



# Alexion OneSource™ Inpatient Support Program

## WHAT IS THE ALEXION ONESOURCE INPATIENT SUPPORT PROGRAM?



**The Alexion OneSource Inpatient Support Program is a voluntary support program** offered by Alexion Pharmaceuticals, Inc. that provides up to **3 doses** of ULTOMIRIS<sup>®</sup> (ravulizumab-cwvz) medication free of charge to eligible patients who have a physician-determined urgent medical need to initiate treatment in an inpatient setting. The Program does not assist with infusion-related costs.

### WHO IS ELIGIBLE FOR THE PROGRAM?

#### Patients may be eligible for the Inpatient Support Program if they meet all of the following criteria:

- Are enrolled in OneSource, a personalized patient support program offered by Alexion\*
- Reside and receive treatment in the United States or its territories
- Have a prescription/medication order for ULTOMIRIS and be one of the following:
  - A patient with atypical hemolytic uremic syndrome (aHUS)
  - An adult with anti-acetylcholine receptor (AChR) antibody positive generalized myasthenia gravis (gMG)
  - An adult with anti-aquaporin-4 (AQP4) antibody-positive neuromyelitis optica spectrum disorder (NMOSD)
- Have a medically urgent need to initiate ULTOMIRIS in an inpatient setting, as determined by a healthcare provider
- Have commercial insurance and are not beneficiaries or recipients of any federal, state, or government-funded healthcare 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

\*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 under the Program without a signed patient consent form. If a patient/caregiver/healthcare proxy declines to sign a patient consent, no further medication will be dispensed under the Program and the patient will be discharged from the Program.

The prescribing physician and site of care pharmacy must attest that they will not seek reimbursement from any source for the free Product received.

By participating in the Program, participants acknowledge that they understand and agree to comply with the complete Terms and Conditions, available at <u>www.AlexionOneSource.com/ISPTerms</u>.

Please see Indications & Important Safety Information on page 3 and full accompanying <u>Prescribing Information</u> and <u>Medication Guide</u> for ULTOMIRIS, including Boxed WARNING regarding serious meningococcal infections.





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### HOW TO ENROLL IN THE INPATIENT SUPPORT PROGRAM

Visit <u>www.AlexionOneSource.com/ISP</u> to complete the following steps:



#### Healthcare Provider:

 Identify a patient in an inpatient setting who has an urgent medical need to start treatment and complete the Inpatient Support Program Form



#### Site of Care Pharmacy Receiving the Free Alexion Product:

Attest to the Program's-terms and conditions through the Inpatient Support Program Form



#### Patient or Legal Representative:

Complete the OneSource Patient Services Enrollment Form

OneSource is a complimentary, personalized patient support program offered by Alexion and is tailored to the specific needs of patients.

OneSource will review the forms to confirm eligibility and will coordinate with the patient and their healthcare team on next steps to start therapy.

For urgent requests outside of our regular business hours (8:30 AM EST to 8:00 PM EST) or during weekends and holidays when Alexion is closed, please call 1-888-765-4747. Select option 3, then option 1 to speak with a representative.

Patients may be able to transition to another inpatient healthcare facility or to an outpatient facility while receiving support through this Program.

Call OneSource for more information about additional requirements and available support while managing this transition.



CONTACT ONESOURCE AT: PHONE: 1.888.765.4747 EMAIL: OneSource@Alexion.com WEBSITE: www.AlexionOneSource.com/ISP

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# INDICATIONS & IMPORTANT SAFETY INFORMATION INDICATIONS

#### What is ULTOMIRIS?

ULTOMIRIS is a prescription medicine used to treat:

- adults and children 1 month of age and older with a disease called atypical Hemolytic Uremic Syndrome (aHUS). ULTOMIRIS is not used in treating people with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).
- adults with a disease called generalized Myasthenia Gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive.
- adults with a disease called Neuromyelitis Optica Spectrum Disorder (NMOSD) who are anti-aquaporin 4 (AQP4) antibody positive.

It is not known if ULTOMIRIS is safe and effective in children younger than 1 month of age.

It is not known if ULTOMIRIS is safe and effective for the treatment of gMG or NMOSD in children.

#### **IMPORTANT SAFETY INFORMATION**

## What is the most important information I should know about ULTOMIRIS?

ULTOMIRIS is a medicine that affects your immune system and may lower the ability of your immune system to fight infections.

