ALEXION®
AstraZeneca Rare Disease

Navigating Insurance for ULTOMIRIS® (ravulizumab-cwvz)

A Guide to understanding insurance for patients who have been prescribed ULTOMIRIS and their caregivers.

Please see Important Safety Information on pages 2-4 and 40-44 and the full Prescribing Information and Medication Guide for ULTOMIRIS, including Boxed WARNING regarding serious meningococcal infections.

INDICATIONS & SELECT IMPORTANT SAFETY INFORMATION for ULTOMIRIS

What is ULTOMIRIS?

ULTOMIRIS is a prescription medicine used to treat:

- adults and children 1 month of age and older with a disease called Paroxysmal Nocturnal Hemoglobinuria (PNH).
- 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.

Please see Important Safety Information on pages 2-4 and 40-44 and the full Prescribing Information and Medication Guide for ULTOMIRIS, including Boxed WARNING regarding serious meningococcal infections.

SELECT IMPORTANT SAFETY INFORMATION for ULTOMIRIS (cont.)

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.
  2. 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.
  4. 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.

Please see Important Safety Information on pages 2-4 and 40-44 and the full Prescribing Information and Medication Guide for ULTOMIRIS, including Boxed WARNING regarding serious meningococcal infections.

SELECT IMPORTANT SAFETY INFORMATION for ULTOMIRIS (cont.)

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.

Please see Important Safety Information on pages 2-4 and 40-44 and the full Prescribing Information and Medication Guide for ULTOMIRIS, including Boxed WARNING regarding serious meningococcal infections.

Navigating Patient Insurance

This guide is an educational resource to help patients and their caregivers understand health insurance coverage of ULTOMIRIS® (ravulizumab-cwvz).

Learn about the different types of health insurance plans

Identify your health insurance plan's coverage of ULTOMIRIS

Understand the process that health insurance plans use to approve treatment for ULTOMIRIS and know your options if coverage is denied

Learn about potential options for financial assistance for patients and resources that Alexion offers that may help you navigate the access process

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Things to Consider When Choosing an Insurance Plan

Assess All of the Health Plan Options Available to You

Each health plan has different health and prescription drug benefits, so make sure you do research to ensure your health needs are covered.

It's a good idea to contact your employer's benefit staff or the insurance company to understand the benefit details. When exploring your options, there are several critical factors in selecting your plan, including the following:

How much will I have to pay for insurance through a monthly premium?

Are my preferred doctors, specialists, emergency care, and hospital admissions covered?

Are my medications covered by the plan?

Are prior authorizations (PAs) required for my medications? If so, do I meet the criteria? Does the PA criteria align with my diagnosis?

How much will I have to pay out-of-pocket for my services and medications?

Please see Important Safety Information on pages 2-4 and 40-44 and the full Prescribing Information and Medication Guide for ULTOMIRIS, including Boxed WARNING regarding serious meningococcal infections.

Closely Examine All Out-of-Pocket (OOP) Costs

Deductibles, copayments, and coinsurances can impact your overall healthcare expenses. This is covered in more detail on page 17.

Check if starting or renewing coverage will impact OOP costs. (For example, will prescription drugs cost more at the beginning of the year until your OOP limit is met?)

Does the plan have limits on OOP expenses?

Engage a Health Plan Representative to Answer Your Questions

To ensure you understand your healthcare (or insurance) coverage, contact the insurance company and have a representative review your list of medications and how they are covered so you can anticipate costs. For example, is your medication covered by the insurance plan? Does it require copayment? Does it go toward your deductible? If you are eligible for Medicare, Medicare offers a plan finder tool online for those searching to understand coverage and costs for prescription drugs.

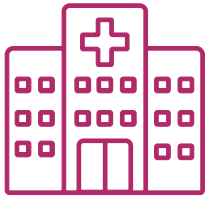
Make a Personal Connection

Work with a particular person within your employer's benefits team or the insurance company and have their name and direct phone number on hand. Having a relationship with a real person can help you get your questions answered and may help you to resolve issues more quickly.

Common Types of Health Insurance

Common Types of Health Insurance

Health insurance is a benefit that helps you pay for medical services and medications. In the United States, there is a mix of public and private health insurance.[1,2]



Private (Commercial) Insurance

There are two types of private health insurance: group health insurance offered by your employer or individual coverage offered by a health insurance company.[2]

Group Health Insurance[3]:

- Offered through your employer
- The monthly premium cost is typically shared by your employer and you
- There is an annual enrollment period to choose your health insurance plan option

Individual Market Coverage[4]:

- Health insurance coverage is offered directly from private health insurance companies
- You shop for and purchase an individual plan directly through a Marketplace website (eg, healthcare.gov)
- The Marketplace enrollment period is November 1 to December 15[5]
- You pay the entire monthly individual plan's premium, but you may have access to a subsidy to cover a portion of your monthly premium

Public (Federal or State) Insurance

Medicare covers people[6]:

- Aged 65 or older
- Aged <65 with certain disabilities
- With end-stage renal (kidney) disease and amyotrophic lateral sclerosis (ALS)

Medicaid[7]:

- Covers people with low incomes and some disabled people
- Funded partly by the federal government and partly by individual states

Veterans Health Administration (VA)/ TRICARE Department of Defense (DoD)[8]:

TRICARE DoD and the VA provide health coverage for US military service members, veterans, and their families—this includes people who are or have been in the military such as[9]:

- Active-duty service members
- National Guard and Reserve members
- Retirees
- Families of retirees

Private Health Insurance

There are different types of private payer health insurance plans designed to meet different needs. Some types of plans restrict your provider choices or encourage you to get care from the plan's network of doctors, hospitals, pharmacies, and other medical service providers. Others pay a greater share of costs for providers outside the plan's network.

