ULTOMIRIS® (ravulizumab-cwvz)
Initiation Guide

ULTOMIRIS is FDA approved to treat adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody-positive

SELECT IMPORTANT SAFETY INFORMATION[1]

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS

Life-threatening meningococcal infections/sepsis have occurred in patients treated with ULTOMIRIS. Meningococcal infection may become rapidly life-threatening or fatal if not recognized and treated early.

- **Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccination in patients with complement deficiencies.**
- **Immunize patients with meningococcal vaccines at least 2 weeks prior to administering the first dose of ULTOMIRIS, unless the risks of delaying ULTOMIRIS therapy outweigh the risk of developing a meningococcal infection. See *Warnings and Precautions* for additional guidance on the management of the risk of meningococcal infection.**
- **Vaccination reduces, but does not eliminate, the risk of meningococcal infections. Monitor patients for early signs of meningococcal infections and evaluate immediately if infection is suspected.**

ULTOMIRIS is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS). Under the ULTOMIRIS REMS, prescribers must enroll in the program. Enrollment in the ULTOMIRIS REMS program and additional information are available by telephone: 1-888-765-4747 or at www.ultomirisrems.com.

Please see Important Safety Information throughout and full Prescribing Information for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening meningococcal infections/sepsis.

ULTOMIRIS®
(ravulizumab-cwvz)
injection for intravenous use
300 mg/3 mL vial

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Meningococcal Vaccinations

Because of how ULTOMIRIS works, vaccination against meningococcal infection is required. Life-threatening meningococcal infections have occurred in patients treated with ULTOMIRIS.[1]

The 2022 Advisory Committee on Immunization Practices (ACIP) recommends the following meningococcal vaccination regimens for adult patients (aged ≥19 years) with persistent complement component deficiency or in patients receiving complement inhibitors, including patients receiving ULTOMIRIS.[2,3]

MenACWY		MenB-4C		MenB-FHbp
2 DOSES	+	2 DOSES	OR	3 DOSES
At least 8 weeks apart		At least 1 month apart		0, 1-2, and 6 months[a]
A single booster dose every 5 years if risk remains		A single booster dose 1 year following completion of primary series and every 2-3 years if risk remains		
		MenB vaccines are not interchangeable		
		You must receive the same product for all doses		

[a]For MenB-FHbp, if dose 2 was administered at least 6 months after dose 1, dose 3 is not needed.[2]

Immunize patients with both types of meningococcal vaccines at least 2 weeks prior to administering the first dose of ULTOMIRIS[1,2]

- **Vaccinate for meningococcal disease according to the most current ACIP recommendations for patients with complement deficiencies.**
- **Administer booster doses in patients in accordance with ACIP recommendations, considering the duration of ULTOMIRIS therapy**
- Immunize patients without a history of meningococcal vaccination at least 2 weeks prior to receiving the first dose of ULTOMIRIS
- If urgent ULTOMIRIS therapy is indicated in an unvaccinated patient, the meningococcal vaccines should be administered as soon as possible
  - Patients should receive antibacterial drug prophylaxis from time of ULTOMIRIS initiation until 2 weeks after vaccination, in order to minimize the risk of infection in unvaccinated, unprotected patients
- The benefits and risks of antibiotic prophylaxis for prevention of meningococcal infections in patients receiving ULTOMIRIS have not been established

Please see Important Safety Information throughout and full Prescribing Information for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening meningococcal infections/sepsis.

Continued on next page

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Monitoring Patients[1]

Vaccination reduces, but does not eliminate, the risk of meningococcal infections. 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 steps to be taken to seek immediate medical care. Meningococcal infections may become rapidly life-threatening or fatal if not recognized and treated early.

Monitor patients receiving ULTOMIRIS for early signs and symptoms of meningococcal infections.

Signs and symptoms of meningococcal infections include:

- Headache with nausea or vomiting
- Headache and fever
- Headache with a stiff neck or back
- Fever with or without a rash
- Confusion
- Muscle aches with flu-like symptoms
- Eyes sensitive to light

Evaluate patients immediately if an infection is suspected.

