Featuring additional data from CHAMPION-MG's randomized controlled period (RCP) and open-label extension (OLE) studies

For your adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody-positive[1]

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

Control the symptom journey ahead[1-4,a]

[a]Based on the MG-ADL, a categorical scale that assesses the impact on daily function of 8 signs or symptoms that are typically affected in gMG.[1]

MG-ADL, Myasthenia Gravis Activities of Daily Living.

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

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)*].

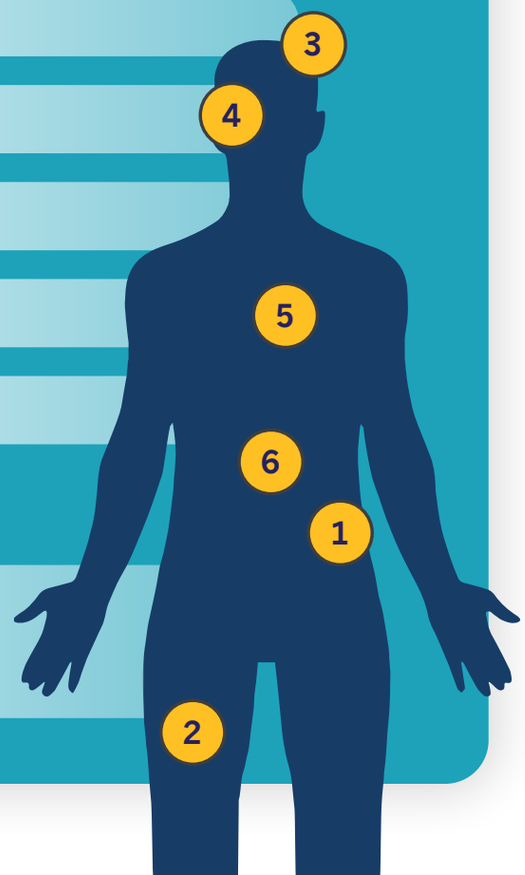
Please see additional Important Safety Information throughout and full Prescribing Information for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

Corticosteroids are a widely prescribed first-line immunotherapy, but come with risks[5-7]

These risks come with long-term use. It's important to consider dose reduction and discontinuation when treating with corticosteroids.[5,6]

Adverse events associated with long-term corticosteroid use include[6]

1. Metabolic conditions (weight gain, hyperglycemia, diabetes)
2. Osteoporosis
3. Neuropsychiatric symptoms
4. Ophthalmologic conditions
5. Cardiovascular issues (hypertension and arrhythmias)
6. Gastrointestinal issues

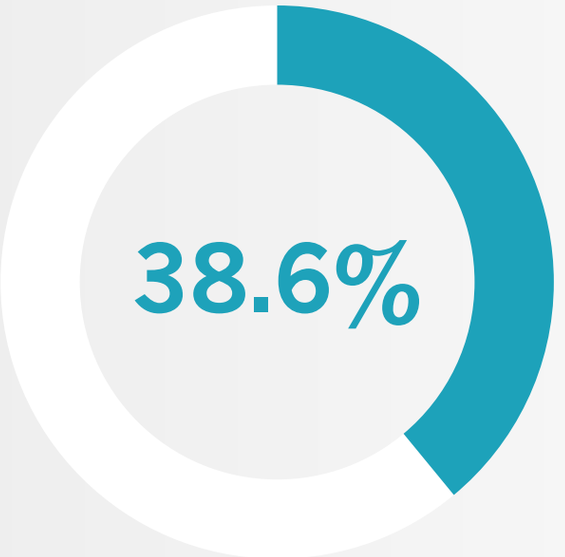


Additional systemic adverse events[6]

- Electrolyte imbalances
- Increased risk of infection
- Myopathy

Are conventional treatments working for your patients?

Under the threat of breakthrough symptoms, your patients with gMG need symptom control as early as possible[8,9]



of patients may experience MG-related hospitalizations, most striking within the first 2-3 years of disease onset.[9,a]

Not all patients experience an improvement in symptoms.[8,9]

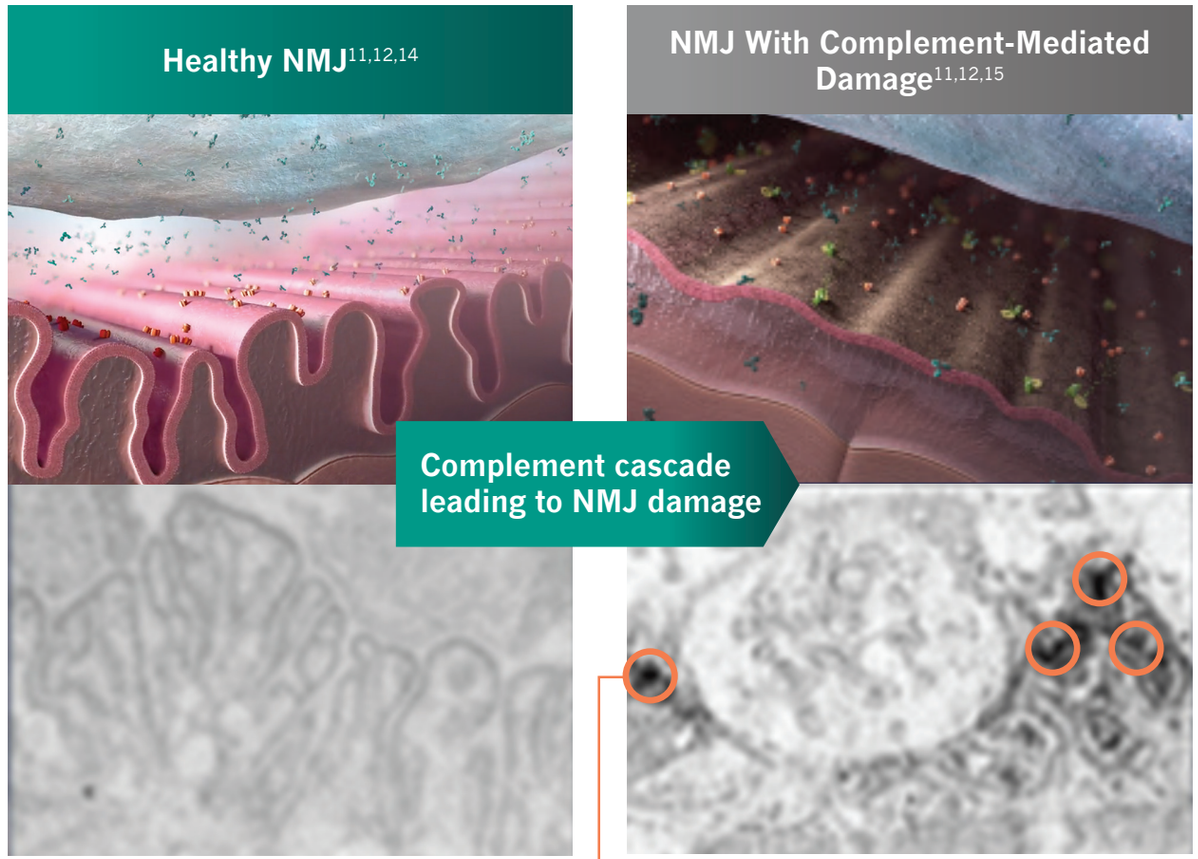
[a]This retrospective longitudinal cohort study evaluated 1149 adult patients with gMG living in England, using data recorded from 1997 to 2016.[9]

gMG, generalized myasthenia gravis; MG, myasthenia gravis.

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

In gMG, the complement cascade causes damage at the NMJ[10-12]

Alteration of folds in the muscle membrane reduces the efficiency of neuromuscular transmission[13]



Typical folds in the muscle membrane

Simplified membrane morphology
Circled areas indicate deposition of C9 (MAC component).

gMG, generalized myasthenia gravis; MAC, membrane attack complex; NMJ, neuromuscular junction.

