PRESCRIBER FORM – PNH/ATYPICAL-HUS

FAX: 1.800.420.5150 **MAIL:** 100 College Street New Haven, CT 06510 **PHONE:** 1.888.765.4747 8:30 AM to 8 PM ET Monday-Friday **EMAIL:** OneSource@Alexion.com

ULTOMIRIS® (ravulizumab-cwvz) SOLIRIS® (eculizumab) ONESOURCE® Personalized Patient Support from Alexion

OneSource™ is a complimentary, personalized patient support program offered by Alexion. It's designed to support patients' specific needs throughout treatment. For more information, visit www.AlexionOneSource.com. Contact OneSource if you have any questions while completing the forms.

INSTRUCTIONS FOR HEALTHCARE PROFESSIONALS:

To enroll your patient in OneSource, please follow these steps:

1. Have your patient complete all required sections and read the Authorization to Share Health Information on the **Patient Services Enrollment Form**
2. Complete all required sections on **PAGE 1**
3. Sign the Prescriber Certification on **PAGE 2**
4. **FAX PAGES 1-2 of the completed form** and **copies of the front and back of the patient's medical insurance and pharmacy coverage cards** to OneSource

Fields in red with asterisks are required.*

STEP 1: PATIENT INFORMATION

PATIENT NAME (FIRST, LAST)*	DATE OF BIRTH (MM/DD/YYYY)*	PATIENT PHONE NUMBER*	PATIENT EMAIL

LEGAL PATIENT REPRESENTATIVE* (THIS SECTION IS REQUIRED IF PATIENT IS A MINOR)

NAME (FIRST, LAST)	PHONE NUMBER	RELATIONSHIP TO PATIENT	EMAIL

STEP 2: CLINICAL DIAGNOSIS

INDICATION (check one)*:

- ☐ PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (PNH) ICD-10: D59.5
- ATYPICAL HEMOLYTIC UREMIC SYNDROME (aHUS) ICD-10:
  - ☐ D59.39 Other hemolytic-uremic syndrome
  - ☐ D59.32 Hereditary hemolytic-uremic syndrome
  - ☐ D59.30 Hemolytic-uremic syndrome, unspecified
  - ☐ D59.31 Infection-associated hemolytic-uremic syndrome, **excluding** Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS)

STEP 3: INSURANCE INFORMATION

You may complete this section **OR** attach copies of patient's medical and pharmacy insurance card(s).

☐ COPIES OF PATIENT'S INSURANCE CARD(S) ATTACHED
☐ PATIENT DOES NOT HAVE INSURANCE

	PRIMARY MEDICAL INSURANCE	SECONDARY MEDICAL INSURANCE	PHARMACY COVERAGE
INSURANCE PROVIDER			
INSURANCE PHONE #			
CARDHOLDER NAME			
CARDHOLDER DATE OF BIRTH			
MEMBER ID			
POLICY #			
GROUP #			
BIN/PCN #			

STEP 4: HEALTHCARE PRESCRIBER INFORMATION

FIRST NAME*	LAST NAME*	
ADDRESS*		PHONE NUMBER*
CITY*	STATE*	ZIP*
PRACTICE NAME	TAX ID #*	NPI #*
OFFICE CONTACT NAME	EMAIL	FAX NUMBER

STEP 5: SITE OF CARE

SELECT OPTION A OR B BELOW:

☐ **A) PLEASE PROVIDE ASSISTANCE LOCATING AN INFUSION SITE.** PLEASE COORDINATE DIRECTLY WITH: ☐ HEALTHCARE PROVIDER ☐ PATIENT

☐ **B) ASSISTANCE IS NOT NEEDED.** PATIENT WILL BE INFUSED AT: ☐ PRESCRIBER'S OFFICE ☐ PATIENT'S HOME ☐ PREFERRED INFUSION SITE (PLEASE SPECIFY BELOW)

SITE OF CARE NAME	NPI #	TAX ID #
ADDRESS		
CITY	STATE	ZIP
OFFICE CONTACT FOR FOLLOW-UP		PHONE NUMBER

Please see Indications & Important Safety Information on page 3 and full Prescribing Information and Medication Guide for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections, also available on www.ULTOMIRIS.com.

Please see Indications & Important Safety Information on page 4 and full Prescribing Information and Medication Guide for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections, also available on www.SOLIRIS.net.

