Inpatient Support Program Prescriber and Pharmacy Form

ONESOURCE® Personalized Patient Support from Alexion | ULTOMIRIS® (ravulizumab-cwvz) injection for intravenous use 300 mg/3 mL vial

THIS SECTION IS FOR ALEXION USE ONLY: CPEP OR P-ID_____ OneSource™ Support Specialist _____

INSTRUCTIONS:
- ✓ Please complete this form.
- ✓ Fax the completed form to OneSource at **1.800.420.5150** or email it to **OneSource@Alexion.com**.
- ✓ For more information on the Alexion Inpatient Support Program, contact OneSource at **1.888.765.4747**.

Fields in red with asterisks are required.*

PATIENT INFORMATION

CLINICAL DIAGNOSIS* ☐ NEUROMYELITIS OPTICA SPECTRUM DISORDER (NMOSD) ICD-10: G36.00

PATIENT NAME (FIRST, LAST)*	PATIENT DATE OF BIRTH (MM/DD/YYYY)*	PATIENT GENDER* ☐ MALE ☐ FEMALE ☐ UNKNOWN

ADDRESS	CITY	STATE	ZIP

PATIENT PHONE NUMBER	PATIENT EMAIL

LEGAL PATIENT REPRESENTATIVE NAME	LEGAL PATIENT REPRESENTATIVE PHONE NUMBER	LEGAL PATIENT REPRESENTATIVE EMAIL

PATIENT INSURANCE INFORMATION

ATTACH COPIES OF MEDICAL AND PHARMACY INSURANCE CARDS OR COMPLETE BELOW

PRIMARY INSURANCE NAME	POLICYHOLDER NAME	POLICY ID #	GROUP #

SECONDARY INSURANCE NAME	POLICYHOLDER NAME	POLICY ID #	GROUP #

PHARMACY COVERAGE NAME	POLICYHOLDER NAME	POLICY ID #	GROUP #

PHARMACY COVERAGE BIN #	PHARMACY COVERAGE PCN #

PRIOR AUTHORIZATION DATE (MM/DD/YYYY)	PRIOR AUTHORIZATION STATUS

HEALTHCARE PROVIDER INFORMATION

NAME (FIRST, LAST)*	EMAIL*

ADDRESS*	CITY*	STATE*	ZIP*

PHONE*	FAX*	NPI #*	TAX ID #

SITE OF CARE INFORMATION

NAME*	EMAIL*

ADDRESS*	CITY*	STATE*	ZIP*

PHONE*	FAX*	NPI #*	TAX ID #

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

ALEXION® AstraZeneca Rare Disease

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Fields in red with asterisks are required.*

PATIENT INFORMATION

PATIENT NAME (FIRST, LAST)*

PATIENT DATE OF BIRTH (MM/DD/YYYY)*

INPATIENT SUPPORT PROGRAM PRESCRIPTION

THERAPY	DIRECTIONS FOR ADMINISTRATION	QUANTITY	REFILLS
☐ 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: _____	☐ 300 mg/3 mL VIALS: *NDC 25682-0025-01*	REFILLS: 0
	MAINTENANCE DOSE: SIG: INFUSE INTRAVENOUSLY _____ mg EVERY 8 WEEKS. START 2 WEEKS AFTER THE LOADING DOSE IS COMPLETE. OTHER: _____	☐ 300 mg/3 mL VIALS: *NDC 25682-0025-01*	REFILLS: *(up to 2)*
		☐ 1100 mg/11 mL VIALS: *NDC 25682-0028-01*	REFILLS: *(up to 2)*

PATIENT VACCINATION INFORMATION

Has the patient received **meningococcal vaccination** or **antibiotic prophylaxis** consistent with the Advisory Committee on Immunization Practices (ACIP) recommendations? ☐ YES ☐ NO

NOTE: This product is only available only through a restricted program called the ULTOMIRIS and SOLIRIS REMS (Risk Evaluation and Mitigation Strategy) because of the risk of serious meningococcal infections. Further information is available at www.UltSolREMS.com or 1-888-765-4747.

INPATIENT SUPPORT PROGRAM (ISP) TERMS AND CONDITIONS

Among other requirements, patients must have commercial insurance and not be beneficiaries or recipients of any federal, state, or government-funded healthcare program. Users may not seek or obtain coverage or reimbursement for the free Product provided through the Program, directly or indirectly, from any other party, including from the patient, third-party payer, or any government healthcare program. Alexion product provided through ISP shall only be used for the prescribed patient and must not be resold, offered for sale or trade, or returned for credit. To qualify for the Program, patients must have commercial insurance (not part of a federal- or state-funded healthcare program). Patients must contact OneSource if their insurance situation changes or they are no longer prescribed an Alexion product. For more complete information about ISP eligibility and other terms & conditions, see www.AlexionOneSource.com/ISP.

CERTIFICATION

PRESCRIBER CERTIFICATION

By signing below, I attest that: (i) I am prescribing the above product 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 under no obligation to prescribe the above product and I have not received, nor will I receive, any benefit from Alexion for prescribing the product; (iii) the information provided on this form is complete, current, and accurate to the best of my knowledge; and (iv) I have read and agree to the Inpatient Support Program Terms and Conditions available at AlexionOneSource.com/ISP. 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 HERE

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

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

PHARMACY CERTIFICATION

By signing below, I attest that I have read and agree to the Inpatient Support Program Terms and Conditions available at AlexionOneSource.com/ISP.

SIGN HERE

PHARMACIST SIGNATURE (NO STAMPS)* DATE (MM/DD/YYYY)*

PHARMACIST FIRST & LAST NAME (PLEASE PRINT)*

INDICATION & IMPORTANT SAFETY INFORMATION

INDICATION

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

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*. 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

Administration of ULTOMIRIS 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, including lower back pain, abdominal pain, muscle spasms, drop or elevation in blood pressure, rigors, limb discomfort, drug hypersensitivity (allergic reaction), and dysgeusia (bad taste). These reactions did not require discontinuation of ULTOMIRIS. If signs of cardiovascular instability or respiratory compromise occur, interrupt ULTOMIRIS and institute appropriate supportive measures.

ADVERSE REACTIONS

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.

USE IN SPECIFIC POPULATIONS

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to ULTOMIRIS during pregnancy. Healthcare providers and patients may call 1-833-793-0563 or go to www.UltomirisPregnancyStudy.com to enroll in or to obtain information about the registry.

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 ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

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