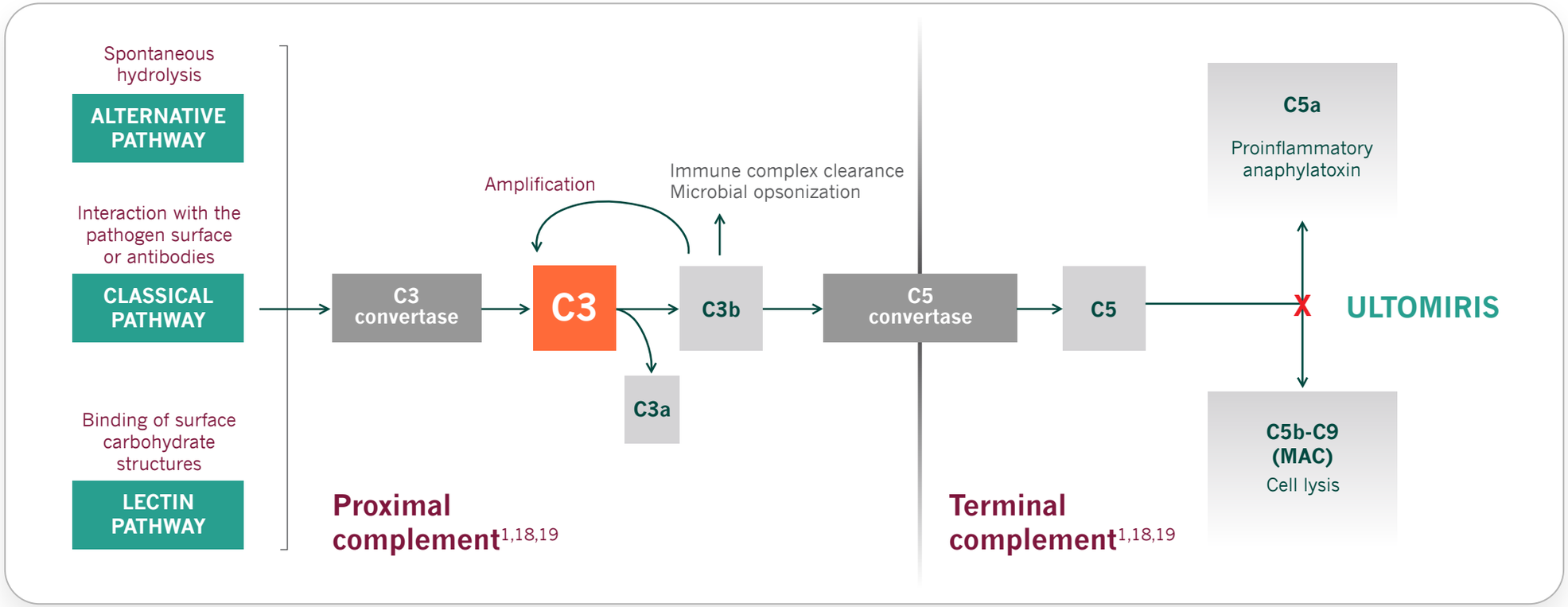
Left image: Reprinted from *Mayo Clin Proc*, 52(5), Engel AG, et al. 267-280. © 2009, with permission from Elsevier.

Right image: Sahashi K, et al. *J Neuropathol Exp Neurol*. 1980;39(2):160-172. © 1980 by permission of Oxford University Press.

The first and only long-acting complement C5 inhibitor[1,16,17]

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

ULTOMIRIS® inhibits the complement protein C5—a key driver of damage to the NMJ in gMG[1,13]



The precise mechanism by which ULTOMIRIS exerts its therapeutic effect in gMG patients is not known.[1]

gMG, generalized myasthenia gravis; MAC, membrane attack complex; NMJ, neuromuscular junction.

SELECT IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

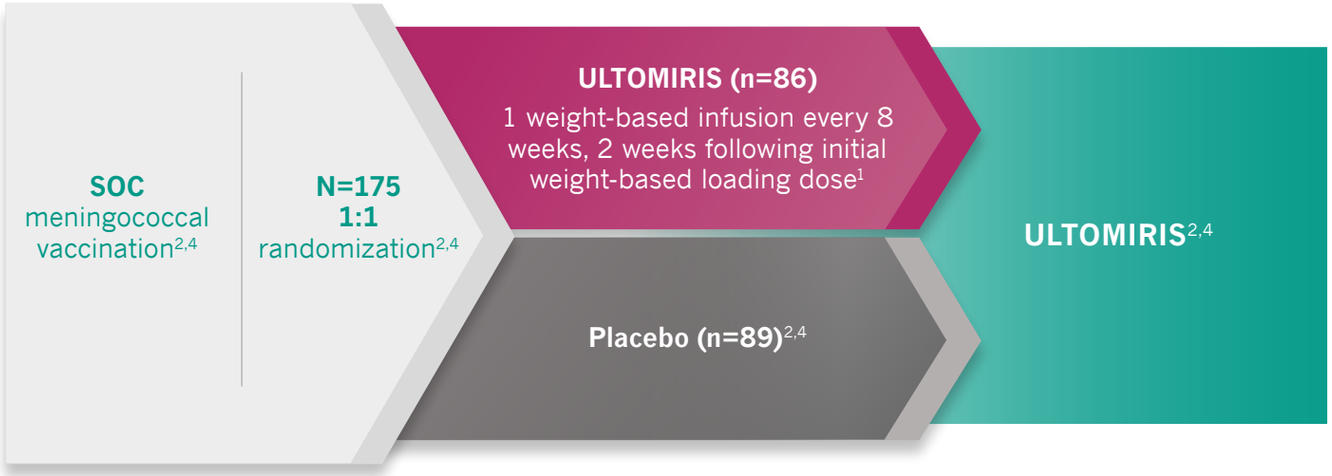
Please see additional Important Safety Information throughout and full Prescribing Information for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

Studied in one of the longest randomized clinical trials of a gMG treatment, in a broad population of patients[2,4]

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

CHAMPION-MG was a randomized, multicenter, double-blind, placebo-controlled trial with an open-label extension (OLE)[1,2,4]

Patients were randomized to receive either ULTOMIRIS® (n=86) or placebo (n=89) for 26 weeks and were subsequently allowed to enter the OLE period for up to 4 years.[1,2,4]



More than 90% of patients had MGFA class II or III gMG with mild or moderate weakness at baseline[2]

Screening & randomization	Randomized-controlled treatment (double-blind)	Open-label extension
2-4 weeks	26 weeks	OLE (up to 4 years) ULTOMIRIS (n=78)[4] Placebo (n=83)[4]

gMG, generalized myasthenia gravis; MGFA, Myasthenia Gravis Foundation of America; SOC, standard of care.

SELECT IMPORTANT SAFETY INFORMATION

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.

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

Key inclusion and exclusion criteria for the CHAMPION-MG study

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

Key **inclusion** criteria[2]

Patients enrolled in this trial had to have:

- An MGFA clinical classification of class II through IV
- gMG (diagnosed for at least 6 months) with a positive serologic test for anti-AChR antibodies
- MG-ADL total score ≥6
- Vaccinations against meningococcal infections

Patients on concomitant ISTs were required to be on stable doses throughout the primary treatment period.

Key **exclusion** criteria[2]

Patients were excluded from this trial if they had:

- Any active or untreated thymoma or history of thymic carcinoma or thymic malignancy
- History of thymectomy, thymomectomy, or any thymic surgery within 12 months prior to screening
- Clinical features consistent with myasthenic crisis/exacerbation or clinical deterioration at the time of the screening visit or at any time prior to randomization
- Therapies that were used within the following time frames:
  - IVIg or PE within 4 weeks prior to randomization (Day 1)
  - Rituximab within 6 months prior to screening
  - Any previous treatment with complement inhibitors

AChR, acetylcholine receptor; gMG, generalized myasthenia gravis; IST, immunosuppressive therapy; IVIg, intravenous immunoglobulin; MG-ADL, Myasthenia Gravis Activities of Daily Living; MGFA, Myasthenia Gravis Foundation of America; PE, plasma exchange.

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (continued)

Serious Meningococcal Infections (continued)

Life-threatening and fatal meningococcal infections have occurred in both vaccinated and unvaccinated patients treated with complement inhibitors.

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

The majority of symptomatic patients were already being treated with an IST[2]

In the randomized, multicenter, double-blind, placebo-controlled CHAMPION-MG trial, approximately 90% of patients were taking an IST at baseline across both treatment arms[1,2]

- 47% of patients were taking 2 or more ISTs[2]

43% of patients received IVIg in the 2 years prior to trial screening[20]

Over 80% of patients were receiving acetylcholinesterase inhibitors, 70% were receiving corticosteroids, and 68% were receiving non-steroidal immunosuppressants at study entry[1]

Patients on concomitant medications to treat gMG were permitted to continue on therapy at stable doses throughout the course of the study, and those medications could be adjusted as necessary during the open-label extension (OLE).[4]

gMG, generalized myasthenia gravis; IST, immunosuppressive therapy; IVIg, intravenous immunoglobulin.

SELECT IMPORTANT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS (continued)
Serious Meningococcal Infections (continued)
Revaccinate patients in accordance with ACIP recommendations considering the duration of ULTOMIRIS therapy.

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

Multiple measures of gMG were studied in CHAMPION-MG[1]

Primary endpoint

- Change from baseline to Week 26 in the **Myasthenia Gravis Activities of Daily Living** (MG-ADL) total score[1,a]

Secondary endpoints[b,c]

- Change from baseline to Week 26 in the **Quantitative Myasthenia Gravis** (QMG) total score[1,d]
- The proportion of patients with **improvements of at least 5 points** in their **QMG** total score[1]
- Change in **revised Myasthenia Gravis Quality of Life 15-item scale** (MG-QoL15r)[2]
- Change in **Neurological Quality of Life** (Neuro-QoL) **Fatigue** assessment[2]
- The proportion of patients with **improvements of at least 3 points** in their **MG-ADL** total score[1]

CHAMPION-MG baseline characteristics[1,2]

Baseline Characteristics	ULTOMIRIS® (n=86)	Placebo (n=89)
Mean age at first infusion (years)	**58**	**53**
Mean age at gMG diagnosis (years)	**49**	**44**
Mean time from diagnosis to study participation (years [range])	**10** (0.5-39.5)	**10** (0.5-36.1)
Sex, male (%)	**49**	**49**
Sex, female (%)	**51**	**51**
Race, White (%)	**78**	**69**
Race, Asian (%)	**17**	**18**
Race, Black or African American (%)	**2**	**4**
Race, not reported (%)	**2**	**6**
Mean baseline weight, kg (lb)	**92** (201.9)	**91** (200.4)

[a]The MG-ADL is a categorical scale that assesses the impact on daily function of 8 signs or symptoms that are typically affected in gMG. Each item is assessed on a 4-point scale where a score of 0 represents normal function and a score of 3 represents loss of ability to perform that function. The total score ranges from 0 to 24, with the higher scores indicating more impairment.[1]

[b]Hierarchical testing proceeded from the first to the fifth endpoint, and if statistical significance was not achieved (*P*-value >0.05), then subsequent endpoints were not considered statistically significant.[2]

[c]All secondary endpoints measured change from baseline to Week 26.[1]

[d]The QMG is a 13-item categorical scale assessing muscle weakness. Each item is assessed on a 4-point scale where a score of 0 represents no weakness and a score of 3 represents severe weakness. The total score ranges from 0 to 39, where higher scores indicate more severe impairment.[1]

gMG, generalized myasthenia gravis.

