



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**

INDICATION

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

SELECT IMPORTANT SAFETY INFORMATION

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.

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 REMS.

Please see Important Safety Information on pages [1](#) and [10-11](#) and the accompanying full [Prescribing Information](#) for ULTOMIRIS® (ravulizumab-cwvz), including Boxed WARNING regarding serious and life-threatening meningococcal infections/sepsis.

Product Overview¹

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

ULTOMIRIS is administered as an intravenous (IV) infusion with a weight-based dosing regimen.

ULTOMIRIS is supplied in 2 vial sizes:

- 1100 mg/11 mL single-dose vial
- 300 mg/3 mL single-dose vial

Infusions for gMG usually occur in a physician office, infusion center, hospital outpatient clinic, or patient home.

Purpose of This Guide

Alexion Pharmaceuticals, Inc. has developed the ULTOMIRIS Coding and Billing Guide to provide objective and publicly available coding and billing information.

This document is provided for informational purposes only and is not legal advice or official guidance from payers. It is not intended to increase or maximize reimbursement by any payer. Alexion does not warrant, promise, guarantee, or make any statement that the use of this information will result in coverage or payment for ULTOMIRIS or that any payment received will cover providers' costs. Alexion is not responsible for any action providers take in billing for, or appealing, ULTOMIRIS claims.

Hospitals and physicians are responsible for compliance with Medicare and other payer rules and requirements and for the information submitted with all claims and appeals. Before any claims or appeals are submitted, hospitals and physicians should review official payer instructions and requirements, should confirm the accuracy of their coding or billing practices with these payers, and should use independent judgment when selecting codes that most appropriately describe the services or supplies provided to a patient.

Please visit www.ULTOMIRIS.com for additional information, or call 1-888-765-4747 to speak with the Alexion OneSource[™] Team.

Please see Important Safety Information on pages [1](#) and [10-11](#) and the accompanying full [Prescribing Information](#) for ULTOMIRIS[®] (ravulizumab-cwvz), including **Boxed WARNING regarding serious and life-threatening meningococcal infections/sepsis.**

Coding for ULTOMIRIS® (ravulizumab-cwvz) in Adult Patients with Anti-AChR Antibody-Positive gMG

Diagnosis Coding

The following *International Classification of Diseases, 10th Revision, Clinical Modification* (ICD-10-CM) codes may be appropriate to describe adult patients diagnosed with gMG who are anti-AChR antibody-positive:

ICD-10-CM Diagnosis Code ²	Code Descriptor
G70.00	Myasthenia gravis without (acute) exacerbation
G70.01	Myasthenia gravis with (acute) exacerbation

Drug Coding

The following drug-specific Healthcare Common Procedure Coding System (HCPCS) billing code can be reported on medical claim forms to payers:

HCPCS Code ^{3,a}	Code Descriptor
J1303	Injection, ravulizumab-cwvz, 10 mg

^aApplies to all available ULTOMIRIS vials/National Drug Codes (NDCs).

Some payers may also require the use of HCPCS modifier -RE to indicate ULTOMIRIS was administered in full compliance with the REMS program.

Some payers, including Medicaid, require drugs like ULTOMIRIS to be billed on medical claims with the product's NDC in addition to the HCPCS code. Payers typically require healthcare professionals to use the Health Insurance Portability and Accountability Act (HIPAA)-compliant, 11-digit NDC format⁴:

11-Digit NDC ^{1,4}	Code Descriptor	Strength
25682-0025-01	ULTOMIRIS (ravulizumab-cwvz, single-use vial)	300 mg/3 mL
25682-0028-01	ULTOMIRIS (ravulizumab-cwvz, single-use vial)	1100 mg/11 mL

Please note that payers have different guidance for placement of the NDC on medical claims. Typically, the 11-digit NDC is reported without any dashes or other punctuation.⁴

Please see Important Safety Information on pages [1](#) and [10-11](#) and the accompanying full [Prescribing Information](#) for ULTOMIRIS® (ravulizumab-cwvz), including **Boxed WARNING** regarding serious and life-threatening meningococcal infections/sepsis.