Inform patients that they will be given an ULTOMIRIS Patient Safety Card that they should carry with them at all times. This card describes symptoms which, if experienced, should prompt the patient to immediately seek medical evaluation.

Consider discontinuation of ULTOMIRIS in patients who are undergoing treatment for serious meningococcal infections.

See additional information on monitoring patients for infusion reactions on page 4.

SELECT IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- Patients with unresolved *Neisseria meningitidis* infection.
- Patients who are not currently vaccinated against *Neisseria meningitidis*, unless the risks of delaying ULTOMIRIS treatment outweigh the risks of developing a meningococcal infection.

WARNINGS AND PRECAUTIONS

Serious Meningococcal Infections
Risk and Prevention

Life-threatening meningococcal infections have occurred in patients treated with ULTOMIRIS. The use of ULTOMIRIS increases a patient's susceptibility to serious meningococcal infections (septicemia and/or meningitis). Meningococcal disease due to any serogroup may occur. *(continued on next page)*

Please see Important Safety Information throughout and full Prescribing Information for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening meningococcal infections/sepsis.

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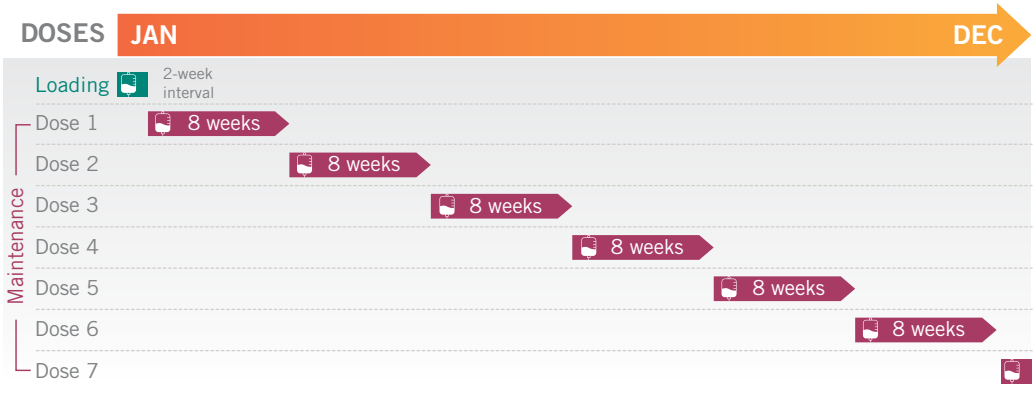
Recommended Dosing Regimen[1]

For adult patients (≥18 years of age) with anti-AChR antibody-positive gMG, ULTOMIRIS treatment begins with a loading dose, followed by maintenance dosing.



The recommended dosing regimen in adult patients (≥40 kg) with gMG consists of a loading dose followed by maintenance dosing, administered by intravenous infusion. Dosing is based on the patient's body weight. Starting 2 weeks after administering the loading dose, begin maintenance doses once every 8 weeks[1]

Ensure patients understand that they should adhere to the recommended dosing regimen consistently unless otherwise advised by you.

Indication	Body weight range (kg)	Loading dose (mg)	Maintenance dose (mg) and dosing interval	
gMG	40 to <60	2,400	3,000	Every 8 weeks
	60 to <100	2,700	3,300	
	≥100	3,000	3,600	

Monitoring for adverse reactions during and after ULTOMIRIS administration[1]

- The infusion may be slowed or stopped at the physician's discretion
- Patients need to be monitored during the infusion and for at least 1 hour following completion for signs or symptoms of an infusion-related reaction
- Interrupt ULTOMIRIS infusion and institute appropriate supportive measures if signs of cardiovascular instability or respiratory compromise occur

SELECT IMPORTANT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS

Serious Meningococcal Infections
Risk and Prevention
Vaccinate or revaccinate for meningococcal disease according to the most current ACIP recommendations for patients with complement deficiencies. Immunize patients without history of meningococcal vaccination at least 2 weeks prior to the first dose of ULTOMIRIS. If ULTOMIRIS must be initiated immediately in an unvaccinated patient, administer meningococcal vaccine(s) as soon as possible and provide 2 weeks of antibacterial drug prophylaxis. (*continued on next page*)

Please see Important Safety Information throughout and full Prescribing Information for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening meningococcal infections/sepsis.