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (continued)

Serious Meningococcal Infections (continued)

Note that ACIP recommends an administration schedule in patients receiving complement inhibitors that differs from the administration schedule in the vaccine prescribing information.

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

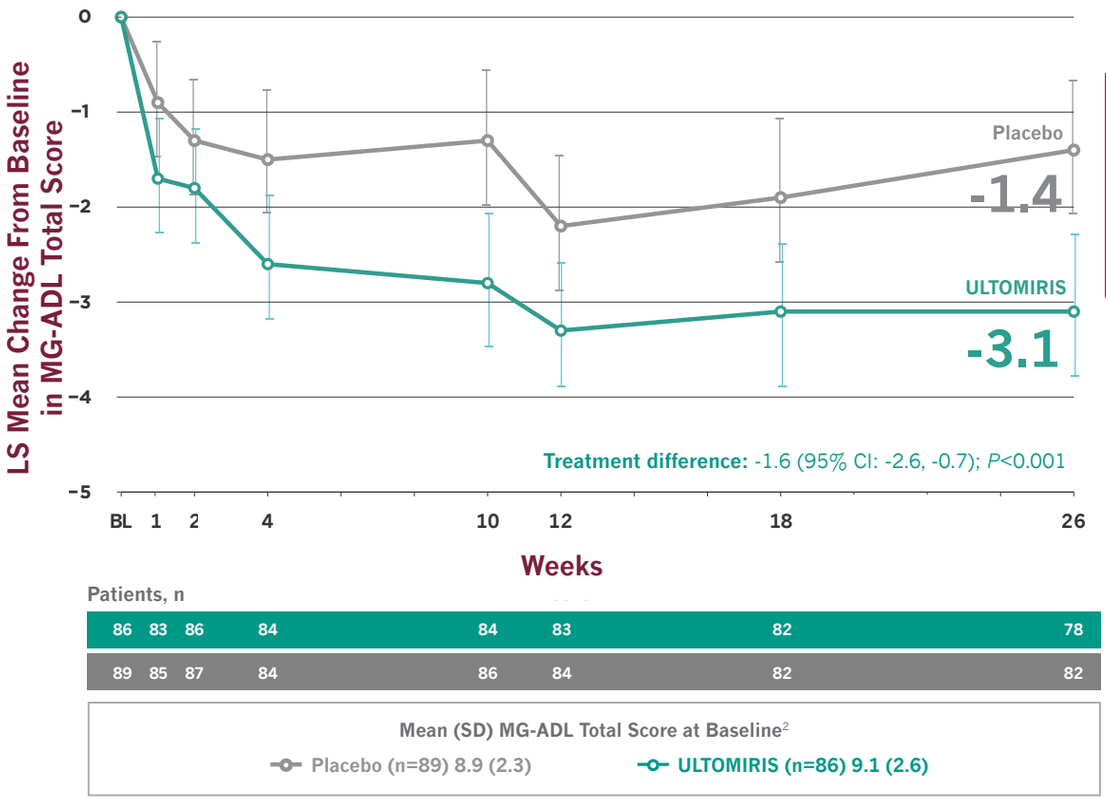
Proven to deliver improvement in MG activities of daily living (MG-ADL)[1,4]

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

Among patients in the ULTOMIRIS® treatment arm,

Improvements in MG-ADL total scores were observed within 1 week of treatment and sustained through Week 26[1,4,a]

ULTOMIRIS demonstrated efficacy vs placebo at Week 26 (-3.1 vs -1.4, respectively [*P*<0.001])[1,2]



More than 2x greater improvement vs placebo[1,2]

[a]MG-ADL is a patient-reported, 8-item assessment reflecting functional impairment of ocular, bulbar, respiratory, and limb symptoms with a maximum total score of 24.[21]

CHAMPION-MG STUDY LIMITATIONS:

Data shown are least-squares means and 95% confidence intervals (CIs), using a mixed model for repeated measures; 95% CIs were not adjusted for multiplicity.[1,2]

Time to response was part of the planned efficacy analysis, but the primary endpoint was at Week 26. Therefore, results should be interpreted with caution.

BL, baseline; LS, least squares; MG, myasthenia gravis; SD, standard deviation.

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (continued)

Serious Meningococcal Infections (continued)

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.

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

MG-ADL Scale[21]

	0=Normal	1	2	3=Most severe	
Talking	Normal	Intermittent slurring or nasal speech	Constant slurring or nasal speech, but can be understood	Difficult-to-understand speech	
Chewing	Normal	Fatigue with solid food	Fatigue with soft food	Gastric tube	
Swallowing	Normal	Rare episode of choking	Frequent choking necessitating changes in diet	Gastric tube	
Breathing	Normal	Shortness of breath with exertion	Shortness of breath at rest	Ventilator dependence	
Impairment of ability to brush teeth or comb hair	None	Extra effort, but no rest periods needed	Rest periods needed	Cannot do one of these functions	
Impairment of ability to arise from a chair	None	Mild, sometimes uses arms	Moderate, always uses arms	Severe, requires assistance	
Double vision	None	Occurs, but not daily	Daily, but not constant	Constant	
Eyelid droop	None	Occurs, but not daily	Daily, but not constant	Constant	

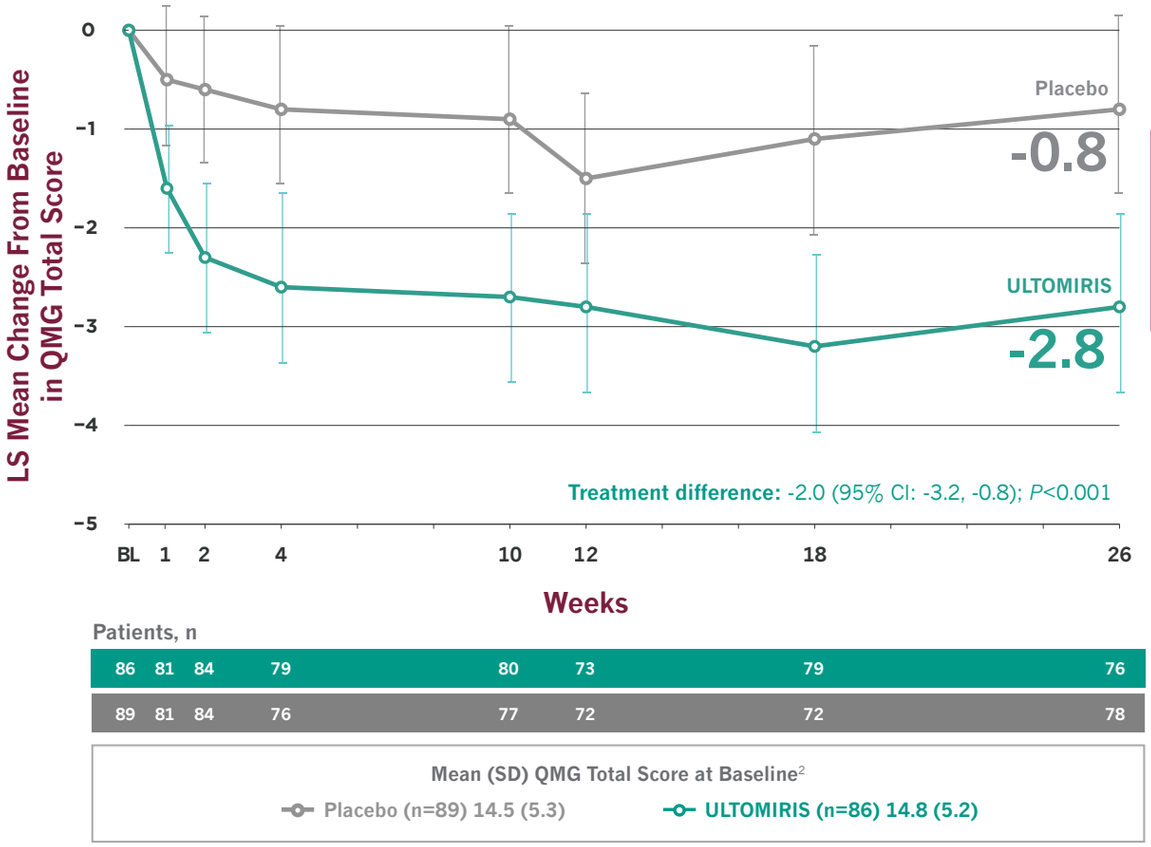
MG-ADL, Myasthenia Gravis Activities of Daily Living.
The information on this page is intended as educational information for healthcare providers.
It does not replace a healthcare provider's judgment or clinical diagnosis.
Assessment adapted from: myasthenia.org/Portals/0/ADL.pdf.