PRESCRIBER FORM – PNH/ATYPICAL-HUS

FAX: 1.800.420.5150 **MAIL:** 100 College Street New Haven, CT 06510 **PHONE:** 1.888.765.4747 8:30 AM to 8 PM ET Monday-Friday **EMAIL:** OneSource@Alexion.com

ULTOMIRIS (ravulizumab-cwvz) SOLIRIS (eculizumab) ONESOURCE Personalized Patient Support from Alexion

Fields in red with asterisks are required.*

PATIENT INFORMATION

PATIENT NAME (FIRST, LAST)* DATE OF BIRTH (MM/DD/YYYY)*

STEP 6: PRESCRIPTION (OPTIONAL) YOU MAY USE THIS SECTION TO PROVIDE A PRESCRIPTION FOR ULTOMIRIS OR SOLIRIS, OR YOU MAY PROVIDE A SEPARATE PRESCRIPTION.

A

☐ PLEASE PROVIDE SUMMARY OF BENEFIT INVESTIGATION FOR ULTOMIRIS AND SOLIRIS PATIENT WEIGHT: _____

☐ Rx **ULTOMIRIS** 100 mg/mL HCPCS CODE: J1303 PER UNIT

LOADING DOSE:

SIG: INFUSE INTRAVENOUSLY _____ mg ON DAY 0. COVERS THE PATIENT FOR THE FIRST 2 WEEKS.

☐ OTHER: _____

QTY OF 300 mg/3 mL VIALS: _____ REFILLS: 0

☐ **NO LOADING DOSE, PATIENT IS ON THERAPY**

MAINTENANCE DOSE:

SIG: INFUSE INTRAVENOUSLY _____ mg EVERY _____ WEEKS. START 2 WEEKS AFTER COMPLETION OF LOADING DOSE.

☐ OTHER: _____

QTY OF 300 mg/3 mL VIALS: _____ REFILLS: _____

QTY OF 1100 mg/11 mL VIALS: _____ REFILLS: _____

☐ Rx **SOLIRIS** 10 mg/mL HCPCS CODE: J1300 PER UNIT

LOADING DOSE:

SIG: INFUSE INTRAVENOUSLY _____ mg WEEKLY FOR THE FIRST 4 WEEKS, FOLLOWED BY _____ mg FOR THE FIFTH WEEK.

☐ OTHER: _____

QTY OF 300 mg/30 mL VIALS: _____ REFILLS: 0

☐ **NO LOADING DOSE, PATIENT IS ON THERAPY**

MAINTENANCE DOSE:

SIG: INFUSE INTRAVENOUSLY _____ mg EVERY 2 WEEKS. START 2 WEEKS AFTER THE 5TH WEEK'S DOSE IS COMPLETE.

☐ OTHER: _____

QTY OF 300 mg/30 mL VIALS: _____ REFILLS: _____

B

☐ I WOULD LIKE TO TRANSITION MY PATIENT FROM SOLIRIS TO ULTOMIRIS ANTICIPATED ULTOMIRIS START DATE: _____

☐ PLEASE PROVIDE SUMMARY OF BENEFIT INVESTIGATION FOR ULTOMIRIS PATIENT WEIGHT: _____

☐ **ULTOMIRIS** 100 mg/mL HCPCS CODE: J1303 PER UNIT

☐ **LOADING DOSE:**

SIG: INFUSE INTRAVENOUSLY _____ mg ON DAY 0. COVERS THE PATIENT FOR THE FIRST 2 WEEKS.

☐ OTHER: _____

QTY OF 300 mg/3 mL VIALS: _____ REFILLS: 0

☐ **NO LOADING DOSE, PATIENT IS ON THERAPY**

MAINTENANCE DOSE:

SIG: INFUSE INTRAVENOUSLY _____ mg EVERY _____ WEEKS. START 2 WEEKS AFTER COMPLETION OF LOADING DOSE.

☐ OTHER: _____

QTY OF 300 mg/3 mL VIALS: _____ REFILLS: _____

QTY OF 1100 mg/11 mL VIALS: _____ REFILLS: _____

HAS YOUR PATIENT RECEIVED ANY DOSES OF A MENINGOCOCCAL VACCINE OR ANTIBIOTIC PROPHYLAXIS? IF SO, PLEASE PROVIDE RELEVANT INFORMATION.

*See ACIP recommendations below.**

Alexion complement-inhibitor therapies are available only through a restrictive program under a Risk Evaluation and Mitigation Strategy (REMS). Vaccination dates provided as part of this form are used to confirm vaccination prior to starting treatment.