Some examples of common plan types:

 **Preferred Provider Organization (PPO)**	Features a broad choice of network providers with the ability to go out of network for a higher out-of-pocket cost. A popular plan type, PPOs are less restrictive than other types like HMOs as referrals to providers are usually not required.[10]
 **Health Maintenance Organization (HMO)**	A type of health insurance plan that usually limits coverage to care from doctors who work for or contract with the HMO. Referrals are generally required for specialists. HMOs also generally won't cover out-of-network care except in an emergency. An HMO may require you to live or work in its service area to be eligible for coverage.[10]
 **Point of Service (POS)**	A type of plan where you pay less if you use doctors, hospitals, and other healthcare providers that belong to the plan's network. A hybrid of PPOs and HMOs, POS plans require you to get a referral from your primary care doctor in order to see a specialist.[10]
 **Exclusive Provider Organization (EPO)**	A managed care plan where items and services are covered only if you use doctors, specialists, or hospitals in the plan's network (except in an emergency).[10]

Medicare

What is Medicare?

Medicare is a federal system of health insurance for people over 65 years of age, people under age 65 with certain disabilities, and people of any age with end-stage renal (kidney) disease or amyotrophic lateral sclerosis (ALS).[6]

Medicare has 4 parts to help cover items and services:

Original Medicare (sometimes called Traditional Medicare) is insurance administered by the federal government. It consists of Part A, which covers hospital services, and Part B, which covers services like doctor appointments, laboratory tests, and X-rays.

PART A

Covers inpatient hospital stays, skilled nursing facility stays, hospice care, and home health services.[6] Your out-of-pocket (OOP) cost may vary by length of stay. ULTOMIRIS® (ravulizumab-cwvz) may be covered under Part A when administered during an inpatient hospital stay.

PART B

Covers doctor's office visits, medications administered by your doctor (such as ULTOMIRIS infusions), and other services like lab tests.[6] Your OOP expense is generally 20% of the cost of the service, but Medigap coverage may help pay for this expense. ULTOMIRIS is often covered under Medicare Part B.[6]

You can also purchase a Medicare Supplement Insurance (Medigap) plan from a health plan. Medigap helps pay for healthcare costs such as copayments and coinsurance. You must have Medicare Part A and Part B in order to purchase a Medigap plan.

Medicare (cont.)

Medicare has 4 parts to help cover items and services (cont.):

PART C

Part C is sometimes referred to as a Medicare Advantage plan. With Medicare Advantage, you'll still pay a premium for Medicare Part B, but all your benefits will be bundled under a single plan from a private insurance company.[6] Medicare Advantage plans may also offer prescription drug coverage. Medicare Advantage plans are administered by private insurance companies that contract with the federal government. Your out-of-pocket (OOP) expense may vary by the health insurance plan. ULTOMIRIS® (ravulizumab-cwvz) is generally covered for both inpatient stays and when administered at your doctor's office.

PART D

If you have Original Medicare, you can enroll in a Part D plan from a health insurance company to cover prescription drugs (tablets, capsules, or those you can administer yourself).[6] Your OOP expense can include the following: deductible, initial coverage phase, donut hole, and catastrophic coverage. If you are receiving home infusions, ULTOMIRIS will be billed under Part D and you will be responsible for both your OOP expenses, as well as potential additional ancillary costs such as drug administration services.

Medicaid

Medicaid provides low-cost or free health coverage to millions of Americans, including eligible low-income adults, children, pregnant women, elderly adults, and people with disabilities. Medicaid is administered by states, according to federal requirements. The program is funded jointly by states and the federal government.[7] Medicaid is the single largest source of health coverage in the United States.

Each state has different income requirements, the number of people in your household, family status, and other factors to determine coverage.[7] Contact your state's Medicaid office for more information about the eligibility guidelines.

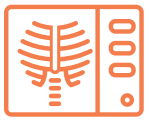
Medicaid can help cover medical costs by paying for items and services such as[7]:


Hospital visits


Home healthcare


Doctor or nurse visits


Medical tests


X-rays


Transportation to medical care

Your state may also help pay for some other care, including:


Medications


Occupational therapy


Case management


Medical equipment and procedures


Physical therapy

What If You Have 2 Types of Insurance?

