PRESCRIBER START FORM - NEUROLOGY

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) Injection for Intravenous Use 300 mg/3 mL vial
SOLIRIS® (eculizumab) Injection for Intravenous Use 300 mg/30 mL vial
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. If applicable, **fax the Vaccination Order Form (PAGE 3)** to OneSource as well.

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

STEP 2: CLINICAL DIAGNOSIS

SOLIRIS and ULTOMIRIS are FDA approved for antibody-positive status. If a payer requires prior authorization and/or has a clinical policy, they may require proof of antibody status.

INDICATION (check one)*:
- ☐ ICD-10: G70.00 Myasthenia gravis without (acute) exacerbation
- ☐ ICD-10: G70.01 Myasthenia gravis with (acute) exacerbation
- ☐ ICD-10: G36.00 Neuromyelitis optica [Devic] (NMOSD)

ANTIBODY STATUS (check one)*:
- ☐ ANTI-AChR ANTIBODY POSITIVE (gMG)
- ☐ ANTI-AQP4 ANTIBODY POSITIVE (NMOSD)
- ☐ UNKNOWN (CONTACT ONESOURCE FOR QUESTIONS)

STEP 3: INSURANCE INFORMATION

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

☐ PLEASE PROVIDE SUMMARY OF BENEFIT INVESTIGATION FOR ULTOMIRIS AND SOLIRIS

☐ 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*	PROVIDER EMAIL*
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 4 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 5 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 START FORM - NEUROLOGY

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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: CLINICAL INFORMATION

CHECK ALL PREVIOUS GENERALIZED MYASTHENIA GRAVIS (gMG) THERAPIES:

- ☐ AZATHIOPRINE
- ☐ EFGARTIGIMOD
- ☐ IVIg
- ☐ MYCOPHENOLATE MOFETIL
- ☐ PLASMAPHERESIS
- ☐ PREDNISONE
- ☐ PYRIDOSTIGMINE
- ☐ RITUXIMAB
- ☐ OTHER

MGFA CLASSIFICATION: _____

CURRENT MG-ADL SCORE: _____

CHECK ALL PREVIOUS NEUROMYELITIS OPTICA SPECTRUM DISORDER (NMOSD) THERAPIES:

- ☐ AZATHIOPRINE
- ☐ CYCLOPHOSPHAMIDE
- ☐ INEBILIZUMAB
- ☐ METHOTREXATE
- ☐ MITOXANTRONE
- ☐ MYCOPHENOLATE MOFETIL
- ☐ RITUXIMAB
- ☐ SATRALIZUMAB
- ☐ STEROID
- ☐ OTHER

NUMBER OF RELAPSES IN LAST 12 MONTHS: _____ 24 MONTHS: _____

EDSS SCORE: _____

Abbreviations: AChR, acetylcholine receptor; EDSS, Expanded Disability Status Scale; IVIg, intravenous immunoglobulin; MG-ADL, Myasthenia Gravis Activities of Daily Living; MGFA, Myasthenia Gravis Foundation of America.

STEP 7: PRESCRIPTION

YOU MAY USE THIS SECTION TO PROVIDE A PRESCRIPTION FOR ULTOMIRIS OR SOLIRIS, OR YOU MAY PROVIDE A SEPARATE PRESCRIPTION.

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

PATIENT WEIGHT: _____

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

MAINTENANCE DOSE:

SIG: INFUSE INTRAVENOUSLY _____ mg EVERY 8 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 5TH WEEK.

☐ OTHER: _____

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

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: _____

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**

✓ Continue to **PAGE 3** to fill out a **vaccination prescription**†

*The current ACIP guidelines recommend a regimen of MenACWY AND MenB doses prior to starting a complement inhibitor treatment.
†You may also provide a separate prescription.

STEP 8: 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; (iv) I am under no obligation to prescribe ULTOMIRIS or SOLIRIS and I have not received, nor will I receive, any benefit from Alexion for prescribing ULTOMIRIS or SOLIRIS; and (v) 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 4 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 5 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.

