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

A GUIDE TO

COMMON PRIOR AUTHORIZATION CRITERIA FOR ULTOMIRIS® (ravulizumab-cwvz)

For Anti-Acetylcholine Receptor (AChR) Antibody-Positive Generalized Myasthenia Gravis (gMG)

INDICATION

ULTOMIRIS is indicated for the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody-positive.

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS

ULTOMIRIS, a complement inhibitor, increases the risk of serious infections caused by *Neisseria meningitidis* [*see Warnings and Precautions (5.1)*] Life-threatening and fatal meningococcal infections have occurred in patients treated with complement inhibitors. These infections may become rapidly life-threatening or fatal if not recognized and treated early.

- **Complete or update vaccination for meningococcal bacteria (for serogroups A, C, W, Y, and B) at least 2 weeks prior to the first dose of ULTOMIRIS, unless the risks of delaying ULTOMIRIS therapy outweigh the risk of developing a serious infection. Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against meningococcal bacteria in patients receiving a complement inhibitor. See *Warnings and Precautions (5.1)* for additional guidance on the management of the risk of serious infections caused by meningococcal bacteria.**
- **Patients receiving ULTOMIRIS are at increased risk for invasive disease caused by *Neisseria meningitidis,* even if they develop antibodies following vaccination. Monitor patients for early signs and symptoms of serious meningococcal infections and evaluate immediately if infection is suspected.**

Because of the risk of serious meningococcal infections, ULTOMIRIS is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called ULTOMIRIS and SOLIRIS REMS [*see Warnings and Precautions (5.2)*].

Please see Important Safety Information on page 1 and pages 5-6 and full Prescribing Information for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

COMMON PRIOR AUTHORIZATION CRITERIA FOR ULTOMIRIS® (ravulizumab-cwvz) FOR THE TREATMENT OF ANTI-AChR ANTIBODY-POSITIVE gMG

Many commercial, Medicare Advantage, and Managed Medicaid plans require prior authorization (PA) or precertification for use of ULTOMIRIS in anti-AChR antibody-positive gMG. Although requirements vary by plan, there are common criteria that may be used for ULTOMIRIS. Please verify current requirements for ULTOMIRIS for anti-AChR antibody-positive gMG, including whether a PA is required, with each individual plan.

PA Process Tips

Contact your Alexion Field Reimbursement Manager for information about plan-specific PA requirements or general questions about submitting PA requests.

For personalized support on behalf of a specific patient, the patient must enroll in OneSource™ and provide consent for these optional services. Your Field Reimbursement Manager will be able to provide educational support for the above services once the enrollment form is submitted and approved.

WHEN A PLAN MEMBER IS A CANDIDATE FOR ULTOMIRIS FOR ANTI-AChR ANTIBODY-POSITIVE gMG BASED ON PAYER CRITERIA

Medicare Part A and Medicare Part B Plans

Medicare Part A and Part B may not require PA for beneficiaries to receive ULTOMIRIS. However, you should always verify benefits before ordering ULTOMIRIS and initiating treatment.

Commercial, Medicare Advantage, and Managed Medicaid Plans

Below are common criteria that are required by many commercial, Medicare Advantage, and Managed Medicaid plans.

Date of Birth

- Only adult patients are eligible to receive ULTOMIRIS

Relevant Lab Results for gMG

- Because ULTOMIRIS is approved only for anti-AChR antibody-positive gMG, a positive serologic test for anti-AChR antibodies must be documented

Clinical Findings (both required)

- Member meets Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV criteria
- Member has a Myasthenia Gravis-Specific Activities of Daily Living (MG-ADL) total score ≥6

Thymectomy Criteria for gMG (only for select regional plans)

- Medical documentation of thymectomy if patient is 50 years of age or younger or has a thymoma

Prior Treatment Failure, Intolerance, or Contraindications

Medical record documentation of therapeutic failure, intolerance, or contraindication:

- 2 or more immunosuppressive agents used alone or in combination (eg, azathioprine, cyclophosphamide, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus) for 12 months, OR
- 1 or more immunosuppressive agents as either monotherapy or combination therapy and required chronic plasmapheresis or plasma exchange over the preceding 12 months
- Some plans may also require medical record documentation of therapeutic failure, intolerance, or contraindication to monotherapy or combination therapy with corticosteroids, cholinesterase inhibitors, efgartigimod alfa-fcab or efgartigimod alfa and hyaluronidase-qvfc, rituximab, or intravenous immunoglobulin (IVIg)

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Who May Prescribe?