YES

Antibiotic prophylaxis administered? ☐ Yes ☐ No If yes, start date: ___ / ___ / ___

Patient has received or is scheduled to receive the required vaccinations per ACIP guidelines. Please complete the following information:

MenACWY	MenB	MenABCWY
1st Dose Date: ___ / ___ / ___ ☐ Menveo ☐ Menactra ☐ MenQuadfi	1st Dose Date: ___ / ___ / ___ ☐ Bexsero ☐ Trumenba	1st Dose Date: ___ / ___ / ___ ☐ Penbraya
2nd Dose Date: ___ / ___ / ___ ☐ Menveo ☐ Menactra ☐ MenQuadfi	2nd Dose Date: ___ / ___ / ___ ☐ Bexsero ☐ Trumenba	2nd Dose Date: ___ / ___ / ___ ☐ Penbraya
✓ **Sign prescriber certification below**	3rd Dose Date: ___ / ___ / ___ *(3rd dose - Trumenba ONLY)*	

NO

☐ Patient needs **VACCINATION SUPPORT** from OneSource

✓ **Sign prescriber certification below**

*The current ACIP guidelines recommend a regimen of MenACWY AND MenB doses prior to starting a complement inhibitor treatment.

STEP 7: PRESCRIBER CERTIFICATION

By signing below, I attest that: (i) I am prescribing ULTOMIRIS or SOLIRIS for the patient identified above based on my clinical judgment that it is medically necessary for the diagnosis identified on this form and I will be supervising the patient's treatment; (ii) I am authorized under applicable law to prescribe ULTOMIRIS or SOLIRIS and I have verified and complied with all applicable prescription requirements; (iii) I am authorizing Alexion to forward the patient's prescription to a pharmacy by any means under applicable law; and (iv) the information provided on this form is complete, current, and accurate to the best of my knowledge. I also acknowledge that Alexion will use and share the personal data collected about me (as the prescriber) in accordance with the Privacy Notice on the Alexion website at https://alexion.com/Legal#privacy.

SIGN ONE*

PRESCRIBER'S SIGNATURE (NO STAMPS) - **DISPENSE AS WRITTEN** DATE (MM/DD/YYYY)

PRESCRIBER'S SIGNATURE (NO STAMPS) - **MAY SUBSTITUTE** DATE (MM/DD/YYYY)

Please verify your local prescribing requirements (eg, New York prescribers must provide a separate prescription).

Please see Indications & Important Safety Information on page 3 and full Prescribing Information and Medication Guide for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections, also available on www.ULTOMIRIS.com.

Please see Indications & Important Safety Information on page 4 and full Prescribing Information and Medication Guide for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections, also available on www.SOLIRIS.net.

IMPORTANT SAFETY INFORMATION AND INDICATIONS, INCLUDING BOXED WARNING FOR ULTOMIRIS

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS

ULTOMIRIS, 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 ULTOMIRIS, unless the risks of delaying ULTOMIRIS 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 ULTOMIRIS 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, ULTOMIRIS 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)*].

CONTRAINDICATIONS

- Initiation in patients with unresolved serious *Neisseria meningitidis* infection.

WARNINGS AND PRECAUTIONS

Serious Meningococcal Infections

ULTOMIRIS, 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 ULTOMIRIS therapy. 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 ULTOMIRIS therapy is indicated in a patient who is not up to date with meningococcal vaccines according to ACIP recommendations, provide 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 ULTOMIRIS. The benefits and risks of treatment with ULTOMIRIS, 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 they occur. Promptly treat known infections. Meningococcal infection may become rapidly life-threatening or fatal if not recognized and treated early. Consider interruption of ULTOMIRIS 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, ULTOMIRIS 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 the 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 ULTOMIRIS. 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 ULTOMIRIS. Patients must receive counseling about the need to receive meningococcal vaccines and to take antibiotics as directed, signs and symptoms of meningococcal infection, and be instructed to carry the Patient Safety Card at all times during and for 8 months following ULTOMIRIS 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.

ULTOMIRIS blocks terminal complement activation; therefore, patients may have increased susceptibility to infections, especially with encapsulated bacteria, such as infections caused by *Neisseria meningitidis* but also *Streptococcus pneumoniae, Haemophilus influenzae,* and to a lesser extent, *Neisseria gonorrhoeae*. Children treated with ULTOMIRIS 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 ULTOMIRIS are at increased risk for infections due to these organisms, even if they develop antibodies following vaccination.