Some people may have two types of health insurance coverage and your insurance plans will need to coordinate benefits between the two. When you have more than one health plan, a coordination of benefits policy decides which plan pays first. The health plan that pays first is the primary payer or primary insurer, which pays up to a certain amount. The plan that pays the cost not covered by the primary payer (also called the cost gap) is the secondary payer or secondary insurer.

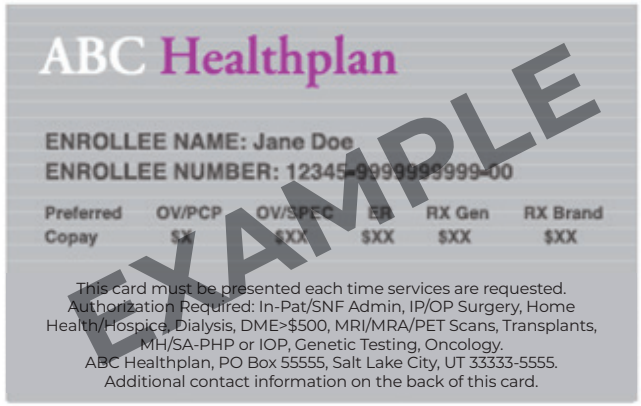
The Coordination of Benefits Form you receive from your health plan will tell you which plan is your primary health plan and which one is secondary.

People who have both Medicare and Medicaid insurance are known as "dual eligibles."[11] Dual eligibles may receive Medicaid benefits plus premium and cost-sharing assistance for drug coverage under Medicare Part D. Partial dual-eligible beneficiaries may have a cost-sharing responsibility. This is not the case for full dual-eligible beneficiaries.

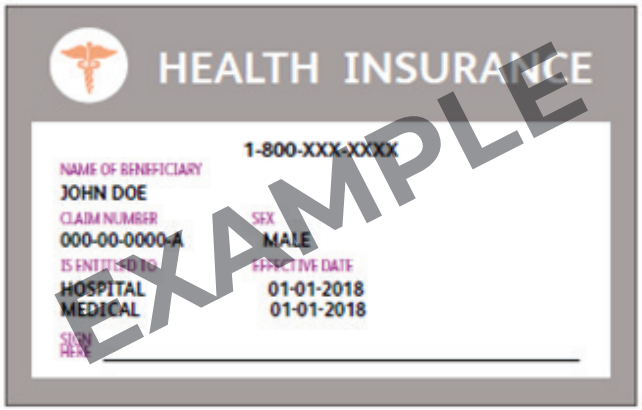
It is important that both insurances know about each other, and it is the patient's responsibility to make sure the two plans know about each other.

Your Health Insurance Cards

Sample Private Health Insurance Card



Sample Medicare Universal Identification Card



Your insurance company will give you a health insurance card as proof of insurance. Doctors' offices use this information to process your healthcare claims. Some cards include the copay costs you may need to pay for different services or drugs.

Your physician office or care team may ask for your:

Member ID Number	This number is unique to you. It identifies you as an individual who is covered and allows you to access your benefits when you need care.
Group Number	If you received insurance through an employer, a group number will also be listed on your card. This helps identify the benefits you receive through your employer's plan. Your care team may use this number to file claims.

A Patient's Cost Responsibilities

The Amount You Will Pay for Your Treatment Depends on Your Healthcare Plan

Health plans pay a portion of the cost of medical care and medicines. You—the patient—will often have to pay a portion or "share" of the cost as well. Each plan is different when it comes to your out-of-pocket (OOP) costs for treatments and procedures. Listed below are the types of cost-sharing you may encounter depending on your insurance.

Premium[12]

The premium is the monthly fee you pay for coverage. Policies with lower premiums will likely require you to pay more in the form of deductibles and copayments when you make use of medical services. Examine the terms carefully; a policy with a low premium does not mean it is the least expensive in terms of your overall OOP costs for services and medications.

Deductible[13]

The deductible is the OOP amount you pay for your medical care before the insurer pays its share. There are exceptions to this. Some healthcare plans (including those obtained through the insurance Marketplace) cover the entire cost of certain preventive services. A policy may also have different deductibles for certain aspects of the plan, such as prescription drugs.

Copayment ("Copay")[14]

A copayment is a fixed dollar amount you pay for a specific service, procedure, or drug each time you receive care or fill a prescription.

Coinsurance[15]

A coinsurance is a fixed percentage of the cost of all services and prescription drugs a policyholder is required to pay. The coinsurance for certain services or prescription drugs may vary. Some insurers use coinsurance rather than copayments, while others use a combination of the two.

OOP Expense[16]

Your OOP expense is what you have to pay for accessing your medication. Generally, your OOP cost may include your portion of a deductible payment or your copayment or coinsurance (depending on what your plan requires).

OOP Maximum[17]

Your OOP maximum is the maximum amount of OOP expenses you will pay in a given plan year. Private insurance companies are required to have an OOP maximum.

Paying for Your Treatment

Your summary of benefits will tell you exactly what you need to pay for: your premium, your annual deductible, copays, and your annual maximum out-of-pocket (OOP) costs. Your maximum OOP cost is the most you will pay for covered services in a plan year before your health plan pays 100% of the costs of covered benefits.