Add items for MG-ADL total score

Improvement in muscle strength demonstrated by QMG total score from baseline through Week 26[1,2]

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

ULTOMIRIS® demonstrated 3.5x greater improvement vs placebo in the key secondary endpoint, change from baseline in QMG total score, through Week 26 (-2.8 points for ULTOMIRIS vs -0.8 points for placebo [*P*<0.001])[1,2]



3.5x greater improvement vs placebo[1,2]

Improvements in QMG scores were seen across the ocular, bulbar, and limb domain scores from baseline to Week 26[22]

CHAMPION-MG STUDY LIMITATION:

Change from baseline in QMG individual symptom domains was an exploratory endpoint. Results or clinical outcomes should be interpreted with caution.

BL, baseline; CI, confidence interval; LS, least squares; QMG, Quantitative Myasthenia Gravis; SD, standard deviation.

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (continued)

Serious Meningococcal Infections (continued)

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*.

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

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

QMG Scale[23]

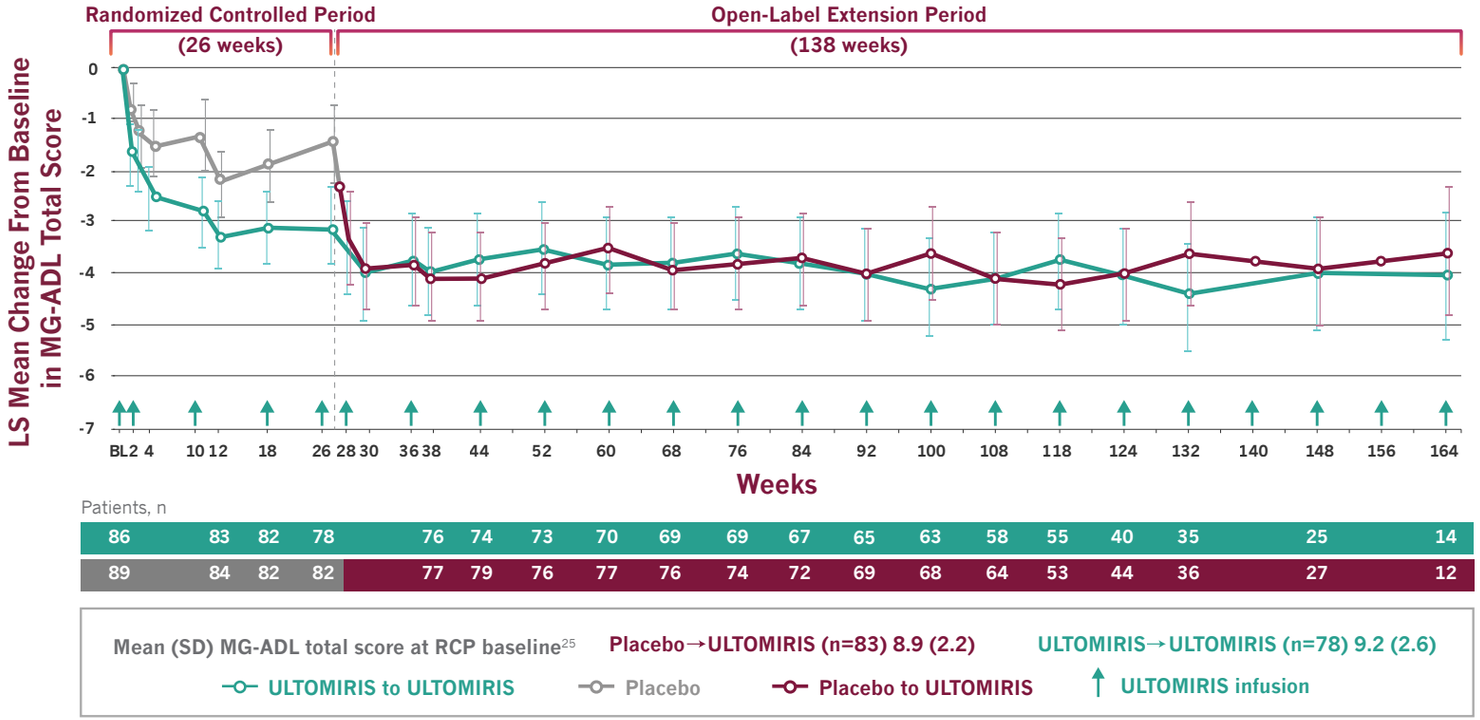
	0=None	1=Mild	2=Moderate	3=Severe	
Double vision on lateral gaze Right or left (circle one), seconds	61	11-60	1-10	Spontaneous	
Ptosis (upward gaze), seconds	61	11-60	1-10	Spontaneous	
Facial muscles	Normal lid closure	Complete, weak, some resistance	Complete, without resistance	Incomplete	
Swallowing 4 oz of water (1/2 cup)	Normal	Minimal coughing or throat clearing	Severe coughing/choking or nasal regurgitation	Cannot swallow (test not attempted)	
Speech after counting aloud from 1 to 50 (onset of dysarthria)	None at 50	Dysarthria at 30-49	Dysarthria at 10-29	Dysarthria at 9	
Right arm outstretched (90-degree sitting), seconds	240	90-239	10-89	0-9	
Left arm outstretched (90-degree sitting), seconds	240	90-239	10-89	0-9	
Forced vital capacity	≥80	65-79	50-64	<50	
Right-hand grip, kgW **Men** **Women**	 ≥45 ≥30	 15-44 10-29	 5-14 5-9	 0-4 0-4	
Left-hand grip, kgW **Men** **Women**	 ≥35 ≥25	 15-34 10-24	 5-14 5-9	 0-4 0-4	
Head lifted (45-degree supine), seconds	120	30-119	1-29	0	
Right leg outstretched (45-degree supine), seconds	100	31-99	1-30	0	
Left leg outstretched (45-degree supine), seconds	100	31-99	1-30	0	
				Add items for QMG total score	

kgW, kilogram weight; QMG, Quantitative Myasthenia Gravis.
The information on this page is intended as educational information for healthcare providers.
It does not replace a healthcare provider's judgment or clinical diagnosis.
Assessment adapted from: myasthenia.org/Portals/0/QMG.pdf.

Reduction in MG-ADL total score in CHAMPION-MG was observed in the OLE period through Year 3[4,24]

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

Reduction in MG-ADL total score observed through Week 164[4,24]



4-Point reduction in MG-ADL total scores[25]

ULTOMIRIS® → ULTOMIRIS[25]
- **LS mean change from RCP baseline at Week 164:** -4.0 (95% CI: -5.3, -2.8)

Placebo → ULTOMIRIS[25]
- **LS mean change from OLE baseline at Week 138:** -2.1 (95% CI: -3.3, -0.9)

Reduction observed when switching from placebo to ULTOMIRIS following Week 26

- **2.1-point reduction after 138 weeks** (at Week 164 in CHAMPION-MG OLE)

The OLE period began following Week 26, when all patients received ULTOMIRIS and results were observed through Week 164. Patients who completed the RCP had the option to enter the OLE.[4,25]

BL, baseline; CI, confidence interval; LS, least squares; MG-ADL, Myasthenia Gravis Activities of Daily Living; OLE, open-label extension; RCP, randomized controlled period; SD, standard deviation.

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (continued)

Serious Meningococcal Infections (continued)

