Inpatient Support Program Prescriber and Pharmacy Form

for atypical hemolytic uremic syndrome (aHUS)

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

PLEASE READ THE TERMS & CONDITIONS BELOW AND COMPLETE THE FORM STARTING ON PAGE 2

Alexion OneSource™ Inpatient Support Program Terms & Conditions

The Alexion OneSource Inpatient Support for aHUS Program ("Program") is a voluntary support program offered by Alexion Pharmaceuticals, Inc. ("Alexion") to help patients who have a physician-determined urgent medical need to initiate ULTOMIRIS® (ravulizumab-cwvz) ("Product") in an inpatient setting. The Program provides up to three dispenses of the Product free of charge to eligible patients. The Program does not assist with any infusion-related costs. All patients, healthcare providers, healthcare settings, and dispensers who participate in the Program (collectively, "Users") must accept and abide by these terms and conditions (the "Terms").

Eligibility: Patients are eligible for the Program if they meet ALL the following criteria:

- Are enrolled in OneSource, a personalized patient support program offered by Alexion
    - In the event the patient/caregiver/healthcare proxy is unable to sign the OneSource patient consent form at the time of Program enrollment, Alexion reserves the right to authorize the dispensing of one dose of ULTOMIRIS under circumstances of medical urgency at the request of the physician. This is contingent upon the understanding that the patient/caregiver/healthcare proxy will sign the OneSource patient consent for enrollment into OneSource within five (5) business days of dispensing product. No further medication will be dispensed without a signed patient consent form.
        - If a patient/caregiver/healthcare proxy declines to sign a patient consent, no further Product will be dispensed under the Program and the patient will be discharged from the Program.
- Reside and receive treatment in the United States or its territories
- Have a prescription/medication order for the Product with atypical hemolytic uremic syndrome (aHUS)
- Have a medically urgent need to initiate Product in an inpatient setting, as determined by a healthcare provider
- Prescribed on-label therapy as indicated in the product PI
- Have commercial insurance and are not beneficiaries or recipients of any federal, state, or government-funded healthcare program, including Medicaid, Medicare (including Medicare Part D), Medicare Advantage Plans, Medigap, Veterans Affairs, Department of Defense or TRICARE, or other federal or state programs (including any state prescription drug assistance programs)
- Are not taking any C5-inhibitor therapies at the time of Program initiation
- To remain eligible to receive free Product through the Program following discharge to an outpatient setting, Users must initiate any procedures required by the payer (eg, request prior authorization) and must be awaiting a final payer coverage decision

Participation Rules: To enroll in the Program, Users must provide documentation demonstrating eligibility and any other information requested by OneSource and update OneSource of any changes in insurance coverage (eg, approval of a prior authorization) and/or expected site of care transitions. Users are responsible for complying with all obligations or requirements set forth by their insurer(s). 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. Product may not be sold, resold, traded, distributed for sale, or returned for credit.

Additional Terms and Disclosures: The Program is not a health insurance or a benefit plan, nor does it obligate the prescription, use, or recommendation of any specific medication, healthcare provider, or healthcare setting. Participation in the Program is not conditioned on any past, present, or future purchase of the Product or any other Alexion product. This is a voluntary program. Patients may choose not to enroll in the Program and may still receive the Product. Patients may participate in OneSource without participating in the Program. After enrolling in the Program, patients may opt out at any time by contacting OneSource. Alexion reserves the right to rescind, revoke, or amend the Program and these Terms without notice. Alexion further reserves the right to terminate any User's participation in the Program if Alexion determines in its sole discretion that they have not complied with any of these Terms.

If during the Program approval time frame, Alexion is made aware a participating patient is a beneficiary or recipient of any federal, state, or government-funded healthcare program, including Medicaid, Medicare (including Medicare Part D), Medicare Advantage Plans, Medigap, Veterans Affairs, Department of Defense or TRICARE, or other federal or state programs (including any state prescription drug assistance programs), **the hospital will be responsible** for reimbursing Alexion the cost of the Product that was provided free of charge.

Additional Healthcare Provider, Healthcare Setting, and Dispenser Terms and Disclosures:

- Participating healthcare providers, healthcare settings, and dispensers each must hold a valid license under applicable laws. Both the prescriber and the dispenser must be REMS-certified.
- Product must first be administered in an inpatient setting to eligible patients who have an urgent medical need to initiate the Product pursuant to a valid prescription from a licensed provider and in compliance with REMS requirements.
- After the initial loading dose, the Program can provide up to two additional dispenses of Product free of charge to eligible patients. Accordingly, an individual patient may receive no more than three dispenses of Product through the Program.
- Upon completion of enrollment (which consists of patient enrollment in OneSource, OneSource verifying eligibility, prescribers completing the Inpatient Support Program Form, and healthcare setting agreement to these Terms), participating healthcare settings will be eligible to order the Product.
- Participating healthcare settings must have adequate controls to track utilization of the Product and must establish adequate controls to ensure that the Product is appropriately segregated, dispensed, and tracked to ensure compliance with these Terms. For each order, the participating healthcare setting certifies and acknowledges the following:
    - It maintains adequate controls to track utilization of the Product, including maintaining Product separate from any commercially purchased units of ULTOMIRIS and tracking the number of units of Product dispensed since last order and the associated dispense date/month;
    - The participating patient begins the Product in an inpatient setting, and no patient has received more than three dispenses of Product;
    - It has not and will not seek reimbursement for any program Product; it has or will appropriately document that the Product was free in any reimbursement request
- Healthcare settings understand that the Product is commercially labeled and not labeled as samples or free drug but that they must treat the Product as free product in accordance with these Terms.
- Program participant names and the free Product disbursements may be reported as required by applicable laws. Once reported, this information may be made publicly available.

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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* 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)

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* (REQUIRED IF PATIENT IS A MINOR)	LEGAL PATIENT REPRESENTATIVE PHONE NUMBER	LEGAL PATIENT REPRESENTATIVE EMAIL

PATIENT INSURANCE INFORMATION (commercial only)

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 Indication & Important Safety Information on page 4 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: _____	☐ QTY of 300 mg/3 mL VIALS:_____ *NDC 25682-0025-01*	REFILLS: _____
	MAINTENANCE DOSE: SIG: INFUSE INTRAVENOUSLY _____ mg EVERY _____ WEEKS. START 2 WEEKS AFTER THE LOADING DOSE IS COMPLETE. OTHER: _____	☐ QTY of 300 mg/3 mL VIALS:_____ *NDC 25682-0025-01*	REFILLS: *(up to 2)* _____
		☐ QTY of 1100 mg/11 mL VIALS:_____ *NDC 25682-0028-01*	REFILLS: *(up to 2)* _____

PATIENT VACCINATION INFORMATION

HAS THE PATIENT RECEIVED **MENINGOCOCCAL VACCINATION** AND/OR **ANTIBIOTIC PROPHYLAXIS** CONSISTENT WITH THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP) RECOMMENDATIONS? ☐ YES ☐ NO

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

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 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/aHUS-ISPTerms. 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/aHUS-ISPTerms.

SIGN HERE

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

PHARMACIST FIRST & LAST NAME (PLEASE PRINT)*

IMPORTANT SAFETY INFORMATION AND INDICATION, INCLUDING BOXED WARNING

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

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

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 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.

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.

INDICATION

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).

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