Coding for ULTOMIRIS® (ravulizumab-cwvz) in Anti-AChR Antibody-Positive gMG

Drug Administration Services

Payers may offer separate coverage and reimbursement for drug administration services. The following are possible ICD, 10th Revision, Procedure Coding System (ICD-10-PCS) procedure codes to report the administration of ULTOMIRIS in inpatient settings:

ICD-10-PCS ⁵	Code Descriptor
3E0330M	Introduction of monoclonal antibody into peripheral vein, percutaneous approach
3E0430M	Introduction of monoclonal antibody into central vein, percutaneous approach
3E033GC	Introduction of other therapeutic substance into peripheral vein, percutaneous approach
3E043GC	Introduction of other therapeutic substance into central vein, percutaneous approach

The following Current Procedural Terminology (CPT®) codes may be appropriate to report administration of ULTOMIRIS in physician offices and hospital outpatient facilities. Individual payer policies should be reviewed for reporting requirements.

CPT Code ⁶	Code Descriptor
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis; initial, up to one hour
+ 96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (list separately in addition to primary procedure)
96413 ^a	Chemotherapy administration, intravenous infusion technique, up to one hour, single or initial substance/drug
+ 96415 ^a	Chemotherapy administration, intravenous infusion technique; each additional hour (list separately in addition to primary procedure)

^aBilling 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).⁷

Please see Important Safety Information on pages [1](#) and [10-11](#) and the accompanying full [Prescribing Information](#) for ULTOMIRIS® (ravulizumab-cwvz), including **Boxed WARNING** regarding serious and life-threatening meningococcal infections/sepsis.

Coding for Meningococcal Vaccination

Diagnosis Coding

For an encounter strictly for the vaccination, the diagnosis code for prophylactic vaccination is assigned along with the diagnosis code for gMG and any other conditions the patient may have.

ICD-10-CM Diagnosis Code ²	Code Descriptor
Z23	Encounter for immunization

Vaccine Coding

Coverage of meningococcal vaccines may vary by payer. Prescribers should consult respective payer billing guidelines.

CPT Code ⁶	Code Descriptor
90619	Meningococcal conjugate vaccine, serogroups A, C, W, Y, quadrivalent, tetanus toxoid carrier (MenACWY-TT), for intramuscular use
90620	Meningococcal recombinant protein and outer membrane vesicle vaccine, serogroup B (MenB-4C), 2-dose schedule, for intramuscular use
90621	Meningococcal recombinant lipoprotein vaccine, serogroup B (MenB-FHbp), 2- or 3-dose schedule, for intramuscular use
90733	Meningococcal polysaccharide vaccine, serogroups A, C, Y, W-135, quadrivalent (MPSV4), for subcutaneous use
90734	Meningococcal conjugate vaccine, serogroups A, C, W, Y, quadrivalent, diphtheria toxoid carrier (MenACWY-D) or CRM197 carrier (MenACWY-CRM), for intramuscular use

Vaccine Administration Coding

The following CPT codes may be appropriate to report administration of meningococcal vaccines in outpatient settings.

CPT Code ⁶	Code Descriptor
90471	Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); 1 vaccine (single or combination vaccine/toxoid)
+ 90472	Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); each additional vaccine (single or combination vaccine/toxoid) (List separately in addition to code for primary procedure)

Please see Important Safety Information on pages [1](#) and [10-11](#) and the accompanying full [Prescribing Information](#) for ULTOMIRIS® (ravulizumab-cwvz), including **Boxed WARNING** regarding serious and life-threatening meningococcal infections/sepsis.

Claim Forms

Sample CMS-1500 (or the electronic equivalent 837P): Physician Office⁸

For an example of a completed CMS-1500 form, go to [page 7](#).

- Item 21 Diagnosis:** Enter the appropriate diagnosis code, eg,
- ICD-10-CM **G70.00** for myasthenia gravis without (acute) exacerbation
 - ICD-10-CM **G70.01** for myasthenia gravis with (acute) exacerbation

Note: Other diagnosis codes may apply.

Item 23 Prior Authorization: Enter the prior authorization number assigned by the payer.