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Recommended Dosing Regimen[1]

Supplemental dosing[1]

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.

Supplemental Dosing of ULTOMIRIS After PE, PP, or IVIg

Body weight range (kg)	Most recent ULTOMIRIS dose (mg)	Supplemental dose (mg) following each PE or PP intervention	Maintenance dose (mg) and dosing interval
40 to <60	2,400	1,200	600
	3,000	1,500	
60 to <100	2,700	1,500	600
	3,300	1,800	
≥100	3,000	1,500	600
	3,600	1,800	
Timing of ULTOMIRIS supplemental dose		**Within 4 hours following each PE or PP intervention**	**Within 4 hours following completion of an IVIg cycle**

Dose Reference Table for ULTOMIRIS 100 mg/mL (3 mL and 11 mL Vials)[1]

Body weight range (kg)	Dose (mg)	ULTOMIRIS volume (mL)	+	NaCl diluent volume (mL)	=	Final volume (mL)	Minimum infusion time (hr)	Maximum infusion rate (mL/hr)
Loading Dose								
40 to <60	2,400	24	+	24	=	48	0.8	64
60 to <100	2,700	27	+	27	=	54	0.6	92
≥100	3,000	30	+	30	=	60	0.4	144
Maintenance Dose								
40 to <60	3,000	30	+	30	=	60	0.9	65
60 to <100	3,300	33	+	33	=	66	0.7	99
≥100	3,600	36	+	36	=	72	0.5	144
Supplemental Dose								
40 to <60	600	6	+	6	=	12	0.25	48
	1,200	12	+	12	=	24	0.42	57
	1,500	15	+	15	=	30	0.5	60
60 to <100	600	6	+	6	=	12	0.2	60
	1,500	15	+	15	=	30	0.36	83
	1,800	18	+	18	=	36	0.42	86
≥100	600	6	+	6	=	12	0.17	71
	1,500	15	+	15	=	30	0.25	120
	1,800	18	+	18	=	36	0.28	129

SELECT IMPORTANT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS

Serious Meningococcal Infections
Risk and Prevention

In clinical studies, 2 adult patients with gMG were treated with ULTOMIRIS less than 2 weeks after meningococcal vaccination. All of these patients received antibiotics for prophylaxis of meningococcal infection until at least 2 weeks after meningococcal vaccination. The benefits and risks of antibiotic prophylaxis for prevention of meningococcal infections in patients receiving ULTOMIRIS have not been established. Consider discontinuation of ULTOMIRIS in patients who are undergoing treatment for serious meningococcal infection. *(continued on next page)*

Please see Important Safety Information throughout and full Prescribing Information for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening meningococcal infections/sepsis.

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Administering

It is important to carefully adhere to the following preparation and administration instructions for ULTOMIRIS.[1]

Immunize patients with meningococcal vaccines at least 2 weeks prior to administering the first dose of ULTOMIRIS, unless the risks of delaying ULTOMIRIS therapy outweigh the risk of developing meningococcal infections.

Patients who initiate ULTOMIRIS treatment less than 2 weeks after receiving meningococcal vaccine(s) must receive appropriate prophylactic antibiotics until 2 weeks after vaccination.

Each vial of ULTOMIRIS is intended for a single dose only.

Do not mix ULTOMIRIS 100 mg/mL (3 mL and 11 mL vials) and 10 mg/mL (30 mL vial) concentrations together.