Factors that can affect how much you will be asked to pay for your treatment:

Office visit vs hospital stay

Cost of drug or position on formulary

How and where the treatment is given: via a pill taken at home or as an infusion in a clinic

Plan deductible
Copay amount
Coinsurance rate

Other costs, depending on your insurance coverage

Please see Important Safety Information on pages 2-4 and 40-44 and the full Prescribing Information and Medication Guide for ULTOMIRIS, including Boxed WARNING regarding serious meningococcal infections.

What to Do If Your Insurance Changes

It is important to track and understand changes in your health insurance if they occur. For example, if you change eligibility from Medicaid to Medicare, if your employer changes its health plan provider as part of the annual enrollment process, or if you change jobs, all of these changes may result in you having a new insurance plan. As a result, you may have to go through a reauthorization process for your medications with your new plan.

- Some health plans require you to get an authorization for your treatment. If your insurance changes, your doctor will need to find out if an authorization is required
- If your primary insurance plan changes, your doctor needs to know so they can submit the claim to the right plan as you may not have coverage with your old plan if you are now on a new health plan

Let your doctor/office know if your insurance changes. Your insurance may change if you get a new job, your employer changes its insurance company, you go on your spouse's plan through marriage or a new job, or you become eligible for Medicare.

Medical Benefit Coverage for Drugs Like ULTOMIRIS® (ravulizumab-cwvz)

Please see Important Safety Information on pages 2-4 and 40-44 and the full Prescribing Information and Medication Guide for ULTOMIRIS, including Boxed WARNING regarding serious meningococcal infections.

Coverage for Intravenous (IV) Infusions

The medical benefit portion of your health plan typically covers physician and hospital services for things like visits to the doctor, drugs administered by doctors, hospital services and supplies, and some home health services.[18]

The pharmacy benefit typically covers prescription drugs taken orally and self-administered injectable prescription drugs that you can be taught to self-inject at home.[18]

ULTOMIRIS® (ravulizumab-cwvz) is administered as an IV infusion and most payers manage coverage for IV infusions through a health plan's medical benefit.

How Is Your IV Infusion Covered?

Most private insurance covers IV drug infusions through the medical benefit and they are administered in a physician's office or a free-standing infusion clinic. Where you receive your infusion may be dependent on your health plan's coverage.

For public health insurance, if you have original Medicare and receive your IV infusions at a doctor's office or clinic, your infusions are covered under Medicare Part B.[6] If you receive IV infusions while you are admitted to a hospital, they are covered under Medicare Part A because IV drugs are not covered under Medicare Part D.

Depending on your insurance and benefits, you may be able to receive ULTOMIRIS at home via a home infusion.

Paying for an Infusion Treatment Like ULTOMIRIS® (ravulizumab-cwvz)

Typically, you will pay a copay or coinsurance for the visit when you receive your ULTOMIRIS infusion. There may or may not be additional fees for the infusion itself depending on your health plan. The table below outlines out-of-pocket (OOP) expenses by insurance type.

Insurance Type	OOP Expenses	OOP Maximums
Private insurance[19]	Deductibles and your copayment/coinsurance will vary by insurance plan, although you are likely to have a coinsurance for ULTOMIRIS and the administration of it.	Your private insurance plan will have an OOP maximum for a plan year.
Medicare Part B[6]	After the annual deductible is paid, you will usually pay 20% of the cost of the drug and 20% for each infusion. However, supplemental (Medigap) insurance will help cover all or a portion of these costs. A large majority (over 90%) of Medicare patients have some type of supplemental insurance such as Medigap (or a similar plan), which reduces the OOP costs for office-administered drugs such as infusions.	No OOP maximum.
Medicare Part C[6]	Your deductible and copayment/coinsurance will vary by insurance plan.	Your Medicare plan has an annual OOP maximum.
Medicare Part D[6]	You may have four different phases of coverage in Part D, including a deductible, an initial coverage phase, donut hole, and catastrophic coverage.	There is no true OOP maximum in Part D. Once you get to catastrophic coverage, you may pay 5% for the remainder of the plan year.

How do I pay for my medication?

If you have funding concerns or gaps in coverage for your Alexion therapy, you are not alone. OneSource™ can assist you with information on alternative funding options and resources for you. OneSource can also provide information about independent foundations that may be able to assist with out-of-pocket (OOP) costs.

The Alexion OneSource CoPay Program

The Alexion OneSource CoPay Program helps patients pay for eligible OOP medication and infusion costs.

Program eligibility:

1) Patient enrolled in OneSource
2) Patient with commercial insurance who has a valid prescription for a US Food and Drug Administration–approved indication for ULTOMIRIS® (ravulizumab-cwvz)
3) Patient must reside and receive treatment with a Qualifying Alexion Product in the United States or its territories

Alexion ONESOURCE®
CoPay Program

For more information and complete terms and conditions for the Alexion OneSource CoPay Program, visit AlexionOneSource.com

Independent Charitable Foundations

There are a variety of independent foundations that offer assistance for medications used to treat specific medical conditions. These foundations can provide a variety of funding assistance including copay, transportation, and premiums. These foundations are not associated with Alexion.

