/or elevated LDH and /or decreased haptoglobin and/or decrease hemoglobin.

  AND one or more symptoms listed below

  - o Common symptoms: neurologic symptoms (confusion, seizures, stroke, and/or other cerebral abnormalities), renal impairment (elevated creatinine level, decreased eGFR, elevated blood pressure, and/or abnormal urinalysis), gastrointestinal symptoms (diarrhea ± blood, nausea/vomiting, abdominal pain, and/or gastroenteritis/pancreatitis). Other symptoms include cardiovascular symptoms (myocardial infarction, hypertension, arterial stenosis, and/or peripheral gangrene), pulmonary symptoms (dyspnea, pulmonary hemorrhage, and/or pulmonary edema), and visual symptoms (pain and blurred vision, retinal vessel occlusion, and/or ocular hemorrhage).

  AND

  - o Provide documentation for >5% ADAMTS13 (a disintegrin and metalloproteinase with a thrombospondin type 1 motif, member 13) activity and Shiga toxin *Escherichia coli* test results.
- **Denial due to meningococcal vaccinations:** Provide documentation of initial series and/or most recent boosters for meningococcal vaccination (for serogroups A, C, W, Y and B). If vaccinations are pending approval of therapy, please include a scheduled date for patient to receive the vaccinations.[1]
- **Denial due to omission of necessary lab results:** Provide any appropriate or confirmatory lab values [platelet count <150 x 10^9/L or >25% decrease from baseline, presence of schistocytes, elevated LDH, decreased haptoglobin, decreased hemoglobin, and serum creatinine ≥ ULN or required dialysis].[2]
- **Denial due to required step therapy:** Please see respective sections below for supporting statements against the use of step therapy through eculizumab-aagh or eculizumab-aeeb:
  - o **Denial due to use of biosimilar [eculizumab-aagh or eculizumab-aeeb]:** In my medical opinion, [eculizumab-aagh or eculizumab-aeeb] is not an appropriate step therapy for my patient based on the following relevant clinical criteria [below is a list of potential considerations why eculizumab-aagh or eculizumab-aeeb may not be appropriate for your patient given their case or specific clinical presentation. One or more of these reasons may apply to your patient's individual case].

1 Treatment Rationale to Support Appeal (cont'd)

– **Non-medical switching with [eculizumab-aagh or eculizumab-aeeb]**

The patient is currently being treated for aHUS with SOLIRIS. Based on my medical experience, a non-medical switch with [eculizumab-aagh or eculizumab-aeeb] could result in potential interrupted therapy due to treatment logistics (eg, biosimilar REMS requirements) and/or side effects. Since the patient is currently clinically stable on SOLIRIS as shown with [normalization of platelet count, normalization of LDH, ≥25% improvement in serum creatinine from baseline],[1,2] the patient and I have a strong preference to continue using SOLIRIS in treating [his/her/their] aHUS.

– **Patient is allergic, intolerant, or has a medical condition that is not compatible with excipients present in [eculizumab-aagh or eculizumab-aeeb]**

The patient is unable to take [eculizumab-aagh or eculizumab-aeeb] due to a[n] [allergic reaction, intolerance, or incompatible medical conditions]. Due to this [allergic reaction, intolerance, or incompatible medical conditions], it would be in the patient's best interest to continue using SOLIRIS as [he is/she is/they are] currently stable as shown with the [normalization of platelet count, normalization of LDH, ≥25% improvement in serum creatinine from baseline].[1,2]

– **Real-world evidence**

SOLIRIS has 13 years of real-world data.[1,3,4]

Rationale for Reauthorization for Patients Currently Receiving SOLIRIS® (eculizumab)

Health plans often require a PA for patients receiving specialty medications and orphan drugs treating rare diseases. In many cases, after a patient has received a PA, the patient will need a reauthorization (sometimes known as a renewal authorization) after a specified time period. Obtaining a reauthorization for your patient is often required to confirm that the drug continues to be medically necessary, and that the patient has responded to therapy.

- **Denial due to new documentation not previously required:**
  The reauthorization requirements for [Name of patient] have changed since they were initially authorized for treatment with SOLIRIS. [List of additional documentation that is now required] is now required to obtain reapproval for SOLIRIS. I am requesting a medical exception to continue [Name of patient]'s current treatment based on the original authorization criteria because they have had a demonstrated clinical improvement as evidenced by [insert demonstrated clinical response rationale and/or documentation].

- **Denial due to specific reauthorization clinical improvement criteria:**
  In my medical opinion, [Name of patient] is currently responding positively to treatment with SOLIRIS as evidenced by [list specific measures such as: complete TMA response defined by platelet count normalization, LDH normalization, 25% improvement in serum creatinine from baseline, hematologic normalization (normalization of both LDH and platelet count); improvement in eGFR from baseline; reduction or discontinuation of required dialysis treatments].[5] Although [Name of patient] may partially meet [list specific denial reason/specified lab result or clinical measure] reauthorization criteria, I believe SOLIRIS is still the optimal therapy for reaching this patient's treatment goals.