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

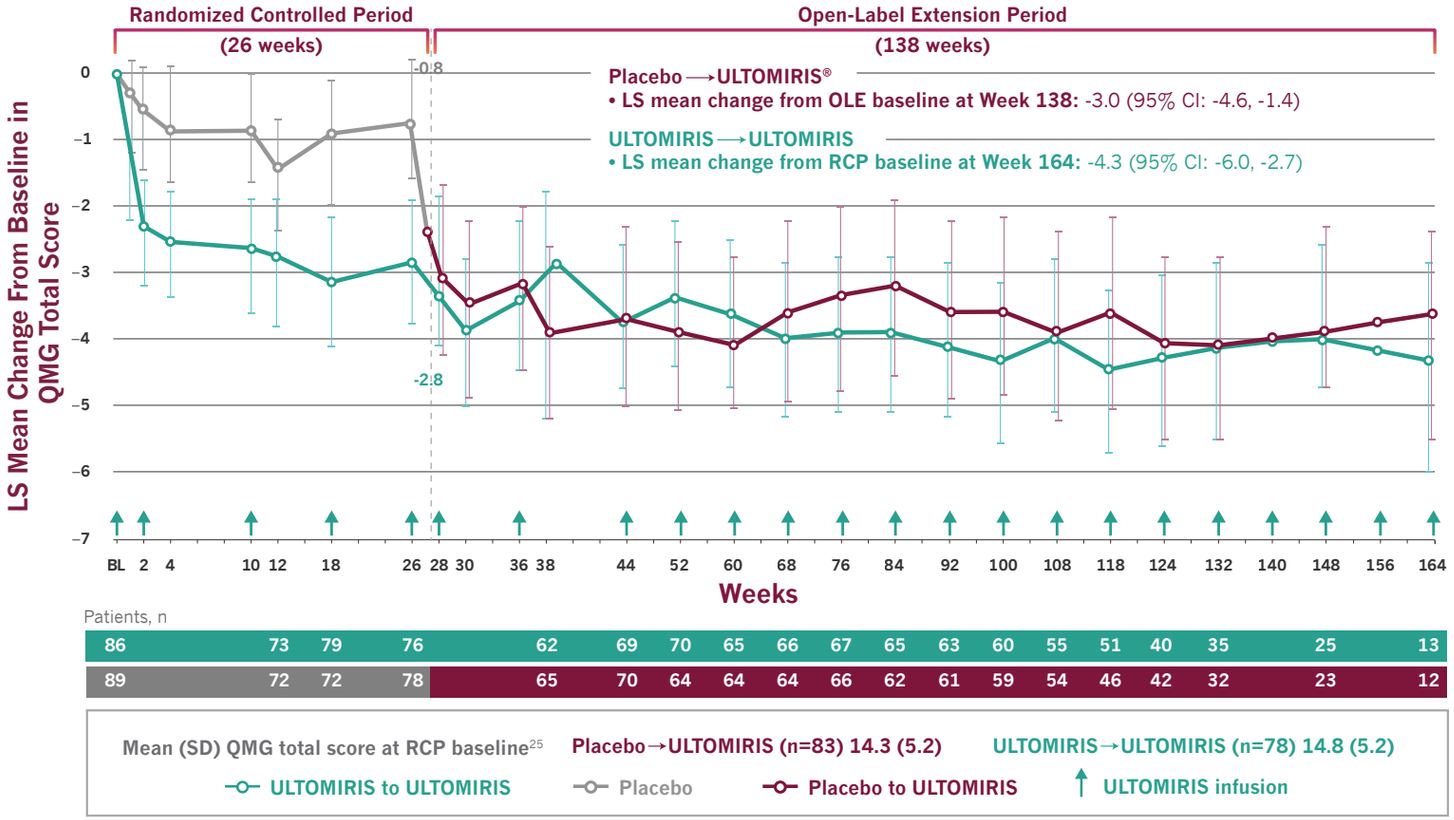
Closely monitor patients for early signs and symptoms of meningococcal infection and evaluate patients immediately if infection is suspected. Inform patients of these signs and symptoms and instruct patients to seek immediate medical care if they occur.

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

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

Reduction in QMG total score observed through 3 years in the OLE[25]

Reduction in QMG total score observed through Week 164[25]



4.3-Point reduction in QMG total scores sustained through Week 164

CHAMPION-MG OLE STUDY LIMITATION:
Results or clinical outcomes should be interpreted with caution since the study was designed to evaluate safety and lacked a control group.

BL, baseline; CI, confidence interval; LS, least squares; OLE, open-label extension; QMG, Quantitative Myasthenia Gravis; RCP, randomized controlled period; SD, standard deviation.

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (continued)

Serious Meningococcal Infections (continued)

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.

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

Safety was evaluated in CHAMPION-MG's 26-week randomized controlled period[1,2]

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

Adverse reactions reported in ≥5% and at greater frequency than placebo in patients treated with ULTOMIRIS®[1]

Adverse Reactions	ULTOMIRIS (n=86), n (%)	Placebo (n=89), n (%)
GASTROINTESTINAL DISORDERS		
Diarrhea	13 (15)	11 (12)
Abdominal pain	5 (6)	0
INFECTIONS AND INFESTATIONS		
Upper respiratory tract infection	12 (14)	7 (8)
Urinary tract infection	5 (6)	4 (4)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		
Back pain	7 (8)	5 (6)
NERVOUS SYSTEM DISORDERS		
Dizziness	8 (9)	3 (3)

- Serious adverse reactions were reported in 20 (23%) patients with gMG receiving ULTOMIRIS and in 14 (16%) patients receiving placebo[1]
- 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[1]
- Of these infections, 1 fatal case of COVID-19 pneumonia was identified in a patient treated with ULTOMIRIS and 1 case of infection led to discontinuation of ULTOMIRIS[1]
- The most frequent adverse reactions occurring in ≥10% of patients taking ULTOMIRIS were diarrhea and upper respiratory tract infection[1]

gMG, generalized myasthenia gravis.

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

Safety was also evaluated in the open-label extension study[25]

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

Adverse reactions reported in ≥10% of patients treated with ULTOMIRIS® during the randomized controlled period or the open-label extension period up to data cutoff[25]

Adverse Reactions	ULTOMIRIS (n=169),[a] n (%)
INFECTIONS AND INFESTATIONS	
COVID-19	**61 (36.1)**
Urinary tract infection	**21 (12.4)**
Nasopharyngitis	**20 (11.8)**
NERVOUS SYSTEM DISORDERS	
Headache	**39 (23.1)**
GASTROINTESTINAL DISORDERS	
Diarrhea	**29 (17.2)**
Nausea	**22 (13.0)**
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	
Arthralgia	**23 (13.6)**
Back pain	**22 (13.0)**
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	
Fatigue	**18 (10.7)**
Dizziness	**17 (10.1)**

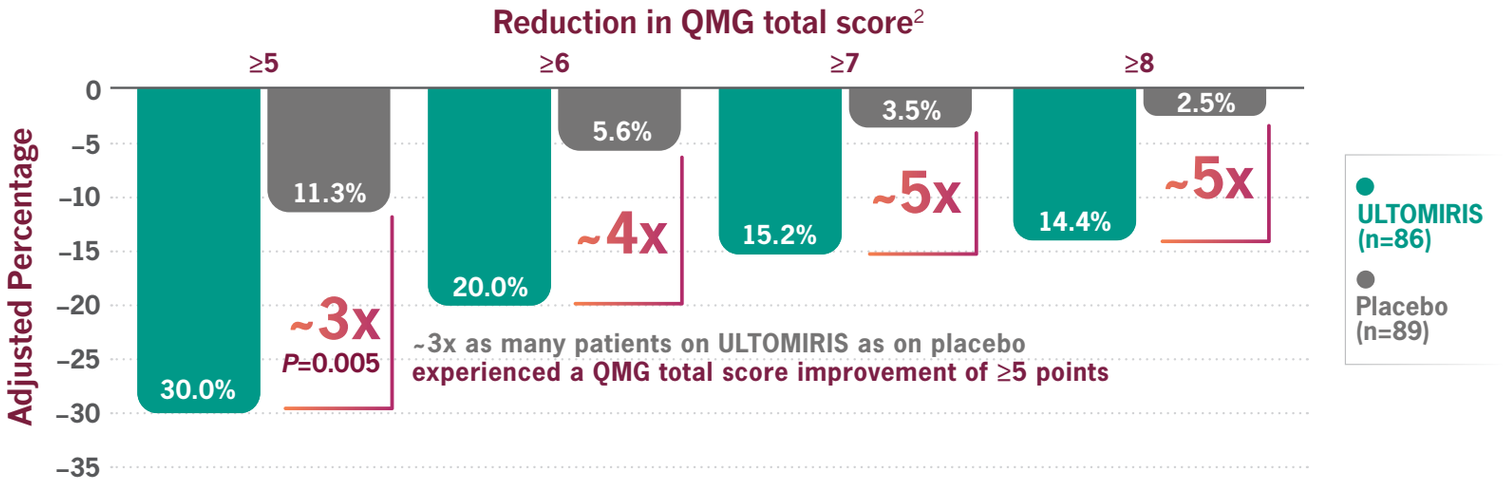
[a] Includes data available for all patients who received ≥1 dose of ULTOMIRIS in the randomized controlled period or the open-label extension period, up to Week 164 at data cutoff.[25]

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

Observed improvements in QMG total score at Week 26[1]

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

Patients treated with ULTOMIRIS® were more likely to experience a larger improvement in QMG total score[1]



The proportion of patients taking ULTOMIRIS who achieved a ≥5-point improvement in QMG total score at Week 26 was greater than the proportion of patients taking placebo.[1]

30% of patients taking ULTOMIRIS had a ≥5-point improvement in QMG total score at Week 26 vs 11.3% taking placebo (*P*=0.005).[1]

Endpoints related to quality of life[2]

- Change from baseline to Week 26 in MG-QoL15r: -3.3 for ULTOMIRIS and -1.6 for placebo
- Change from baseline to Week 26 in the Neuro-QoL Fatigue score: -7.0 for ULTOMIRIS and -4.8 for placebo
- MG-QoL15r didn't reach statistical significance. Due to hierarchical testing, Neuro-QoL wasn't considered for statistical significance

Observed MG-ADL total score changes with ULTOMIRIS[1,2]

- More patients taking ULTOMIRIS achieved a ≥3-point improvement in MG-ADL total score vs placebo
- 57% of patients taking ULTOMIRIS had a ≥3-point improvement in MG-ADL total score vs 34% of patients taking placebo[a]

[a]Due to hierarchical testing, ≥3-point improvement in MG-ADL total score was not considered statistically significant.[2]