OneSource™ can only refer patients to independent third-party foundations that may be able to help with the patient's out-of-pocket costs. The foundations make their own determinations about what (if any) assistance they will provide.

Some of these foundations are listed below—eligibility requirements can be found directly on the foundations' websites. Alexion does not endorse or guarantee reimbursement or support from the organizations listed below.

NORD®
National Organization for Rare Disorders

www.rarediseases.org

203-202-8833

The Assistance Fund

www.tafcares.org

855-845-3663

Navigating the Approval Process for ULTOMIRIS® (ravulizumab-cwvz)

Please see Important Safety Information on pages 2-4 and 40-44 and the full Prescribing Information and Medication Guide for ULTOMIRIS, including Boxed WARNING regarding serious meningococcal infections.

Navigating Your Health Plan's Approval Process for ULTOMIRIS® (ravulizumab-cwvz)

After you are prescribed ULTOMIRIS, your doctor's office may research your health plan's coverage, a process called a Benefits Investigation. OneSource™, Alexion's personalized patient support program, can also conduct a simultaneous Benefits Investigation to make sure that there is complete understanding of your insurance benefits. After a Benefits Investigation, you and your doctor can have a complete picture of ULTOMIRIS coverage and will understand any requirements to access ULTOMIRIS and your out-of-pocket (OOP) costs for ULTOMIRIS.

Please see Important Safety Information on pages 2-4 and 40-44 and the full Prescribing Information and Medication Guide for ULTOMIRIS, including Boxed WARNING regarding serious meningococcal infections.

Understanding the Statement of Benefits

After you receive treatment, your health plan will send you a Summary of Benefits (SOB), Explanation of Benefits (EOB), or Medicare Summary Notice (MSN). The MSN is a summary of Medicare Part A and Part B covered items and services.

These statements are not bills; they are records of the items and services you received. They will tell you how much your treatment or care costs, how much your plan will pay toward those costs, and how much you may need to pay. Your SOB, EOB, or MSN will also tell you if items and services aren't covered by your health plan.

The information provided in this Summary is communicated verbally by OneSource™ or populated in writing by the payer with information collected from your insurance provider. This document may seem overwhelming and concerning, but it provides a picture of any restrictions that need to be managed.

Prior Authorization (PA)

Your health insurance or plan may require a PA for ULTOMIRIS® (ravulizumab-cwvz) before you can receive an infusion. Following the Benefits Investigation, your doctor's office may need to complete and submit a request for coverage approval from your health plan before you start treatment. PA requirements vary among health plans.

PAs are very common for drugs that treat rare diseases, such as ULTOMIRIS. A PA helps a health plan decide if the treatment is medically necessary, and they also allow health plans to make sure that drugs are being used appropriately.

Documents and information commonly submitted with a PA by your HCP's office may include:


Your medical history


Test results confirming your diagnosis


Any supporting medical articles about the disease and drug


Diagnosis


Baseline functional exam results and any needed baseline labs


Letter of Medical Necessity


A treatment plan to show that the treatment they chose for you is medically necessary and will be used correctly


Patient notes and medical history


Site of care for infusion/ treatment

Medical Exception (ME)

Depending on your health plan's coverage, your physician may need to request an ME for treatment with ULTOMIRIS® (ravulizumab-cwvz). This is a special request for treatment that requires additional paperwork from your doctor's office. ME requests are usually more complex than PAs and may require more specific documentation such as a Letter of Medical Necessity from your doctor's office.

Some states have laws that require health plans to respond to an ME request within a certain time period.

What to Do If Your ME Request Is Denied

There are many reasons that an ME request may be denied. Fortunately, there are several steps you and your doctor's office can take to try to reverse your health plan's decision, such as ask the plan for a peer-to-peer review, file an appeal, or ask for an external review.

Reauthorization

Depending on your coverage, health plans typically approve ULTOMIRIS® (ravulizumab-cwvz) for a certain length of time or number of doses. Patients receiving ULTOMIRIS require ongoing therapy that may continue beyond the initial period approved by your health plan.

Your physician may be able to see if reauthorization is required when they receive the results of your benefits investigation. Sometimes health plans require rare disease drugs, such as ULTOMIRIS, to be renewed after a certain period and require a reauthorization.

Reauthorization periods for ULTOMIRIS may vary among indications and health plans but are usually either for a specified period of time (sometimes 6 months to 1 year) or cover a set number of maintenance doses. Reauthorizations may depend on your clinical response to a specific treatment, and documentation requirements differ for each health plan and for each indication.

What to Do If Your Reauthorization Request Is Denied

There are many reasons that a reauthorization may be denied. Fortunately, there are several steps you and your doctor's office can take to try to reverse your health plan's decision, such as seek a peer-to-peer review, file an appeal, or request for an external review.

The Approval Process

Approval times can vary from plan to plan.