Use aseptic technique to prepare ULTOMIRIS as follows:

STEP 1

Calculate the number of vials needed

Determine the number of vials to be diluted based on the individual patient's weight and the prescribed dose.

STEP 2

Prior to dilution, visually inspect the solution in the vials

The solution should be free of any particulate matter or precipitation. Do not use if there is evidence of particulate matter or precipitation

Continued on next page

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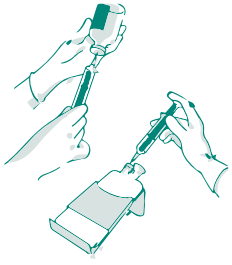
Administering

STEP 3 Dilute in an infusion bag

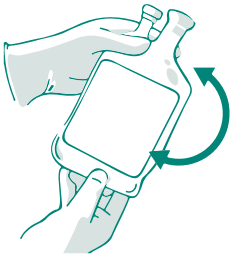
Withdraw the calculated volume of ULTOMIRIS from the appropriate number of vials and dilute in an infusion bag using 0.9% Sodium Chloride Injection, USP to a final concentration of

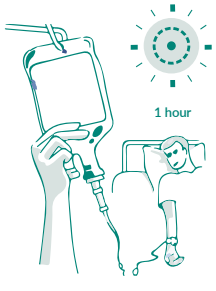
- 50 mg/mL for the 3 mL and 11 mL vial sizes
- 5 mg/mL for the 30 mL vial size



STEP 4 Mix and administer

- Gently mix the ULTOMIRIS infusion solution after dilution. Do not shake. Protect from light. Do not freeze.
- Prior to administration, allow the admixture to adjust to room temperature (18°C - 25°C [64°F - 77°F])
  - Do not heat the admixture in a microwave or with any heat source other than ambient air temperature
  - Inspect visually for particulate matter and discoloration prior to administration
- Administer the diluted solution immediately following preparation. Infusion must be administered through a 0.2 or 0.22 micron filter
- If the diluted ULTOMIRIS infusion solution is not used immediately, storage under refrigeration at 2°C - 8°C (36°F - 46°F) must not exceed 24 hours taking into account the expected infusion time
  - Once removed from refrigeration, administer the diluted ULTOMIRIS solution within 6 hours if prepared with ULTOMIRIS 30 mL vials or within 4 hours if prepared with ULTOMIRIS 3 mL or 11 mL vials





If an adverse reaction occurs during the administration of ULTOMIRIS, the infusion may be slowed or stopped at the discretion of the physician.

Monitor the patient for at least one hour following completion of the infusion for signs or symptoms of an infusion-related reaction.

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Enroll in REMS

Due to the risk of meningococcal infections, prescribers must enroll in our Risk Evaluation and Mitigation Strategy (REMS) program to obtain ULTOMIRIS. Call Customer Operations at 1-888-765-4747 or visit ultomirisrems.com to learn more and enroll.

You must be specifically certified to prescribe ULTOMIRIS. Certification consists of review of REMS educational materials and enrollment in the ULTOMIRIS REMS.

STEP 1

Review the ULTOMIRIS REMS HCP educational materials

- Prescribing Information
- Prescriber Safety Brochure
- Patient Safety Brochure
- ULTOMIRIS Patient Safety Card

The ULTOMIRIS REMS program and SOLIRIS REMS program are not interchangeable.

STEP 2

Enroll in the ULTOMIRIS REMS program

Complete the ULTOMIRIS REMS Prescriber Enrollment online OR print and sign the Prescriber Enrollment Form.

- Mail the form to ULTOMIRIS REMS, Alexion Pharmaceuticals, Inc., 121 Seaport Blvd, Boston, MA 02210
- Fax the form to ULTOMIRIS REMS at **1-877-580-2596**
- Scan and email the form to **rems@alexion.com**

Call **1-888-765-4747** or visit **ultomirisrems.com** for more information.

SELECT IMPORTANT SAFETY INFORMATION

Other Infections

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*. If ULTOMIRIS is administered to patients with active systemic infections, monitor closely for worsening infection.