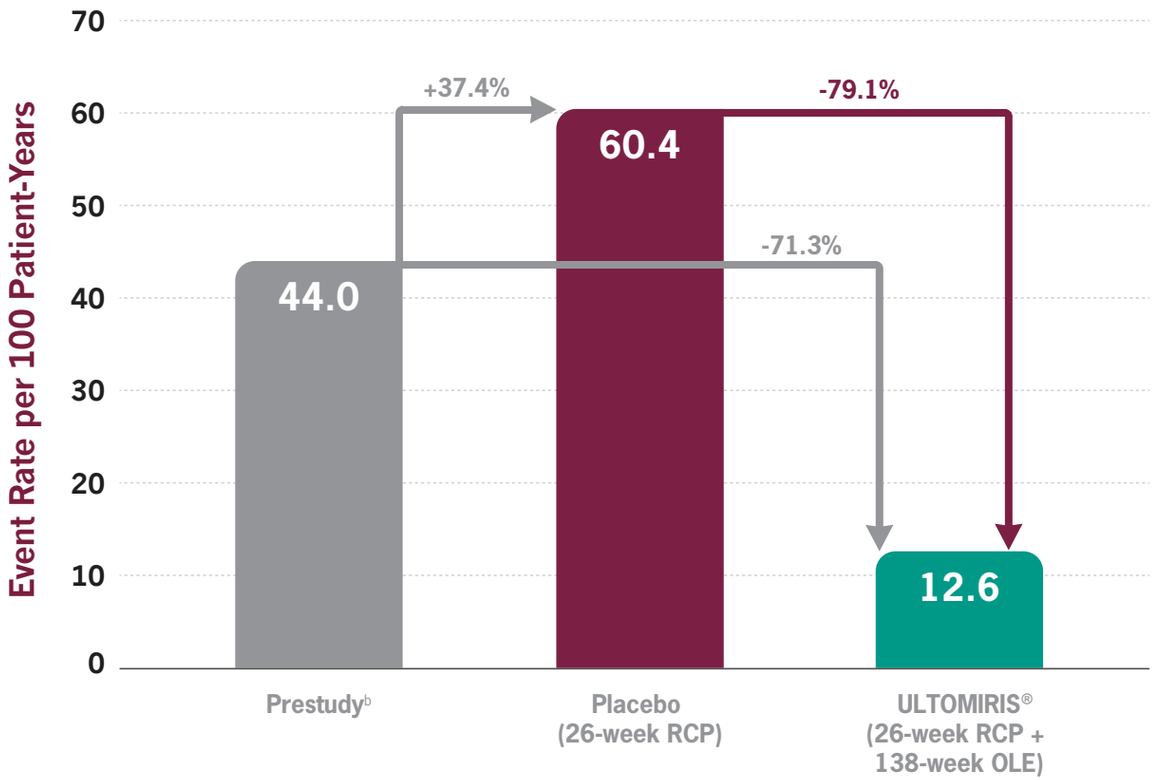
MG-ADL, Myasthenia Gravis Activities of Daily Living; MG-QoL15r, Myasthenia Gravis Quality of Life 15-item scale; Neuro-QoL, Neurological Quality of Life; QMG, Quantitative Myasthenia Gravis.

SELECT IMPORTANT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS (continued)
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.

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

Exploratory endpoint: Clinical deterioration observations

Clinical deterioration events per 100 patient-years[25,a]



[a]Clinical deterioration was defined as myasthenic crisis, need for rescue therapy, or significant symptom worsening on any MG-ADL item, other than double vision or eyelid droop.[4]

[b]1-year prestudy period, events reported by investigators. Patients may have been on other medications to treat generalized myasthenia gravis during this period.[4]

MG-ADL, Myasthenia Gravis Activities of Daily Living; OLE, open-label extension; RCP, randomized controlled period.

This graphic is adapted from Meisel A, Annane D, Vu T, et al. *J Neurol*, 2023, modified from its original presentation, and is used under a Creative Commons Attribution 4.0 International License. To view a copy of this license, visit https://creativecommons.org/licenses/by/4.0/.

CHAMPION-MG STUDY LIMITATION:

Clinical deterioration observation is an exploratory endpoint. Results or clinical outcomes should be interpreted with caution.

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (continued)

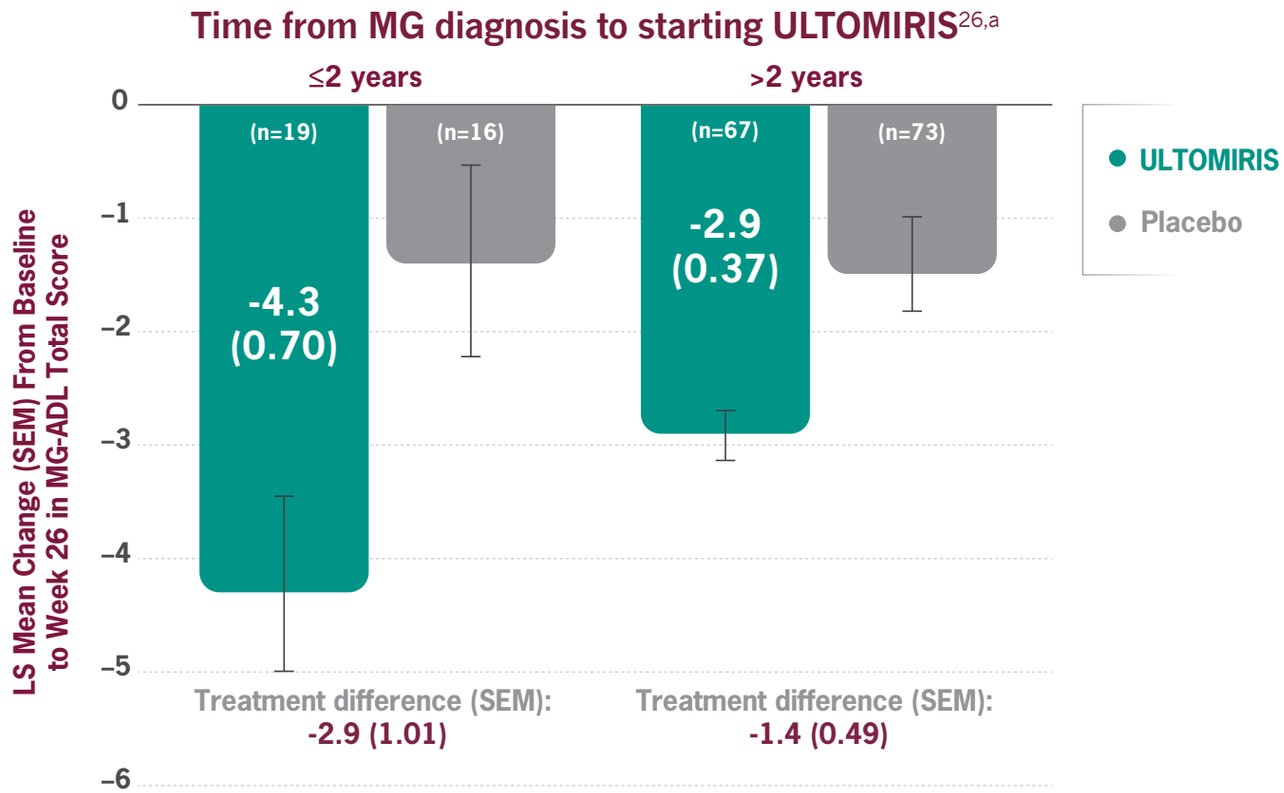
ULTOMIRIS and SOLIRIS REMS (continued)

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.

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

Post hoc subgroup analysis: Impact of early use of ULTOMIRIS® on MG-ADL total score changes

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



Patients who started ULTOMIRIS within 2 years of gMG diagnosis were observed to have experienced a 4.3-point reduction in MG-ADL total scores from baseline. Patients who started after 2 years were observed to have experienced a 2.9-point reduction.[26,a,b]

CHAMPION-MG STUDY LIMITATIONS:

Change in MG-ADL total score reduction with earlier use was not a prespecified endpoint. Differences between the 2 ULTOMIRIS arms were not statistically significant. Results and clinical outcomes should be interpreted with caution.[4]

[a]The numbers of patients indicated in the figure are the numbers of patients included in the MMRM analysis. MG-ADL data were available at both baseline and 26 weeks for 30 patients in the ≤2-years subgroup (17 receiving ravulizumab, 13 receiving placebo) and 130 patients in the >2-years subgroup (61 receiving ravulizumab, 69 receiving placebo). The MMRM analysis used all available longitudinal data for inference, assuming missing at random for missing assessments. Estimates are based on MMRM that includes treatment group, stratification factor region, age at baseline and MG-ADL total score at baseline, study visit, study visit by treatment group interaction, time from diagnosis by treatment group, time from diagnosis by study visit interaction, and time from diagnosis by study visit by treatment group interaction.[26]

[b]In a post hoc analysis of 175 patients at Week 26.[26]

gMG, generalized myasthenia gravis; LS, least squares; MG, myasthenia gravis; MG-ADL, Myasthenia Gravis Activities of Daily Living; MMRM, mixed model for repeated measures; SEM, standard error of the mean.