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE										17a.		17b. NPI		18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES				20. OUTSIDE LAB?		\$ CHARGES		
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)														FROM MM DD YY TO MM DD YY				<input type="checkbox"/> YES <input type="checkbox"/> NO				
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.														22. RESUBMISSION CODE				ORIGINAL REF. NO.				
A. _____ B. _____ C. _____ D. _____														23. PRIOR AUTHORIZATION NUMBER								
E. _____ F. _____ G. _____ H. _____																						
I. _____ J. _____ K. _____ L. _____																						
24. A. DATE(S) OF SERVICE		B. PLACE OF SERVICE		C. EMG		D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances)				E. DIAGNOSIS POINTER		F. \$ CHARGES		G. DAYS OR UNITS		H. PSOT family Plan		I. ID. QUAL.		J. RENDERING PROVIDER ID. #		
From To		SERVICE				CPT/HCPCS MODIFIER																
MM DD YY MM DD YY																						
1																						
2																						
3																						
4																						
5																						
6																						

Item 24A Date(s) of Service: Enter the NDC number in the shaded area and the month, day, and year in the white space below.

Note: Check payer requirements and format for reporting NDC.

Item 24D Procedures/ Services/Supplies: Enter the appropriate CPT/HCPCS codes and modifiers, eg,

- Drug: **J1303** for ULTOMIRIS[®] (ravulizumab-cwvz) per 10 mg
- Administration: **96365** for IV infusion

Note: Some payers may provide specific guidance.

Item 24E Diagnosis Pointer: Enter the letter (A-J) that corresponds to the diagnosis in Item 21.

Item 24G Units: Enter the appropriate number of units of service, eg, ULTOMIRIS 3000 mg is reported with "300" units.

Please see Important Safety Information on pages [1](#) and [10-11](#) and the accompanying full [Prescribing Information](#) for ULTOMIRIS[®] (ravulizumab-cwvz), including Boxed WARNING regarding serious and life-threatening meningococcal infections/sepsis.

Sample CMS-1500 (or the electronic equivalent 837P): Physician Office⁸

Example claim form for an ULTOMIRIS[®] (ravulizumab-cwvz) IV infusion:

To achieve an ULTOMIRIS loading dose of 3000 mg for a patient ≥100 kg, the following vial combination was used:

- 10 single-dose 300 mg/3 mL vials (NDC 25682-0025-01)

Item 21 Diagnosis: Enter the appropriate diagnosis code, eg,
 - ICD-10-CM **G70.00** for myasthenia gravis without (acute) exacerbation
 - ICD-10-CM **G70.01** for myasthenia gravis with (acute) exacerbation

Note: Other diagnosis codes may apply.

Item 23 Prior Authorization: Enter the prior authorization number as obtained prior to services rendered.

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE										17a.		18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES									
										17b. NPI		FROM MM DD YY					TO MM DD YY				
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)										20. OUTSIDE LAB? <input type="checkbox"/> YES <input type="checkbox"/> NO					\$ CHARGES						
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.										22. RESUBMISSION CODE					ORIGINAL REF. NO.						
A. G70.00 B. C. D.										23. PRIOR AUTHORIZATION NUMBER											
E. F. G. H.																					
I. J. K. L.																					
24. A. DATE(S) OF SERVICE		B. PLACE OF SERVICE		C. EMG		D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS MODIFIER				E. DIAGNOSIS POINTER		F. \$ CHARGES		G. DAYS OR UNITS		H. PSOT family Plan		I. ID. QUAL.		J. RENDERING PROVIDER ID. #	
From To																					
MM DD YY MM DD YY		MM DD YY		11		N425682002501 J1303				A		XXX XX		300		NPI					
MM DD YY MM DD YY		11		96365				A		XXX XX		1		NPI							
MM DD YY MM DD YY														NPI							

Item 24A Date(s) of Service: Enter the NDC number in the shaded area and the month, day, and year in the white space below. The “N4” qualifier is required before the NDC; do not include dashes.

Note: Check payer requirements and format for reporting NDC.