Thromboembolic Event Management

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

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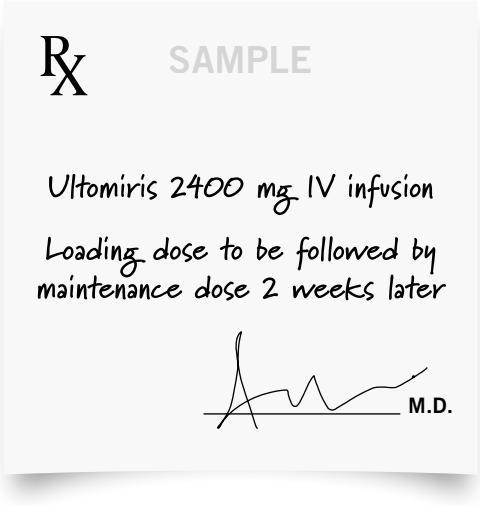
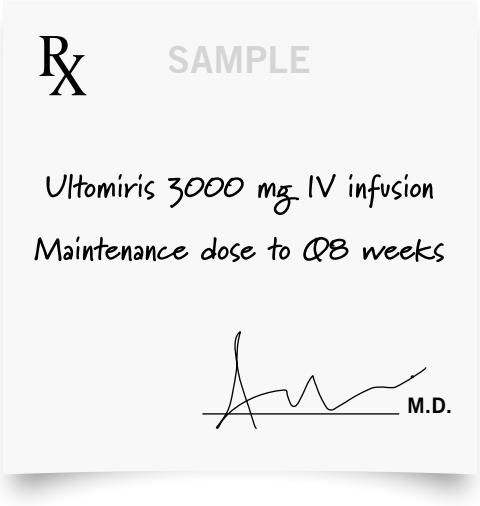
How to Write a Prescription

Treatment begins with a loading dose, followed by maintenance dosing.[1]





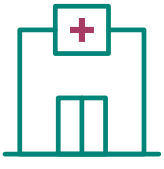
These **sample** prescriptions indicate the loading dose and maintenance dose for ULTOMIRIS in a patient weighing 40 kg.

Administer ULTOMIRIS at the recommended dosage regimen time points. The dosing schedule can occasionally vary within 7 days of the scheduled infusion day—except for the first maintenance dose of ULTOMIRIS.[1]

Treatment sites

ULTOMIRIS is a treatment that is given by IV infusion.[1] Depending on the patient's insurance and location, infusions can be administered at:

A doctor's office



An infusion center

A patient's home

An Alexion OneSource™ representative can assist your patients with locating an infusion center.

SELECT IMPORTANT SAFETY INFORMATION

Infusion-Related Reactions

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

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Ordering and Storing

Place your order with an authorized specialty distributor OR send your completed prescription to the payer-designated specialty pharmacy.

An Alexion Customer Operations Representative will work with either party to facilitate order processing and delivery.

Storage and handling[1]

- Store ULTOMIRIS vials in their original cartons, refrigerated at 2°C to 8°C (36°F to 46°F), to protect from light until time of use.
- If the diluted ULTOMIRIS infusion solution is not used immediately, storage under refrigeration at 2°C - 8°C (36°F - 46°F) must not exceed 24 hours taking into account the expected infusion time. Once removed from refrigeration, administer the diluted ULTOMIRIS infusion solution within 6 hours if prepared with ULTOMIRIS 30 mL vials or within 4 hours if prepared with ULTOMIRIS 3 mL or 11 mL vials.
- **DO NOT FREEZE; DO NOT SHAKE.**

Ordering ULTOMIRIS

Single-dose vials, one vial per carton

NDC 25682-025-01 SINGLE-UNIT, 300 mg/3 mL (100 mg/mL)

NDC 25682-028-01 SINGLE-UNIT, 1,100 mg/11 mL (100 mg/mL)

SELECT IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS

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.

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.