US/ULT-g/0099 V3 03/2024

VACCINATION ORDER FORM

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PATIENT INFORMATION

PATIENT NAME (FIRST, MIDDLE INITIAL, LAST)		PATIENT DATE OF BIRTH (MM/DD/YYYY)	
ADDRESS	CITY	STATE	ZIP
PHONE NUMBER		HEIGHT	WEIGHT

HEALTHCARE PRESCRIBER INFORMATION

FIRST NAME	LAST NAME	PHONE NUMBER	FAX NUMBER
ADDRESS	CITY	STATE	ZIP
OFFICE CONTACT NAME		NPI	

CLINICAL INFORMATION

Primary Diagnosis Description: Encounter for Immunization **ICD-10 CODE:** Z23

MENINGOCOCCAL VACCINATIONS ARE INDICATED FOR PATIENTS, INCLUDING PEOPLE OVER 25 YEARS OF AGE, WHEN ON A COMPLEMENT INHIBITOR TREATMENT.

The Advisory Committee on Immunization Practices (ACIP) recommends a regimen of MenACWY AND MenB doses prior to starting a complement inhibitor treatment. Vaccines should be initiated at least 2 weeks prior to first dose of Alexion Complement Inhibitor. There are two (2) types of meningococcal vaccines available in the United States.

MenACWY — ONE (1) REQUIRED FROM EACH GROUP — MenB

MenB VACCINES ARE NOT INTERCHANGEABLE. PATIENT MUST RECEIVE THE SAME PRODUCT FOR ALL DOSES DURING A VACCINATION SERIES. FOR THE FULL VACCINE SCHEDULE, INCLUDING THE VACCINATION SCHEDULE FOR CHILDREN ≤10 YEARS OLD, PLEASE REFER TO THE ACIP VACCINE RECOMMENDATIONS OR TO ALEXION MEDICAL INFORMATION.

Two quadrivalent meningococcal conjugate (MenACWY) vaccines are currently licensed and available in the United States.

INDICATE VACCINE THE PATIENT NEEDS TO RECEIVE:

- ☐ **MenQuadfi** (meningococcal groups A, C, W, and Y polysaccharide tetanus toxoid conjugate vaccine [MenACWY-TT]) 90619
- ☐ **Menveo** (meningococcal groups A, C, W, and Y oligosaccharide diphtheria CRM conjugate vaccine [MenACWY-CRM]) 907340

Two serogroup B meningococcal (MenB) vaccines are currently licensed and available in the United States.

INDICATE VACCINE THE PATIENT NEEDS TO RECEIVE:

- ☐ **Bexsero** (MenB-4C) 90620
- ☐ **Trumenba** (MenB-FHbp) 90621

MenACWY — DOSING SCHEDULE — MenB

- ☐ **Dose 1:** Day 0
- ☐ **Dose 2:** At least 8 weeks after Day 0
- ☐ **Booster dose**

- ☐ **Dose 1:** Day 0
- ☐ **Dose 2:** For Bexsero: At least (or greater than or equal to) 1 month after Day 0
  For Trumenba: 1-2 months after Day 0
- ☐ **Dose 3** (*Trumenba only*): 6 months after Day 0
- ☐ **Booster dose**

Per CDC recommendations, those who remain at increased risk need regular booster doses. MenACWY: For children under the age of 7 years, administer a booster dose 3 years after completion of the primary series and every 5 years thereafter. For children 7 years old or older and adults, administer a booster dose 5 years after completion of the primary series and every 5 years thereafter. MenB: Administer a booster dose of vaccine 1 year after series completion and then every 2 to 3 years thereafter.