There are several factors that can affect how long it takes for approval, including the Benefits Investigation, completing and submitting a prior authorization form (if required), and the length of the internal review process at your health plan.

If you have more than one insurance plan, a Benefits Investigation must be conducted with each one, and you and your HCP may have to resubmit the necessary paperwork. If your doctor believes the request is urgent, he or she may request an expedited review of the approval request.

Be sure your doctor's office and OneSource™ have all of your health plan and treatment information. Missing or incomplete information can slow down the process.

Health Plan's Coverage Decision

Your health plan will review the information that your doctor's office submits to ensure it meets its coverage requirements. Someone from your plan will contact you and/or your doctor's office with a decision—it is important to communicate this information to your doctor's office as soon as you receive it, and also tell OneSource (if you are enrolled in OneSource).

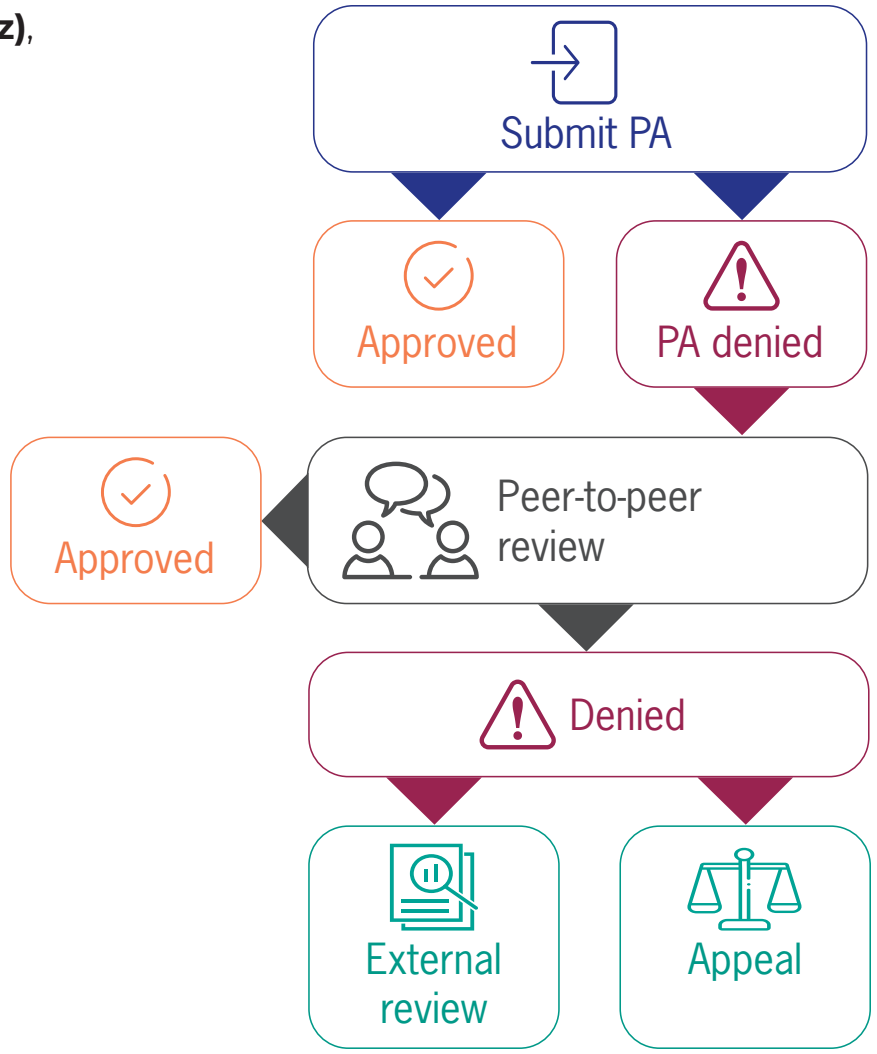
If your request for coverage is denied for some reason, you and your doctor's office can work to appeal the decision.

Denial and Appeal Process

An Overview of the Denial and Appeal Process

If you receive a denial for ULTOMIRIS® (ravulizumab-cwvz), it is important to work with your physician to quickly determine the correct course of action to deal with the denial. Time is of the essence when you are submitting an appeal or pursuing another course of action.

Contact your doctor's office and OneSource™ (if you are an enrolled patient) right away for assistance and to determine the best course of action.



1 Determine the Reason for the Denial

It is important for you to give your denial letter to your physician as he/she will need to review the denial letter as well as the summary of benefits to determine the specific denial reason. Often, a denial is given due to missing or incomplete information. Your physician may be able to provide the missing documentation or correct the information to resubmit within the specified time frame.

An Overview of the Denial and Appeal Process (cont.)

2 Ask Your Physician to Consider a Peer-to-Peer Review

If the reason for denial is misalignment with the clinical policy, your physician may want to consider a peer-to-peer (doctor-to-doctor) review as a next step before submitting a formal appeal. Your role in this step is to work with your physician to determine if this is the appropriate course of action.