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Begin With OneSource™

Connect patients to OneSource for ongoing support.

OneSource is a complimentary, personalized patient support program offered by Alexion available for eligible enrolled adult patients with anti-AChR antibody-positive gMG. Our team is specially trained in rare diseases, and each person plays a unique role in helping to support your needs. OneSource offers assistance with:

EDUCATION

When you have questions about your condition or treatment with ULTOMIRIS, we'll work to find the answers.

Our team of specialists can provide you with:

- Educational materials about your condition
- Details about ULTOMIRIS
- Information about the treatment process

HEALTH INSURANCE NAVIGATION

Health insurance can be complicated. We're here to help make sense of it all.

Our team of specialists can help by:

- Providing information that explains your insurance coverage for ULTOMIRIS
- Addressing financial concerns or gaps in coverage
- Informing you of nearby infusion centers or other treatment location options

ONGOING SUPPORT

When life takes a turn, OneSource™ is ready to keep you on track.

Our team can help:

- Guide you through insurance changes, transitioning to another Alexion medicine, or finding new treatment locations
- Navigate your treatment through life events, such as getting married, starting a new job, moving, or traveling
- Work with your healthcare provider and specialty pharmacy to ensure you keep receiving your medicine as prescribed

COMMUNITY CONNECTIONS

With OneSource™ by your side, you'll never have to go it alone.

Connect with others in the rare disease community who understand your experience. We can share information about:

- In-person and online meetings and events specific to your condition
- Support and resources
- Advocacy groups
- A peer-to-peer program called Peer Connects

Contact OneSource at **1-888-765-4747** or via email at **OneSource@Alexion.com.**

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Alexion OneSource™ CoPay Program

The Alexion OneSource CoPay Program helps patients pay for eligible out-of-pocket medication and infusion costs. For more information, please visit www.AlexionOneSource.com/CoPay.

To be eligible for this program, you must:

- ✓ Be signed up for patient services through OneSource™
- ✓ Have commercial insurance
- ✓ Be prescribed ULTOMIRIS for an FDA-approved indication
- ✓ Reside in the United States or its territories

How My Patient Can Apply for the Program

Fill out the Alexion Patient Start Form

The enrollment form can be found at AlexionOneSource.com

Submit form to OneSource

Have patients review and sign the completed form, then fax the completed form to OneSource at 1-800-420-5150 or email to OneSource@Alexion.com

Receive CoPay ID number from OneSource

You will receive communication from OneSource containing the CoPay ID number

Provide CoPay ID number to site of care

Contact OneSource at **1-888-765-4747** or via email at **OneSource@Alexion.com**

IMPORTANT NOTICE: The Alexion OneSource™ CoPay Program ("Program") pays for eligible out-of-pocket medication and infusion costs, where applicable, associated with ULTOMIRIS up to $15,000 US dollars per calendar year. The Program is not valid for 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). No claim for reimbursement of any out-of-pocket expense amount covered by the Program may be submitted to any third-party payer, whether public or private. This offer cannot be combined with any other rebate/coupon, free trial, or similar offer. Patients residing in Massachusetts or Rhode Island are eligible for assistance with medication costs but are not eligible for assistance with infusion costs. Alexion reserves the right to rescind, revoke, or amend this program without notice. By participating in the Program, participants acknowledge that they understand and agree to comply with the complete terms and conditions, available at AlexionOneSource.com/CoPay.

Please see Important Safety Information throughout and full Prescribing Information for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening meningococcal infections/sepsis.

References: 1. ULTOMIRIS. Prescribing information. Alexion Pharmaceuticals, Inc. **2.** Murthy N, et al. *Ann Intern Med.* 2022;175(3):432-443. **3.** Mbaeyi SA, et al. *MMWR Recomm Rep.*2020;69(9);1-41.

ALEXION® AstraZeneca Rare Disease

ULTOMIRIS® (ravulizumab-cwvz) injection for intravenous use 300 mg/3 mL vial