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (continued)

ULTOMIRIS and SOLIRIS REMS (continued)

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.

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

Post hoc subgroup analysis: Baseline demographics and clinical characteristics by time from MG diagnosis[26]

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

Characteristic	≤2 years from MG diagnosis			>2 years from MG diagnosis		
	ULTOMIRIS (n=19)	Placebo (n=16)	All patients (n=35)	ULTOMIRIS (n=67)	Placebo (n=73)	All patients (n=140)
Female sex, n (%)	5 (26.3)	6 (37.5)	11 (31.4)	39 (58.2)	39 (53.4)	78 (55.7)
Age at first trial infusion, years, mean±SD	62.9±11.97	58.6±13.46	60.9±12.67	56.6±14.08	52.1±16.42	54.3±15.45
Age at MG diagnosis, years, mean±SD	62.0±11.82	57.7±13.47	60.0±12.60	44.8±18.41	40.7±18.78	42.6±18.65
Baseline MG-ADL score, mean±SD	8.8±1.74	9.8±2.51	9.3±2.15	9.2±2.83	8.8±2.22	9.0±2.53
Baseline QMG score, mean±SD	13.5±4.57	13.7±5.65	13.6±5.02	15.2±5.34	14.6±5.20	14.9±5.26
Baseline MGFA classification, n (%)						
Class II	9 (47.4)	12 (75.0)	21 (60.0)	30 (44.8)	27 (37.0)	57 (40.7)
Class III	10 (52.6)	4 (25.0)	14 (40.0)	31 (46.3)	41 (56.2)	72 (51.4)
Class IV	0	0	0	6 (9.0)	5 (6.8)	11 (7.9)
Use of any ISTs[a] at baseline, n (%)	18 (94.7)	14 (87.5)	32 (91.4)	58 (86.6)	67 (91.8)	125 (89.3)
Corticosteroids only	8 (42.1)	5 (31.3)	13 (37.1)	12 (17.9)	13 (17.8)	25 (17.9)
One NSIST only	5 (26.3)	1 (6.3)	6 (17.1)	15 (22.4)	15 (20.5)	30 (21.4)
Corticosteroids + one NSIST	5 (26.3)	8 (50.0)	13 (37.1)	31 (46.3)	39 (53.4)	70 (50.0)

[a]Including corticosteroids; no patients were being treated with >2 ISTs and no patients were being treated with >1 NSIST.[26]

IST, immunosuppressive therapy; MG, myasthenia gravis; MG-ADL, Myasthenia Gravis Activities of Daily Living; MGFA, Myasthenia Gravis Foundation of America; NSIST, nonsteroidal immunosuppressive therapy; QMG, Quantitative Myasthenia Gravis; SD, standard deviation.

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (continued)

ULTOMIRIS and SOLIRIS REMS (continued)

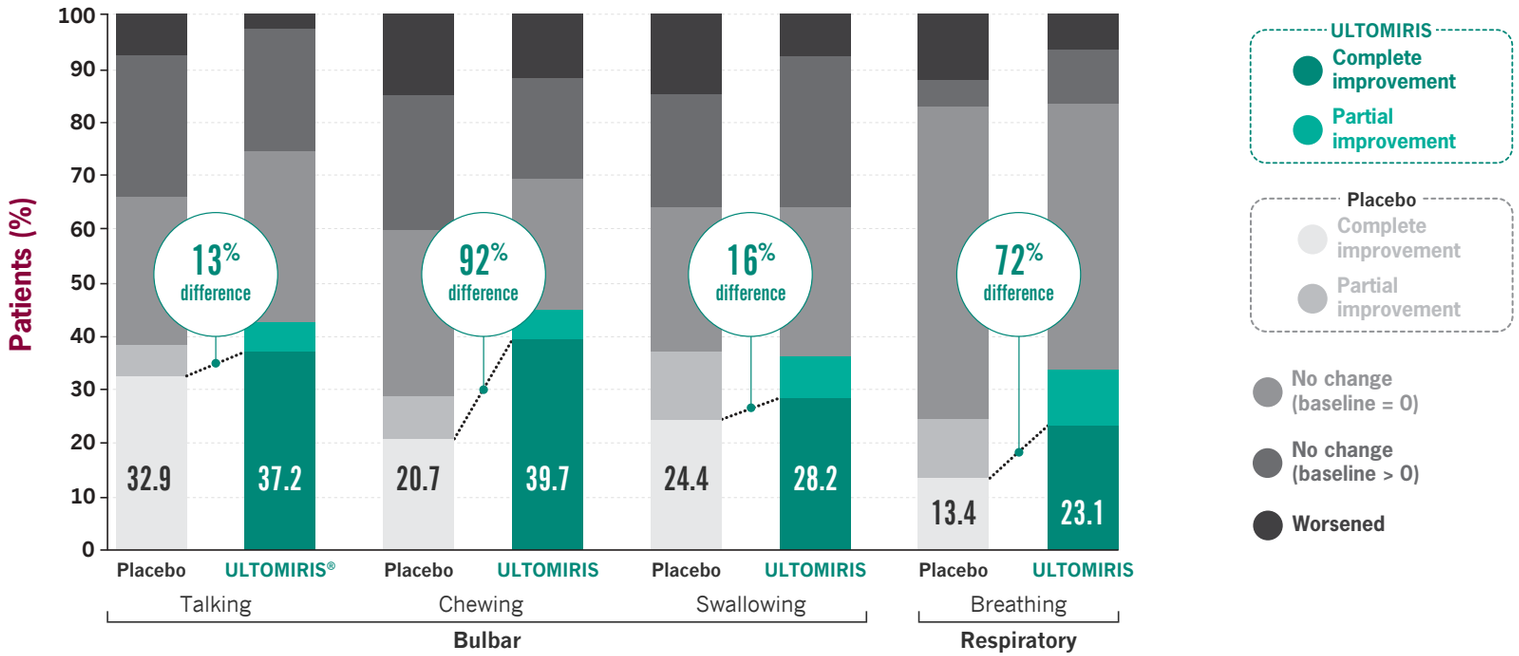
Further information is available at www.UltSolREMS.com or 1-888-765-4747.

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

Post hoc analysis:
Change in severity of MG-ADL items from baseline to Week 26[27]

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

Domain score changes (bulbar and respiratory)[27]



CHAMPION-MG STUDY LIMITATION:

Change in severity of MG-ADL items from baseline to Week 26 was not a prespecified endpoint. Results and clinical outcomes should be interpreted with caution.[4]

MG-ADL, Myasthenia Gravis Activities of Daily Living.

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (continued)

Other Infections

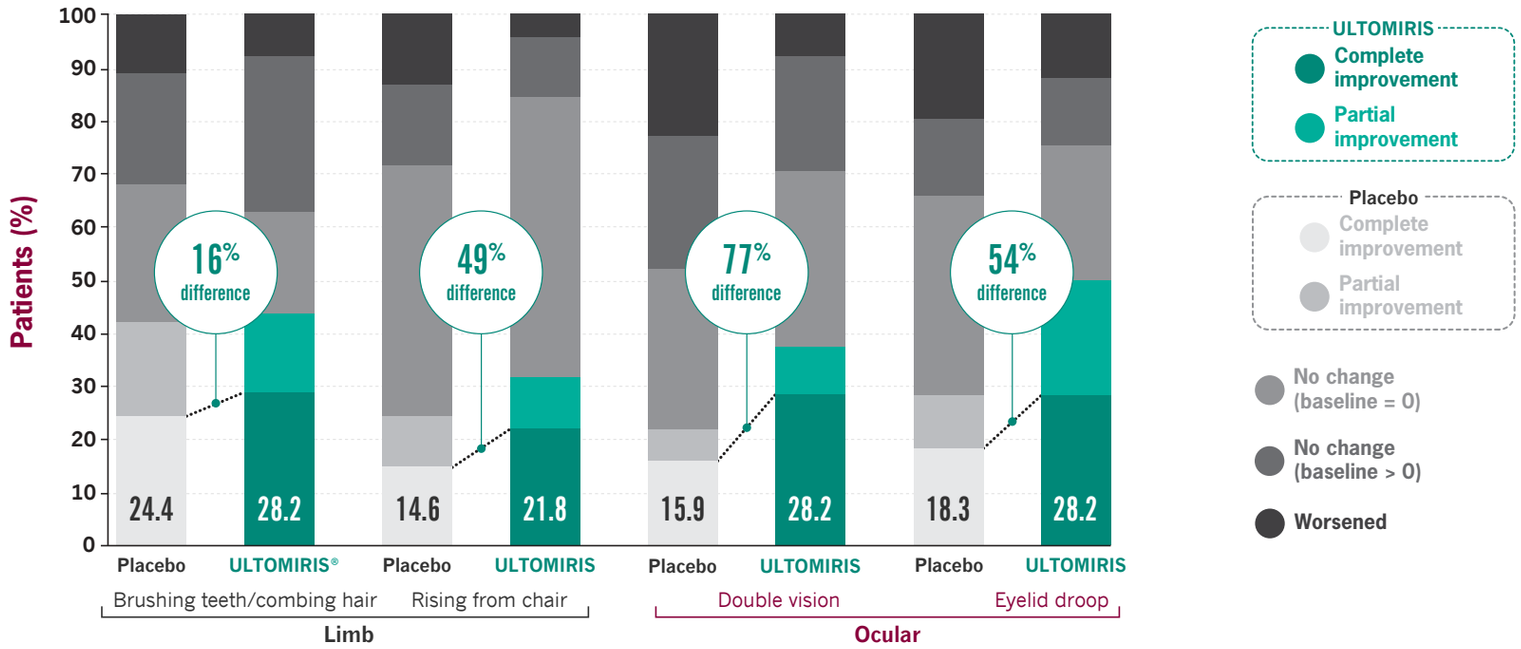
Serious infections with *Neisseria* species (other than *Neisseria meningitidis*), including disseminated gonococcal infections, have been reported.