Item 24D Procedures/ Services/Supplies: Enter the appropriate CPT/HCPCS codes and modifiers, eg,

- Drug: **J1303** for ULTOMIRIS (ravulizumab-cwvz) per 10 mg
- Administration: **96365** for IV infusion

Note: Some payers may provide specific guidance.

Item 24E Diagnosis Pointer: Enter the letter (A-J) that corresponds to the diagnosis in Item 21.

Item 24G Units: Enter the appropriate number of units of service, eg, ULTOMIRIS 3000 mg is reported with “300” units.

Please see Important Safety Information on pages **1** and **10-11** and the accompanying full **Prescribing Information** for ULTOMIRIS[®] (ravulizumab-cwvz), including **Boxed WARNING** regarding serious and life-threatening meningococcal infections/sepsis.

Sample CMS-1450 (UB-04) (or the electronic equivalent 837I): Hospital Outpatient Clinic or Facility⁹

For an example of a completed CMS-1450 form, go to [page 9](#).

Form Locator 42 Revenue Code: Enter the appropriate revenue code, eg,
 - **0636** for ULTOMIRIS® (ravulizumab-cwvz)
 - **0260** for IV infusion
Note: Other revenue codes may apply.

Form Locator 46 Units of Service:
 Enter the appropriate number of units of service, eg, ULTOMIRIS 3000 mg is reported with “300” units.

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES
1						
2						
3						
4						
5						
6						
7						
8						

Form Locator 43 Revenue Description:
 Enter the corresponding code description for the HCPCS listed in Form Locator 44. Enter the NDC number in Form Locator 43.
Note: Check payer requirements and format for reporting NDC.

Form Locator 44 HCPCS: Enter the appropriate CPT/HCPCS codes and modifiers, eg,
 - Drug: **J1303** for ULTOMIRIS (ravulizumab-cwvz) per 10 mg
 - Administration: **96365** for IV infusion
Note: Some payers may provide specific guidance.

19						
20						
21						
22						
23						

PAGE ____ OF ____ CREATION DATE TOTALS

50 PAYER NAME	51 HEALTH PLAN ID	52 REL INFO	53 ASG BEN	54 PRIOR PAYMENTS	55 EST. AMOUNT DUE	56 NPI
						57

Form Locator 67 Principal Diagnosis Code and 67A-67Q Other Diagnosis Codes: Enter the appropriate diagnosis code, eg,
 - ICD-10-CM **G70.00** for myasthenia gravis without (acute) exacerbation
 - ICD-10-CM **G70.01** for myasthenia gravis with (acute) exacerbation
Note: Other diagnosis codes may apply.

58 INSURED'S NAME	59	60	61	62	63	64	65	66	67	68	69	70	71	72	73

67	A	B	C	D	E	F	G	H
	J	K	L	M	N	O	P	Q

69 ADMIT DX	70 PATIENT REASON DX	a.	b.	71 PPS CODE	72 ECI	73

74 PRINCIPAL PROCEDURE CODE	75	76 ATTENDING NPI	QUAL

Please see Important Safety Information on pages [1](#) and [10-11](#) and the accompanying full [Prescribing Information](#) for ULTOMIRIS® (ravulizumab-cwvz), including **Boxed WARNING** regarding serious and life-threatening meningococcal infections/sepsis.

Sample CMS-1450 (UB-04) (or the electronic equivalent 837I): Hospital Outpatient Clinic or Facility⁹

Example claim form for an ULTOMIRIS[®] (ravulizumab-cwvz) IV infusion:

To achieve an ULTOMIRIS loading dose of 3000 mg for a patient ≥100 kg, the following vial combination was used:

- 10 single-dose 300 mg/3 mL vials (NDC 25682-0025-01)

Form Locator 42 Revenue Code: Enter the appropriate revenue code, eg,

- **0636** for ULTOMIRIS
- **0260** for IV infusion

Note: Other revenue codes may apply.