- Some plans require that ULTOMIRIS® (ravulizumab-cwvz) be prescribed by or in consultation with a neurologist, neuromuscular specialist, or other specialist for the treatment of anti-AChR antibody-positive gMG
- ULTOMIRIS is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS). Under the REMS, prescribers must enroll in the program. Proof of prescriber's REMS certification for ULTOMIRIS for anti-AChR antibody-positive gMG may be required

Coding for ULTOMIRIS in Anti-AChR Antibody-Positive gMG

ICD-10-CM diagnosis codes

G70.00	Myasthenia gravis without (acute) exacerbation
G70.01	Myasthenia gravis with (acute) exacerbation

HCPCS code*

J1303	Injection, ravulizumab-cwvz, 10 mg

CPT codes for drug administration

96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis; initial, up to 1 hour
+ 96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (list separately in addition to primary procedure)
96413†	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
+ 96415†	Chemotherapy administration, intravenous infusion technique; each additional hour (list separately in addition to primary procedure)

For comprehensive Coding & Billing guidance, please refer to the CODING AND BILLING GUIDE FOR THE USE OF ULTOMIRIS In Adult Patients With Generalized Myasthenia Gravis (gMG) Who Are Anti-Acetylcholine Receptor (AChR) Antibody-Positive.

Additional Information That May Be Required

- Documentation, including attestation and dates, that the member has received meningococcal vaccinations at least 2 weeks prior to treatment if not previously vaccinated
  - Refer to the most current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccinations in patients with persistent complement component deficiencies or in patients receiving complement inhibitors, including patients receiving ULTOMIRIS
- Physician statement documenting that the patient does not have an active meningococcal infection
- Other lab results or clinical findings, including history of abnormal neuromuscular transmission test demonstrated by single-fiber electromyography or repetitive nerve stimulation, history of positive anticholinesterase test (eg, edrophonium chloride test), demonstrated signs of improvement in myasthenia gravis on oral cholinesterase inhibitors
- Physician assessment of the baseline Quantitative Myasthenia Gravis total score
- The prescription is prescribed by or in consultation with a neurologist

Important Reminder

In order to facilitate a timely review of the PA request when one is required, be sure to submit all requisite documentation together with the fully completed PA/precertification form.

Providers are responsible for timely and accurate submission of PA requests. Alexion Pharmaceuticals does not make any representation or guarantee concerning reimbursement or coverage for any service or item.

CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification.
*Applies to all available ULTOMIRIS vials/National Drug Codes.
†Billing highly complex administration codes (96413 and 96415) requires the provider in the medical record to document the complexity beyond what is required for therapeutic infusions (96365 and 96366).
Source: Information is based on a review of 2023 Medicare Part A coverage and PA criteria for national and large regional US commercial, Medicare Part B, and Medicare Advantage plans. Please check with the individual payer for specific coverage information because coverage policies change, and information can vary.

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KEY RESOURCES AVAILABLE TO YOU

- Connect with an FRM—Alexion Field Reimbursement Managers (FRMs) provide education and support to healthcare provider offices to facilitate patient access to their prescribed Alexion medications
- The ULTOMIRIS gMG Sample Letter of Medical Necessity resource provides a template for responding to a request for letter of medical necessity from a patient's insurance
- The ULTOMIRIS gMG Sample Appeal Letter resource provides a template to appeal a rejection from a patient's insurance

For additional access resources, please visit:

Explore Alexion Access Navigator

ALEXION ACCESS NAVIGATOR

Alexion Access Navigator is a dedicated resource website for US Healthcare Professionals and their offices that contains downloadable access and reimbursement materials for ULTOMIRIS® (ravulizumab-cwvz).