If the peer-to-peer discussion does not resolve the denial, your physician may submit an appeal.

3 Appeal Preparation and Submission Process

You and your physician may decide to submit an appeal to your insurance company to reverse its decision and approve the infused specialty drug. This step is generally handled by your physician. Your physician will review the health plan's appeal process and timelines to determine:

- The specific form to be filled out for an appeal
- The health plan's preferred method of appeal (phone or written)
- Which documentation (appeal letter, original claim, etc) should be included
- If an expedited review is available and appropriate for your situation

Expedited Appeal or Review

In urgent situations, your HCP can request an expedited appeal. An expedited appeal may be granted if your physician believes a delay in treatment would be a risk for you, affect your ability to regain maximum function, or subject you to severe pain. Your health plan must make a decision within a specified time frame with this type of appeal.

An Overview of the Denial and Appeal Process (cont.)

4 Follow-up

Your physician should follow up with the health plan to confirm that the appeal was received and to check on the decision.

5 External Review

If the internal appeals process is exhausted, you or your physician can ask for an external review by independent, accredited medical professionals. The health plan's original denial letter you received should describe how to request an external review.

To request an external review, you or your physician must file a written request within the plan's specified time frame. External review decisions are made as soon as possible, but generally take no longer than 60 days from receipt of request.

Your physician should complete the required documents and submit the appeal as per the instructions of the health plan. Please note that the appeal process may take several weeks.

Alexion Resources to Help You

Please see Important Safety Information on pages 2-4 and 40-44 and the full Prescribing Information and Medication Guide for ULTOMIRIS, including Boxed WARNING regarding serious meningococcal infections.

Meet OneSource™

OneSource is a complimentary, personalized patient support program offered by Alexion. It's designed to support your specific needs.

CoPay Program

Alexion ONESOURCE® CoPay Program

The Alexion OneSource™ CoPay Program helps patients pay for eligible out-of-pocket medication and infusion costs.

Program eligibility

✓	Patient enrolled in OneSource™
✓	Patient with commercial insurance who has a valid prescription for a US Food and Drug Administration–approved indication for ULTOMIRIS® (ravulizumab-cwvz)
✓	Patient must reside and receive treatment with a Qualifying Alexion Product in the United States or its territories

CoPay Program (cont.)

How to Apply for the Alexion OneSource™ CoPay Program

Fill out the Alexion OneSource CoPay Program Enrollment Form

The Enrollment Form can be found at AlexionOneSource.com.

Submit form to OneSource

Fill out the form with patient information and fax 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

Have a question? Received an invoice?

Contact OneSource at 1.888.765.4747

INDICATIONS & IMPORTANT SAFETY INFORMATION for ULTOMIRIS

What is ULTOMIRIS?

ULTOMIRIS is a prescription medicine used to treat:

- adults and children 1 month of age and older with a disease called Paroxysmal Nocturnal Hemoglobinuria (PNH).
- 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.

Please see Important Safety Information on pages 2-4 and 40-44 and the full Prescribing Information and Medication Guide for ULTOMIRIS, including Boxed WARNING regarding serious meningococcal infections.

IMPORTANT SAFETY INFORMATION for ULTOMIRIS (cont.)

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.
  2. 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.
  4. 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.

Please see Important Safety Information on pages 2-4 and 40-44 and the full Prescribing Information and Medication Guide for ULTOMIRIS, including Boxed WARNING regarding serious meningococcal infections.

IMPORTANT SAFETY INFORMATION for ULTOMIRIS (cont.)

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.

Please see Important Safety Information on pages 2-4 and 40-44 and the full Prescribing Information and Medication Guide for ULTOMIRIS, including Boxed WARNING regarding serious meningococcal infections.

IMPORTANT SAFETY INFORMATION for ULTOMIRIS (cont.)

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, and are breastfeeding or plan to breastfeed. It is not known if ULTOMIRIS will harm your unborn baby or if it 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 PNH and you stop receiving ULTOMIRIS, your healthcare provider will need to monitor you closely for at least 16 weeks after you stop ULTOMIRIS. Stopping ULTOMIRIS may cause breakdown of your red blood cells due to PNH. Symptoms or problems that can happen due to red blood cell breakdown include: drop in your red blood cell count, tiredness, blood in your urine, stomach-area (abdomen) pain, shortness of breath, blood clots, trouble swallowing, and erectile dysfunction (ED) in males.

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.

Please see Important Safety Information on pages 2-4 and 40-44 and the full Prescribing Information and Medication Guide for ULTOMIRIS, including Boxed WARNING regarding serious meningococcal infections.

IMPORTANT SAFETY INFORMATION for ULTOMIRIS (cont.)

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, abdominal pain, muscle spasms, changes in blood pressure, tiredness, feeling faint, shaking chills (rigors), discomfort in your arms or legs, bad taste, or drowsiness. 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 PNH are upper respiratory tract infection and headache.

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 1-800-FDA-1088.

Please see the accompanying full Prescribing Information and Medication Guide for ULTOMIRIS, including Boxed WARNING regarding serious meningococcal infections.