NOTE: ALL VACCINES LISTED ABOVE ARE ADMINISTERED INTRAMUSCULARLY AT A DOSE OF 0.5 mL

ANCILLARY ORDERS (HOME ADMINISTRATION ONLY – USE AS NEEDED)

Anaphylaxis Kit - The following items will be dispensed:

- ☑ Diphenhydramine 50 mg/mL 1 mL vial x 1. Inject 25 mg IM PRN for allergic reaction. May repeat x 1 dose in 15 min PRN if no improvement
- ☑ NS 500 mL bag x 1. Infuse 500 mL IV at KVO rate PRN anaphylaxis
- ☑ Epinephrine ampule/vial 1 mg/mL (1:1000) 1 mL x 2 ampules/vials. Inject 0.3 mg SQ PRN for adverse reaction. May repeat x 1 dose in 5 to 15 min PRN

General Anaphylaxis Instructions

Administer emergency medications as ordered. Administer epinephrine as above and repeat dose if necessary. Administer injectable diphenhydramine as above and repeat dose if necessary. Place peripheral IV and administer NS. Initiate CPR if needed. Call EMS (activate the emergency medical system). Monitor vital signs—elevate legs if hypotensive. Notify prescriber and Nursing Director or pharmacist.

PRESCRIBER CERTIFICATION

By signing below, I attest that: (i) based on my clinical judgment, the vaccines identified are medically necessary for the patient and diagnosis identified on this form; (ii) I am authorized under applicable law to prescribe the vaccines identified 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; (iv) I am under no obligation to prescribe the vaccines identified and I have not received, nor will I receive, any benefit from Alexion; and (v) the information provided on this form is complete, current, and accurate to the best of my knowledge.

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

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

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

INDICATIONS & IMPORTANT SAFETY INFORMATION FOR ULTOMIRIS

INDICATIONS

Generalized Myasthenia Gravis (gMG)
ULTOMIRIS is indicated for the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody-positive.

Neuromyelitis Optica Spectrum Disorder
ULTOMIRIS is indicated for the treatment of adult patients with neuromyelitis optica spectrum disorder (NMOSD) who are anti-aquaporin 4 (AQP4) antibody-positive.

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
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*. Patients receiving ULTOMIRIS are at increased risk for infections due to these organisms, even if they develop antibodies following vaccination.

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 gMG
Most common adverse reactions in adult patients with gMG (incidence ≥10%) were diarrhea and upper respiratory tract infection. Serious adverse reactions were reported in 20 (23%) of patients treated with ULTOMIRIS and in 14 (16%) patients receiving placebo. The most frequent serious adverse reactions were infections reported in at least 8 (9%) patients treated with ULTOMIRIS and in 4 (4%) patients treated with placebo. Of these infections, one fatal case of COVID-19 pneumonia was identified in a patient treated with ULTOMIRIS and one case of infection led to discontinuation of ULTOMIRIS.

Adverse Reactions for NMOSD
Most common adverse reactions in adult patients with NMOSD (incidence >10%) were COVID-19, headache, back pain, arthralgia, and urinary tract infection. Serious adverse reactions were reported in 8 (13.8%) patients with NMOSD receiving ULTOMIRIS.

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.

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 accompanying full Prescribing Information for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

INDICATIONS & IMPORTANT SAFETY INFORMATION FOR SOLIRIS® (eculizumab)

INDICATIONS

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.

Neuromyelitis Optica Spectrum Disorder (NMOSD)
SOLIRIS is indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

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*)].

CONTRAINDICATIONS

- SOLIRIS is contraindicated for initiation in patients with unresolved serious *Neisseria meningitidis* infection.

WARNINGS AND PRECAUTIONS

Serious Meningococcal Infections
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 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. Patients receiving SOLIRIS are at increased risk for infections due to these organisms, even if they develop antibodies following vaccination.

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 gMG
The most frequently reported adverse reaction in the gMG placebo-controlled clinical trial (≥10%) was: musculoskeletal pain.

Adverse Reactions for NMOSD
The most frequently reported adverse reactions in the NMOSD placebo-controlled trial (≥10%) were: upper respiratory infection, nasopharyngitis, diarrhea, back pain, dizziness, influenza, arthralgia, pharyngitis, and contusion.

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 accompanying full Prescribing Information for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

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

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

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INSTRUCTIONS FOR PATIENTS:

To enroll in OneSource, please follow these steps:

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.