Monitoring Disease Manifestations after ULTOMIRIS Discontinuation

Treatment Discontinuation for PNH

After discontinuing treatment with ULTOMIRIS, closely monitor for signs and symptoms of hemolysis, identified by elevated LDH along with sudden decrease in PNH clone size or hemoglobin, or re-appearance of symptoms such as fatigue, hemoglobinuria, abdominal pain, shortness of breath (dyspnea), major adverse vascular event (including thrombosis), dysphagia, or erectile dysfunction. Monitor any patient who discontinues ULTOMIRIS for at least 16 weeks to detect hemolysis and other reactions. If signs and symptoms of hemolysis occur after discontinuation, including elevated LDH, consider restarting treatment with ULTOMIRIS.

Treatment Discontinuation for aHUS

ULTOMIRIS treatment of aHUS should be a minimum duration of 6 months. Due to heterogeneous nature of aHUS events and patient-specific risk factors, treatment duration beyond the initial 6 months should be individualized. There are no specific data on ULTOMIRIS discontinuation. After discontinuing treatment with ULTOMIRIS, patients should be monitored for clinical symptoms and laboratory signs of TMA complications for at least 12 months. TMA complications post-discontinuation can be identified if any of the following is observed: Clinical symptoms of TMA include changes in mental status, seizures, angina, dyspnea, thrombosis or increasing blood pressure. In addition, at least two of the following laboratory signs observed concurrently and results should be confirmed by a second measurement 28 days apart with no interruption: a decrease in platelet count of 25% or more as compared to either baseline or to peak platelet count during ULTOMIRIS treatment; an increase in serum creatinine of 25% or more as compared to baseline or to nadir during ULTOMIRIS treatment; or, an increase in serum LDH of 25% or more as compared to baseline or to nadir during ULTOMIRIS treatment. If TMA complications occur after discontinuation, consider reinitiation of ULTOMIRIS treatment or appropriate organ-specific supportive measures.

Thromboembolic Event Management

The effect of withdrawal of anticoagulant therapy during treatment with ULTOMIRIS has not been established. Treatment should not alter anticoagulant management.

Infusion-Related Reactions

Intravenous administration may result in systemic infusion-related reactions, including anaphylaxis and hypersensitivity reactions. In clinical trials, infusion-related reactions occurred in approximately 1 to 7% of patients treated with ULTOMIRIS. These events included lower back pain, drop in blood pressure, limb discomfort, drug hypersensitivity (allergic reaction), dysgeusia (bad taste), and drowsiness. These reactions did not require discontinuation of ULTOMIRIS. If signs of cardiovascular instability or respiratory compromise occur, interrupt ULTOMIRIS infusion and institute appropriate supportive measures.

ADVERSE REACTIONS

Adverse Reactions for PNH

Adverse reactions reported in ≥10% or more of patients with PNH were upper respiratory tract infection and headache. Serious adverse reactions were reported in 15 (6.8%) patients receiving ULTOMIRIS. The serious adverse reactions in patients treated with ULTOMIRIS included hyperthermia and pyrexia. No serious adverse reaction was reported in more than 1 patient treated with ULTOMIRIS. One fatal case of sepsis was identified in a patient treated with ULTOMIRIS. In clinical studies, clinically relevant adverse reactions in 1% of adult patients include infusion-related reactions.

Adverse reactions reported in ≥10% of pediatric patients treated with ULTOMIRIS who were treatment-naïve vs. Eculizumab-experienced were anemia (20% vs. 25%), abdominal pain (0% vs. 38%), constipation (0% vs. 25%), pyrexia (20% vs. 13%), upper respiratory tract infection (20% vs. 75%), pain in extremity (0% vs. 25%), and headache (20% vs. 25%).

Adverse Reactions for aHUS

Most common adverse reactions in patients with aHUS (incidence ≥20%) were upper respiratory tract infection, diarrhea, nausea, vomiting, headache, hypertension and pyrexia. Serious adverse reactions were reported in 42 (57%) patients with aHUS receiving ULTOMIRIS. The most frequent serious adverse reactions reported in more than 2 patients (2.7%) treated with ULTOMIRIS were hypertension, pneumonia and abdominal pain.

Adverse reactions reported in ≥20% of pediatric patients treated with ULTOMIRIS were diarrhea, constipation, vomiting, pyrexia, upper respiratory tract infection, decreased vitamin D, headache, cough, rash, and hypertension.