- **Denial due to change in policy required step edit:**
  [Name of patient] was diagnosed with aHUS on [date] and has received SOLIRIS treatment since [date of first infusion]. [Name of patient] received authorization for SOLIRIS based on initial PA criteria. [He is/She is/They are] currently responding positively to treatment with SOLIRIS as demonstrated by [list specific measures such as: complete TMA response defined by platelet count normalization, LDH normalization, 25% improvement in serum creatinine from baseline, hematologic normalization (normalization of both LDH and platelet count); improvement in eGFR from baseline; reduction or discontinuation of required dialysis treatments].[5] [He is/She is/They are] currently stable on this treatment regimen, and it would be clinically inappropriate to require them to stop treatment with SOLIRIS or switch to another therapy.

2 Optional Medical History

You may find it helpful to include a brief impactful history in your patient's appeal letter with only the most clinically significant facts repeated, such as:

- Lab results confirming diagnosis of aHUS – evidence of TMA including[2]:
  - Platelet count <150 x 10^9/L or >25% decrease from baseline **AND**
  - Schistocytes **AND/OR**
  - Elevated serum LDH **AND/OR**
  - Decreased hemoglobin **AND/OR**
  - Decreased haptoglobin **AND**
  - Evidence of involvement of at least 1 organ system
    - *i.e. renal involvement as indicated by elevated serum creatinine*
- Diagnosis of thrombocytopenic purpura (TTP) (≤5% ADAMTS13 activity) has been excluded[2]
- Absence of Shiga toxin-producing *Escherichia coli* infection[2]

3 Attachments and Supporting Documentation

In the appeal, you only need to include the original appeal letter and new supporting documentation. If you referred to any specific articles or obtained any photographs or attestations, be sure to attach them to the appeal.

Additional resources that may be used in submitting your letter of appeal may include the SOLIRIS Prescribing Information, original denial letter, SOLIRIS Letter of Medical Necessity, or SOLIRIS Access and Reimbursement Guide.

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

eGFR, estimated glomerular filtration rate; **LDH,** lactase dehydrogenase; **REMS,** risk evaluation and mitigation strategy; **ULN,** upper limit of normal; **US,** United States.

References: 1. SOLIRIS. Prescribing Information. Alexion Pharmaceuticals, Inc. **2.** Laurence J, et al. *Clin Adv Hematol Oncol*. 2016;14(11)(suppl 11):2-15. **3.** Nishimura JI, et al. *Int J Hematol.* 2023;118(4):419-431. **4.** Alexion Pharmaceuticals, Inc. SOLIRIS® (eculizumab) Approved by FDA for all patients with atypical hemolytic uremic syndrome (aHUS). Updated September 26, 2011. Accessed December 5, 2024. https://media.alexion.com/static-files/cf993a04-a5ff-4613-8544-796779d0315f **5.** Legendre CM, et al. *N Engl J Med*. 2013;368(23)(suppl):2169-2181.

SELECT IMPORTANT SAFETY INFORMATION FOR SOLIRIS (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.

SELECT IMPORTANT SAFETY INFORMATION FOR SOLIRIS (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Monitoring Disease Manifestations After SOLIRIS Discontinuation

Treatment Discontinuation for aHUS

After discontinuing SOLIRIS, monitor patients with aHUS for signs and symptoms of thrombotic microangiopathy (TMA) complications for at least 12 weeks. In aHUS clinical trials, 18 patients (5 in the prospective studies) discontinued SOLIRIS treatment. TMA complications occurred following a missed dose in 5 patients, and SOLIRIS was reinitiated in 4 of these 5 patients.

Clinical signs and symptoms of TMA include changes in mental status, seizures, angina, dyspnea, or thrombosis. In addition, the following changes in laboratory parameters may identify a TMA complication: occurrence of 2, or repeated measurement of any one of the following: a decrease in platelet count by 25% or more compared to baseline or the peak platelet count during SOLIRIS treatment; an increase in serum creatinine by 25% or more compared to baseline or nadir during SOLIRIS treatment; or, an increase in serum LDH by 25% or more over baseline or nadir during SOLIRIS treatment.

If TMA complications occur after SOLIRIS discontinuation, consider reinstitution of SOLIRIS treatment, plasma therapy [plasmapheresis, plasma exchange, or fresh frozen plasma infusion (PE/PI)], or appropriate organ-specific supportive measures.

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 reactions in the aHUS single arm prospective trials (≥20%) were: headache, diarrhea, hypertension, upper respiratory infection, abdominal pain, vomiting, nasopharyngitis, anemia, cough, peripheral edema, nausea, urinary tract infections, pyrexia.

DRUG INTERACTIONS

Plasmapheresis, Plasma Exchange, or Fresh Frozen Plasma Infusion

Concomitant use of SOLIRIS with plasma exchange (PE), plasmapheresis (PP) or fresh frozen plasma infusion (PE/PI) 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.