Please see Important Safety Information on pages 2-4 and 40-44 and the full Prescribing Information and Medication Guide for ULTOMIRIS, including Boxed WARNING regarding serious meningococcal infections.

Appendix

Glossary of Terms

Coinsurance: A fixed percentage of the cost of all services and prescription drugs a policyholder is required to pay. The coinsurance for certain services or prescription drugs may vary.

Coordination of Benefits: When a patient has more than one health plan, a coordination of benefits policy decides which plan pays first. The health plan that pays first is the primary payer or primary insurer, which will likely pay up to a certain amount. The plan that pays the cost not covered by the primary payer (also called the cost gap) is the secondary payer or secondary insurer.

Copayment: A copayment is a fixed dollar amount a policyholder pays for a specific service, procedure, or drug each time he or she receives care or fills a prescription.

Deductible: The out-of-pocket (OOP) expenses a patient must pay before the payer begins paying for healthcare expenses.

Dual Eligibles: People who receive assistance from both Medicare and Medicaid are known as "dual eligibles." Dual eligibles may receive Medicaid benefits plus premium and cost-sharing assistance for drug coverage under Medicare Part D.

Exclusive Provider Organization (EPO): A managed care plan where services are covered only if you use doctors, specialists, or hospitals in the plan's network (except in an emergency).

Formulary: A list of covered drugs under the pharmacy benefit by a health plan. A formulary is organized by tiers, which are generally differentiated by the cost-sharing requirement for the patient.

Group Health Insurance: Is a type of insurance offered through someone's employer. The cost for the monthly premium is generally shared between the employer and employee. There may be an annual enrollment period to select among several health insurance plan options.

Glossary of Terms (cont.)

Health Maintenance Organization (HMO): A type of health insurance plan that usually limits coverage to care from doctors who work for or contract with the HMO. Referrals are generally required for specialists. HMOs also generally won't cover out-of-network care except in an emergency. An HMO may require you to live or work in its service area to be eligible for coverage.

Individual Market Coverage: Is a type of health insurance offered directly from a private health insurance company. Generally, an individual is likely to shop for and purchase an individual plan through an online website for the insurance Marketplace, like healthcare.gov. The enrollment period for the Marketplace is from November 1 to December 15. While an individual will have to pay the entire monthly premium for an individual plan, they may have access to a subsidy to pay for a portion of the monthly premium.

Medicaid: Medicaid is a type of government insurance that provides low-cost or free health coverage to millions of Americans, including eligible low-income adults, children, pregnant women, elderly adults, and people with disabilities. Medicaid is administered by states, according to federal requirements. The program is funded jointly by states and the federal government. Each state has different requirements for income, the number of people in your household, family status, and other factors.

Medical Benefit: The medical benefit typically covers physician and hospital services for things like visits to the doctor, drugs administered by doctors, hospital services and supplies, and some home health services.

Medical Exception: This is a special request for treatment that requires additional paperwork from your doctor's office. Medical exception requests are usually more complex than prior authorizations and may require more specific documentation such as a Letter of Medical Necessity from your doctor's office. Some states have laws that require health plans to respond to a medical exception request within a certain time period.

Medicare: Medicare is a federal system of health insurance for people over 65 years of age, people under age 65 with certain disabilities, and people of any age with end-stage renal (kidney) disease or amyotrophic lateral sclerosis (ALS).

Out-of-Pocket (OOP): Out-of-pocket (OOP) costs typically include a beneficiary's premium, coinsurance or copay, and deductible. There may also be other OOP costs such as a non-covered product or procedure.

Glossary of Terms (cont.)

Pharmacy Benefit: The pharmacy benefit typically covers prescription drugs taken orally and self-administered injectable prescription drugs that are used at home.

Point of Service (POS): A type of plan where you pay less if you use doctors, hospitals, and other healthcare providers that belong to the plan's network. A hybrid of PPOs and HMOs, POS plans require you to get a referral from your primary care doctor in order to see a specialist.

Preferred Provider Organization (PPO): Features a broad choice of network providers with the ability to go out of network for a higher out-of-pocket (OOP) cost. A popular plan type, PPOs are less restrictive than other types, like HMOs, as referrals to providers are usually not required.

Premium: The premium is the monthly fee a policyholder pays for coverage. Policies with lower premiums will likely require policyholders to pay more in the form of deductibles and copayments when they make use of medical services.

Prior Authorization (PA): A PA is a requirement for prescribers or patients to receive approval for access to a covered product, typically based on cost or ensuring that patients meet clinical criteria appropriate for treatment with the product. Prior authorization is often referred to as a PA.

Private Health Insurance: Private health insurance is a type of health insurance plan funded by a private health insurer and not provided by the federal or state government. Generally, an individual may access private health insurance through their employer (or union) or directly from a health insurance company. Private health insurance may also be referred to as "commercial insurance."

Public Health Insurance: Public health insurance is a type of health insurance offered and managed by the federal or state governments. The two primary examples of public health insurance are Medicare and Medicaid.

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US/ALL/0456 V3 3/2024

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