DRUG INTERACTIONS

Plasma Exchange, Plasmapheresis, and Intravenous Immunoglobulins

Concomitant use of ULTOMIRIS with plasma exchange (PE), plasmapheresis (PP), or intravenous immunoglobulin (IVIg) treatment can reduce serum ravulizumab concentrations and requires a supplemental dose of ULTOMIRIS.

Neonatal Fc Receptor Blockers

Concomitant use of ULTOMIRIS with neonatal Fc receptor (FcRn) blockers (e.g., efgartigimod) may lower systemic exposures and reduce effectiveness of ULTOMIRIS. Closely monitor for reduced effectiveness of ULTOMIRIS.

INDICATIONS

Paroxysmal Nocturnal Hemoglobinuria (PNH)

ULTOMIRIS is indicated for the treatment of adult and pediatric patients one month of age and older with paroxysmal nocturnal hemoglobinuria (PNH).

Atypical Hemolytic Uremic Syndrome (aHUS)

ULTOMIRIS is indicated for the treatment of adult and pediatric patients one month of age and older with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy (TMA).

Limitation of Use:

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

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 the full Prescribing Information and Medication Guide for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections, also available on www.ULTOMIRIS.com.

ALEXION AstraZeneca Rare Disease

IMPORTANT SAFETY INFORMATION AND INDICATIONS, INCLUDING BOXED WARNING FOR SOLIRIS

IMPORTANT SAFTEY 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)*].

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.

Monitoring Disease Manifestations After SOLIRIS Discontinuation

Treatment Discontinuation for PNH

Monitor patients after discontinuing SOLIRIS for at least 8 weeks to detect hemolysis.

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

Adverse Reactions for PNH

The most frequently reported adverse reactions in the PNH randomized trial (≥10% overall and greater than placebo) were: headache, nasopharyngitis, back pain, and nausea.

Adverse Reactions for aHUS

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.

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.

INDICATIONS

Paroxysmal Nocturnal Hemoglobinuria (PNH)

SOLIRIS is indicated for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis.

Atypical Hemolytic Uremic Syndrome (aHUS)

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).

Please see the full Prescribing Information and Medication Guide for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections, also available on www.SOLIRIS.net.

This material is intended only for residents of the United States.

ALEXION® AstraZeneca Rare Disease

PATIENT SERVICES ENROLLMENT FORM

EMAIL: OneSource@Alexion.com
PHONE: 1.888.765.4747 8:30 AM to 8 PM ET Monday–Friday
FAX: 1.800.420.5150
MAIL: 100 College St., New Haven, CT 06510

ONESOURCE®
Personalized Patient Support from Alexion

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INSTRUCTIONS FOR PATIENTS:

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1. Complete all the required information (in red) on **this page** and read the Authorization to Share Health Information on **the next page**
2. Sign the Authorization to Share Health Information section on **this page**
3. Email or fax **this page** and **copies of the front and back of your medical insurance and pharmacy coverage cards** to OneSource (see the email address and fax number above)

Be sure to complete all required fields and sign and date the form. If information is incomplete, it could delay our ability to enroll you in OneSource. OneSource can start offering you personalized support once you submit this form fully and correctly completed.

Fields in red with asterisks are required.* **Contact OneSource if you have any questions while completing the form.**

PATIENT INFORMATION

PATIENT NAME (FIRST, MIDDLE INITIAL, LAST)*	DATE OF BIRTH (MM/DD/YYYY)*	GENDER: ☐ MALE ☐ FEMALE ☐ NON-BINARY PREFER TO SELF-DESCRIBE:
ADDRESS*		
CITY*	STATE*	ZIP*
PRIMARY PHONE NUMBER* ☐ MOBILE ☐ HOME	OK TO SEND A TEXT MESSAGE? ☐ YES ☐ NO OK TO LEAVE A PHONE MESSAGE? ☐ YES ☐ NO	
PATIENT DIAGNOSIS		
PREFERRED LANGUAGE ☐ ENGLISH ☐ SPANISH ☐ OTHER _____	PATIENT EMAIL ☐ NONE	

LEGAL PATIENT REPRESENTATIVE* (REQUIRED IF A PATIENT IS A MINOR)	RELATIONSHIP TO PATIENT	EMAIL
NAME: PHONE:		
DESIGNATED CARE PARTNER	RELATIONSHIP TO PATIENT	EMAIL
NAME: PHONE:		

PRESCRIBING PHYSICIAN'S INFORMATION

PROVIDER NAME	PROVIDER PHONE NUMBER	PROVIDER EMAIL

AUTHORIZATION TO SHARE HEALTH INFORMATION

By signing below, I acknowledge that I have read and agree to the Authorization to Share Health Information terms on the next page.