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES
0636	ULTOMIRIS N425682002501	J1303	MM DD YY	300	XXX XX	
0260	Intravenous infusion, initial, up to 1 hour	96365	MM DD YY	1	XXX XX	

<p>Form Locator 43 Revenue Description: Enter the corresponding code description for the HCPCS listed in Form Locator 44. Enter the NDC number in Form Locator 43.</p> <ul style="list-style-type: none"> - The "N4" qualifier is required before the NDC; do not include dashes. <p><i>Note: Check payer requirements and format for reporting NDC.</i></p>		<p>Form Locator 44 HCPCS: Enter the appropriate CPT/HCPCS codes and modifiers, eg,</p> <ul style="list-style-type: none"> - Drug: J1303 for ULTOMIRIS (ravulizumab-cwvz) per 10 mg - Administration: 96365 for IV infusion <p><i>Note: Some payers may provide specific guidance.</i></p>		<p>Form Locator 46 Units of Service: Enter the appropriate number of units of service, eg, ULTOMIRIS 3000 mg is reported with "300" units.</p>	
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PAGE ____ OF ____		CREATION DATE		TOTALS →	
50 PAYER NAME		51 HEALTH PLAN ID		52 REL INFO	53 ASG BEN.
A		B		54 PRIOR PAYMENTS	
B		C		55 EST. AMOUNT DUE	
C		D		56 NPI	
A		B		57 OTHER PRV ID	
B		C		62 INSURANCE GROUP NO.	
C		D		65 EMPLOYER NAME	
A		B		68	
B		C		69 ADMIN DX	
C		D		70 PATIENT REASON DX	
A		B		71 HIPPS CODE	
B		C		72 ECI	
C		D		73	

<p>Form Locator 67 Principal Diagnosis Code and 67A-67Q Other Diagnosis Codes: Enter the appropriate diagnosis code, eg,</p> <ul style="list-style-type: none"> - ICD-10-CM G70.00 for myasthenia gravis without (acute) exacerbation - ICD-10-CM G70.01 for myasthenia gravis with (acute) exacerbation <p><i>Note: Other diagnosis codes may apply.</i></p>	
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66 DX	G70.00	A	B	C	D	E	F	G	H	68
69 ADMIN DX		a	b	c			a	b	c	73

Please see Important Safety Information on pages 1 and 10-11 and the accompanying full Prescribing Information for ULTOMIRIS[®] (ravulizumab-cwvz), including Boxed WARNING regarding serious and life-threatening meningococcal infections/sepsis.



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.

Online: <https://alexionaccessnavigator.com>

OneSource™ Offers Patient Support

Contact OneSource™:

Phone:
1-888-765-4747

Online:
<https://alexiononesource.com>

SELECT IMPORTANT SAFETY INFORMATION (cont.)

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

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.

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

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.

Please see Important Safety Information on pages [1](#) and [10-11](#) and the accompanying full [Prescribing Information](#) for ULTOMIRIS® (ravulizumab-cwvz), including **Boxed WARNING** regarding serious and life-threatening meningococcal infections/sepsis.

SELECT IMPORTANT SAFETY INFORMATION (cont.)

WARNINGS AND PRECAUTIONS (CONT.)

ULTOMIRIS REMS

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

Under the ULTOMIRIS REMS, prescribers must enroll in the program. Prescribers must counsel patients about the risk of meningococcal infection/sepsis, provide the patients with the REMS educational materials, and ensure patients are vaccinated with meningococcal vaccines.

Additional information on the REMS requirements is available at www.ultomirisrems.com or 1-888-765-4747.

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.

Infusion-Related Reactions

Intravenous administration of ULTOMIRIS may result in systemic infusion-related reactions, including anaphylaxis and hypersensitivity reactions. In clinical trials, infusion-related reactions occurred in approximately 1% of patients treated with ULTOMIRIS. These events included lower back pain, drop in blood pressure, elevation 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 $\geq 10\%$) 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.

Please see Important Safety Information on pages 1 and 10-11 and the accompanying full [Prescribing Information](#) for ULTOMIRIS® (ravulizumab-cwvz), including Boxed WARNING regarding serious and life-threatening meningococcal infections/sepsis.

References

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Please see Important Safety Information on pages [1](#) and [10-11](#) and the accompanying full [Prescribing Information](#) for ULTOMIRIS® (ravulizumab-cwvz), including **Boxed WARNING regarding serious and life-threatening meningococcal infections/sepsis.**