- ULTOMIRIS increases your chance of getting serious meningococcal infections that may quickly become life-threatening or cause death if not recognized and treated early.
  - **1.** You must complete or update meningococcal vaccine(s) at least 2 weeks before your first dose of ULTOMIRIS.
  - If you have not completed your meningococcal vaccines and ULTOMIRIS must be started right away, you should receive the required vaccine(s) as soon as possible.
  - **3.** If you have not been vaccinated and ULTOMIRIS must be started right away, you should also receive antibiotics for as long as your healthcare provider tells you.
  - If you had a meningococcal vaccine in the past, you might need additional vaccines before starting ULTOMIRIS. Your healthcare provider will decide if you need additional meningococcal vaccines.
  - 5. Meningococcal vaccines do not prevent all meningococcal infections. Call your healthcare provider or get emergency medical care right away if you get any of these signs and symptoms of a meningococcal infection: fever, fever with high heart rate, headache and fever, confusion, muscle aches with flu-like symptoms, fever and a rash, headache with nausea or vomiting, headache with a stiff neck or stiff back, or eyes sensitive to light.

Your healthcare provider will give you a Patient Safety Card about the risk of serious meningococcal infection. Carry it with you at all times during treatment and for 8 months after your last ULTOMIRIS dose. Your risk of meningococcal infection may continue for several months after your last dose of ULTOMIRIS. It is important to show this card to any healthcare provider who treats you. This will help them diagnose and treat you quickly.

ULTOMIRIS is only available through a program called the ULTOMIRIS and SOLIRIS Risk Evaluation and Mitigation Strategy (REMS). Before you can receive ULTOMIRIS, your healthcare provider must: enroll in the REMS program; counsel you about the risk of serious meningococcal infections; give you information about the signs and symptoms of serious meningococcal infection; make sure that you are vaccinated against serious infections caused by meningococcal bacteria, and that you receive antibiotics if you need to start ULTOMIRIS right away and are not up to date on your vaccines; give you a **Patient Safety Card** about your risk of meningococcal infection.

#### ULTOMIRIS may also increase the risk of other types of serious

**infections,** including *Streptococcus pneumoniae, Haemophilus influenzae,* and *Neisseria gonorrhoeae*. Your child should receive vaccines against *Streptococcus pneumoniae* and *Haemophilus influenzae* type b (Hib) if treated with ULTOMIRIS. Certain people may be at risk of serious infections with gonorrhea.

#### Who should not receive ULTOMIRIS?

Do not receive ULTOMIRIS if you have a serious meningococcal infection when you are starting ULTOMIRIS.

## Before you receive ULTOMIRIS, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection or fever
- are pregnant or plan to become pregnant. It is not known if ULTOMIRIS will harm your unborn baby.
  - Pregnancy Registry: There is a registry for pregnant women who take ULTOMIRIS to check the health of the pregnant mother and her baby. If you are pregnant or become pregnant while taking ULTOMIRIS, talk to your healthcare provider about how you can join this registry or you may contact the registry at <u>1-833-793-0563</u> or <u>www.UltomirisPregnancyStudy.com</u> to enroll.
- are breastfeeding or plan to breastfeed. It is not known if ULTOMIRIS passes into your breast milk. You should not breastfeed during treatment and for 8 months after your final dose of ULTOMIRIS.

Tell your healthcare provider about all the vaccines you receive and medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements which could affect your treatment.

If you have aHUS, your healthcare provider will need to monitor you closely for at least 12 months after stopping treatment for signs of worsening aHUS or problems related to a type of abnormal clotting and breakdown of your red blood cells called thrombotic microangiopathy (TMA). Symptoms or problems that can happen with TMA may include: confusion or loss of consciousness, seizures, chest pain (angina), difficulty breathing and blood clots or stroke.

#### What are the possible side effects of ULTOMIRIS?

ULTOMIRIS can cause serious side effects including infusion-related reactions. Symptoms of an infusion-related reaction with ULTOMIRIS may include lower back pain, stomach (abdominal) pain, muscle spasms, changes in blood pressure, tiredness, feeling faint, shaking chills (rigors), discomfort in your arms or legs, or bad taste. Stop treatment of ULTOMIRIS and tell your healthcare provider right away if you develop these symptoms, or any other symptoms during your ULTOMIRIS infusion that may mean you are having a serious infusion-related reaction, including: chest pain, trouble breathing or shortness of breath, swelling of your face, tongue, or throat, and feel faint or pass out.

The most common side effects of ULTOMIRIS in people treated for aHUS are upper respiratory tract infection, diarrhea, nausea, vomiting, headache, high blood pressure and fever.

The most common side effects of ULTOMIRIS in people with gMG are diarrhea and upper respiratory tract infections.

# The most common side effects of ULTOMIRIS in people with NMOSD are COVID-19 infection, headache, back pain, urinary tract infection, and joint pain (arthralgia).

Tell your healthcare provider about any side effect that bothers you or that does not go away. These are not all the possible side effects of ULTOMIRIS. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider right away if you miss an ULTOMIRIS infusion or for medical advice about side effects. You may report side effects to FDA at <u>1-800-FDA-1088</u>.

# Please see full accompanying <u>Prescribing Information</u> and <u>Medication Guide</u> for ULTOMIRIS, including Boxed WARNING regarding serious meningococcal infections.

#### This information is intended for United States residents only.

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