SIGN HERE*

SIGNATURE OF PATIENT OR LEGALLY AUTHORIZED REPRESENTATIVE — DATE (MM/DD/YYYY)

CONSENT FOR COPAY PROGRAM (OPTIONAL)

By signing below, I acknowledge that I have read and agree to the Alexion OneSource CoPay Program terms and conditions available at https://alexiononesource.com/CoPay or on request by contacting OneSource at 1.888.765.4747.

SIGNATURE OF PATIENT OR LEGALLY AUTHORIZED REPRESENTATIVE — DATE (MM/DD/YYYY)

CONSENT FOR AUTOMATED TEXT COMMUNICATIONS (OPTIONAL)

By signing below, I give Alexion and companies working at Alexion's direction permission to use automated text (SMS) messages to provide patient support services and to provide information to me about Alexion products, services, programs, or other topics that Alexion thinks may interest me. I understand that (i) I am not required to consent to receiving text messages as a condition of any purchase of Alexion products or enrollment in these programs; (ii) my telecommunication services provider may charge me for any text messages that I receive from Alexion; and (iii) I may opt out of receiving automated text messages from Alexion at any time without affecting my enrollment in these programs.

SIGNATURE OF PATIENT OR LEGALLY AUTHORIZED REPRESENTATIVE — DATE (MM/DD/YYYY)

AUTHORIZATION TO SHARE HEALTH INFORMATION

Alexion Pharmaceuticals, Inc. ("Alexion") offers patient services including educational resources, case management support, and financial assistance for eligible patients.

By signing the prior page, I give permission for my healthcare providers, health plans, other insurance programs, pharmacies, and other healthcare service providers ("My Healthcare Entities") to share information, including protected health information relating to my medical condition, treatment, and health insurance coverage (collectively "My Information") with Alexion and companies working at its direction so that Alexion may use and disclose My Information to:

- review my insurance coverage and eligibility for benefits for treatment with an Alexion product;
- coordinate treatment with an Alexion product, as well as related services, such as arranging home infusion services or vaccination services;
- provide me with educational and promotional materials, contact me about market research or clinical studies, or otherwise contact me about Alexion products, services, programs, or other topics that Alexion thinks may interest me;
- remove identifiers from My Information and combine such resulting information with other information for research, regulatory submissions, business improvement projects, and publication purposes; and
- (as applicable to my Alexion product) review my vaccination and prophylaxis history and provide corresponding patient support, such as sending reminders about potential upcoming vaccinations.

I understand that My Healthcare Entities may receive payment from Alexion in exchange for sharing My Information.

I understand that My Information is also subject to the Alexion Privacy Notice available at https://alexion.com/Legal#privacy, and that the Alexion Privacy Notice provides additional information about Alexion's privacy practices and the rights that may be available to me. Although Alexion has implemented privacy and security controls designed to help protect My Information, I understand that once My Information has been disclosed to Alexion, the Health Insurance Portability and Affordability Act ("HIPAA") may not apply and My Information may be subject to redisclosure.

I understand that I may refuse to sign this Authorization and that My Healthcare Entities may not condition treatment, payment, enrollment, or eligibility for benefits on whether I sign this Authorization. I also understand that if I do not sign this Authorization, I will not be able to receive support through the Alexion OneSource™ Patient Support Program.

This Authorization expires ten (10) years from the date next to my signature, unless I cancel/revoke it sooner, or unless a shorter time frame is required by applicable law.

I understand that I may revoke my authorization, or unsubscribe or modify the services I receive, at any time by mailing a letter to Alexion OneSource Patient Support Program, 100 College Street, New Haven, CT 06510 or by emailing OneSource@Alexion.com. I also understand that modifying my authorization will not affect any use or disclosure of My Information that occurred before Alexion received notice of my cancellation. I also understand I have a right to receive a copy of this Authorization after it is signed and can request a copy at any time by contacting OneSource at 1.888.765.4747.

OneSource Services

Alexion services and support are subject to change. Participation is voluntary, and person(s) may be removed from Alexion services for code of conduct violations.

This material is intended only for residents of the United States.