Online: https://alexionaccessnavigator.com

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IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- Initiation in patients with unresolved serious *Neisseria meningitidis* infection.

WARNINGS AND PRECAUTIONS

Serious Meningococcal Infections

ULTOMIRIS, a complement inhibitor, increases a patient's susceptibility to serious, life-threatening, or fatal infections caused by meningococcal bacteria (septicemia and/or meningitis) in any serogroup, including non-groupable strains. Life-threatening and fatal meningococcal infections have occurred in both vaccinated and unvaccinated patients treated with complement inhibitors.

Revaccinate patients in accordance with ACIP recommendations considering the duration of ULTOMIRIS therapy. Note that ACIP recommends an administration schedule in patients receiving complement inhibitors that differs from the administration schedule in the vaccine prescribing information. If urgent ULTOMIRIS therapy is indicated in a patient who is not up to date with meningococcal vaccines according to ACIP recommendations, provide antibacterial drug prophylaxis and administer meningococcal vaccines as soon as possible. Various durations and regimens of antibacterial drug prophylaxis have been considered, but the optimal durations and drug regimens for prophylaxis and their efficacy have not been studied in unvaccinated or vaccinated patients receiving complement inhibitors, including ULTOMIRIS. The benefits and risks of treatment with ULTOMIRIS, as well as those associated with antibacterial drug prophylaxis in unvaccinated or vaccinated patients, must be considered against the known risks for serious infections caused by *Neisseria meningitidis*.

Vaccination does not eliminate the risk of serious meningococcal infections, despite development of antibodies following vaccination.

Closely monitor patients for early signs and symptoms of meningococcal infection and evaluate patients immediately if infection is suspected. Inform patients of these signs and symptoms and instruct patients to seek immediate medical care if they occur. Promptly treat known infections. Meningococcal infection may become rapidly life-threatening or fatal if not recognized and treated early. Consider interruption of ULTOMIRIS in patients who are undergoing treatment for serious meningococcal infection depending on the risks of interrupting treatment in the disease being treated.

ULTOMIRIS and SOLIRIS REMS

Due to the risk of serious meningococcal infections, ULTOMIRIS is available only through a restricted program called ULTOMIRIS and SOLIRIS REMS.

Prescribers must enroll in the REMS, counsel patients about the risk of serious meningococcal infection, provide patients with the REMS educational materials, assess patient vaccination status for meningococcal vaccines (against serogroups A, C, W, Y, and B) and vaccinate if needed according to current ACIP recommendations two weeks prior to the first dose of ULTOMIRIS. Antibacterial drug prophylaxis must be prescribed if treatment must be started urgently, and the patient is not up to date with both meningococcal vaccines according to current ACIP recommendations at least two weeks prior to the first dose of ULTOMIRIS. Patients must receive counseling about the need to receive meningococcal vaccines and to take antibiotics as directed, signs and symptoms of meningococcal infection, and be instructed to carry the Patient Safety Card at all times during and for 8 months following ULTOMIRIS treatment.

Further information is available at www.UltSolREMS.com or 1-888-765-4747.

Other Infections

Serious infections with *Neisseria* species (other than *Neisseria meningitidis*), including disseminated gonococcal infections, have been reported.

ULTOMIRIS blocks terminal complement activation; therefore, patients may have increased susceptibility to infections, especially with encapsulated bacteria, such as infections caused by *Neisseria meningitidis* but also *Streptococcus pneumoniae*, *Haemophilus influenzae*, and to a lesser extent, *Neisseria gonorrhoeae*. Patients receiving ULTOMIRIS are at increased risk for infections due to these organisms, even if they develop antibodies following vaccination.

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IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS (CONTINUED)

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
Intravenous administration 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 treated with ULTOMIRIS. These events included lower back pain, drop in blood pressure, limb discomfort, drug hypersensitivity (allergic reaction), dysgeusia (bad taste), and drowsiness. These reactions did not require discontinuation of ULTOMIRIS. If signs of cardiovascular instability or respiratory compromise occur, interrupt ULTOMIRIS infusion and institute appropriate supportive measures.

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.

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.

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