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

Post hoc analysis:
Change in severity of MG-ADL items from baseline to Week 26[27] (continued)

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

Domain score changes (limb and ocular)[27]



MG-ADL, Myasthenia Gravis Activities of Daily Living.

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (continued)

Other Infections (continued)

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.

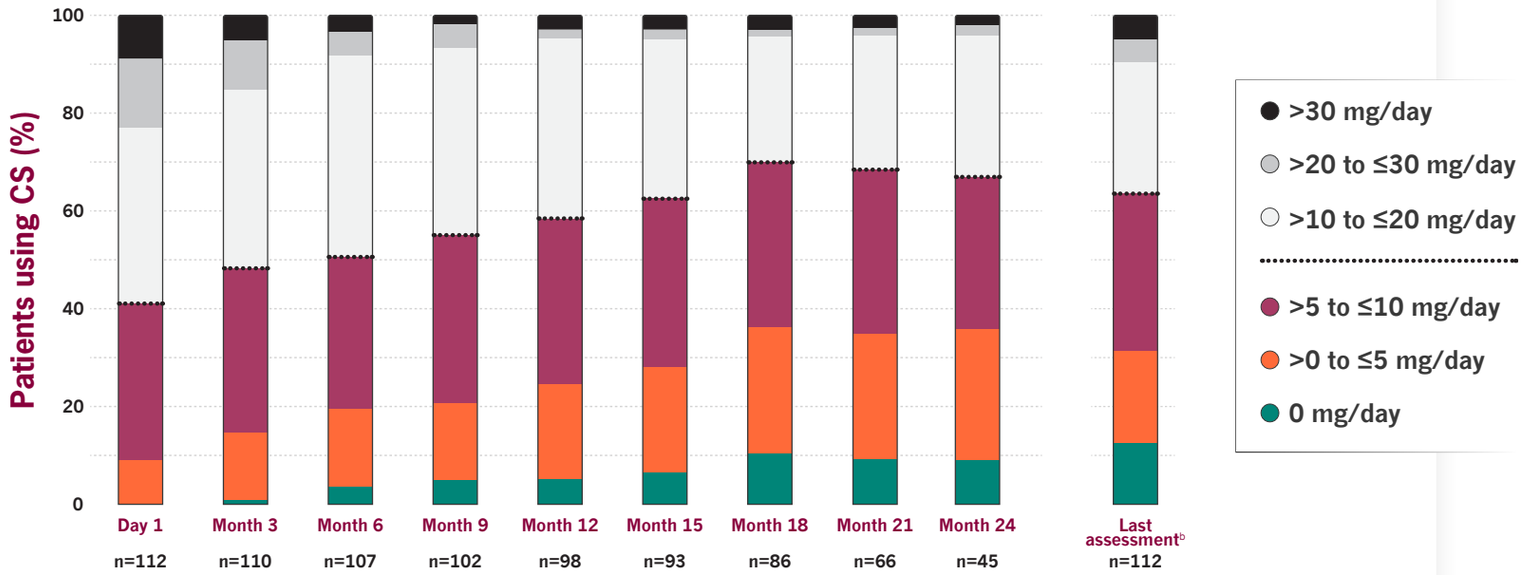
Please see additional Important Safety Information throughout and full Prescribing Information for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

Post hoc analysis: Corticosteroid use was observed in the OLE[25]

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

The change in corticosteroid use was assessed (n=112). Dose changes were only allowed in the OLE period beginning after Week 26 of CHAMPION-MG[25]

Changes in corticosteroid use in the OLE[25,a]



[a]All patients who were receiving corticosteroids at OLE start.[25]
[b]**Last assessment** is the final participant study visit during which outcomes were measured.[25]

CHAMPION-MG OLE STUDY LIMITATIONS: Corticosteroid use was not a prespecified endpoint. Results or clinical outcomes should be interpreted with caution since the study was designed to evaluate safety and lacked a control group. The study was not designed to assess corticosteroid use or outcomes.

CS, corticosteroids; OLE, open-label extension.

SELECT IMPORTANT SAFETY INFORMATION

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.

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

Post hoc analysis: Changes in corticosteroid use in the OLE

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

Proportion of patients receiving steroids during the OLE[25,a]

	Day 1 (n=112)	Month 24 (n=45)	Last assessment (n=112)
Patients taking **≤10 mg** steroids/day	**41%** (46/112)	**67%** (30/45)	**63%** (71/112)
Patients taking **≤5 mg** steroids/day	**9%** (10/112)	**36%** (16/45)	**31%** (35/112)
Patients taking **0 mg** steroids/day	**1%** (1/112)	**9%** (4/45)	**12%** (13/112)

[a]Of those who were receiving corticosteroids at OLE start.[25]

Mean (SD) daily dose of corticosteroids[25]:

- First reported dosage: 17.5 (11.9) mg/day
- Last reported dosage: 11.7 (10.9) mg/day

OLE, open-label extension; SD, standard deviation.

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (continued)

Infusion-Related Reactions

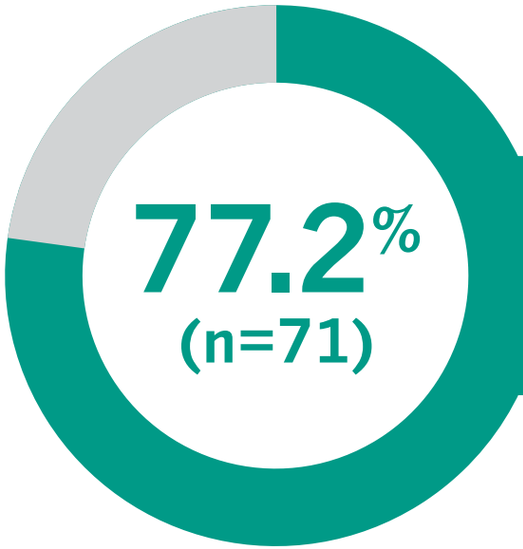
Administration of ULTOMIRIS may result in systemic infusion-related reactions, including anaphylaxis and hypersensitivity reactions.

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

Post hoc analysis: MG-ADL response through Week 164

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

MG-ADL total score reductions during the OLE were observed among ravulizumab responders[25]



were observed to have a **≥2-point reduction[a]** (after first response) for >75% of remaining time in the OLE

67.3% (n=68) were observed to have a **≥3-point reduction[a]** (after first response) for >75% of remaining time in the OLE

[a]Patients in the placebo arm who had the corresponding response during the RCP were excluded.

CHAMPION-MG OLE STUDY LIMITATIONS: Cumulative MG-ADL response was not a prespecified endpoint. Results or clinical outcomes should be interpreted with caution since the study was designed to evaluate safety and lacked a control group.

MG-ADL, Myasthenia Gravis Activities of Daily Living; OLE, open-label extension; RCP, randomized controlled period.

SELECT IMPORTANT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS (continued)
Infusion-Related Reactions (continued)
In clinical trials, infusion-related reactions occurred in approximately 1 to 7% of patients, including lower back pain, abdominal pain, muscle spasms, drop or elevation in blood pressure, rigors, limb discomfort, drug hypersensitivity (allergic reaction), and dysgeusia (bad taste).

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

Post hoc analysis: MG-ADL responders and MSE observed through Week 164

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

Minimal Symptom Expression (MSE) was observed[25,a]

MSE = MG-ADL score of 0 or 1

88% **(141/160)** of patients experienced a **≥2-point reduction** from baseline in MG-ADL total score (at any point) during the study

Of those attaining a ≥2-point reduction in MG-ADL total score,

42% **(59/141)** experienced MSE (at any point) during the study

MAINTAINED MSE

54% **(32/59)** maintained MSE for **more than half** of their remaining time in the RCP and OLE

CHAMPION-MG OLE STUDY LIMITATIONS: Minimal symptom expression was not a prespecified endpoint. Results or clinical outcomes should be interpreted with caution since the study was designed to evaluate safety and lacked a control group.

[a]Nine patients in the placebo group who achieved MSE during the RCP were excluded from the MSE analysis.[25]

MG-ADL, Myasthenia Gravis Activities of Daily Living; OLE, open-label extension; RCP, randomized controlled period.

SELECT IMPORTANT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS (continued)
Infusion-Related Reactions (continued)
These reactions did not require discontinuation of ULTOMIRIS. If signs of cardiovascular instability or respiratory compromise occur, interrupt ULTOMIRIS and institute appropriate supportive measures.

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

Meningococcal vaccination is part of a risk-mitigation strategy that takes into account how C5 inhibitors work[1,28,29]

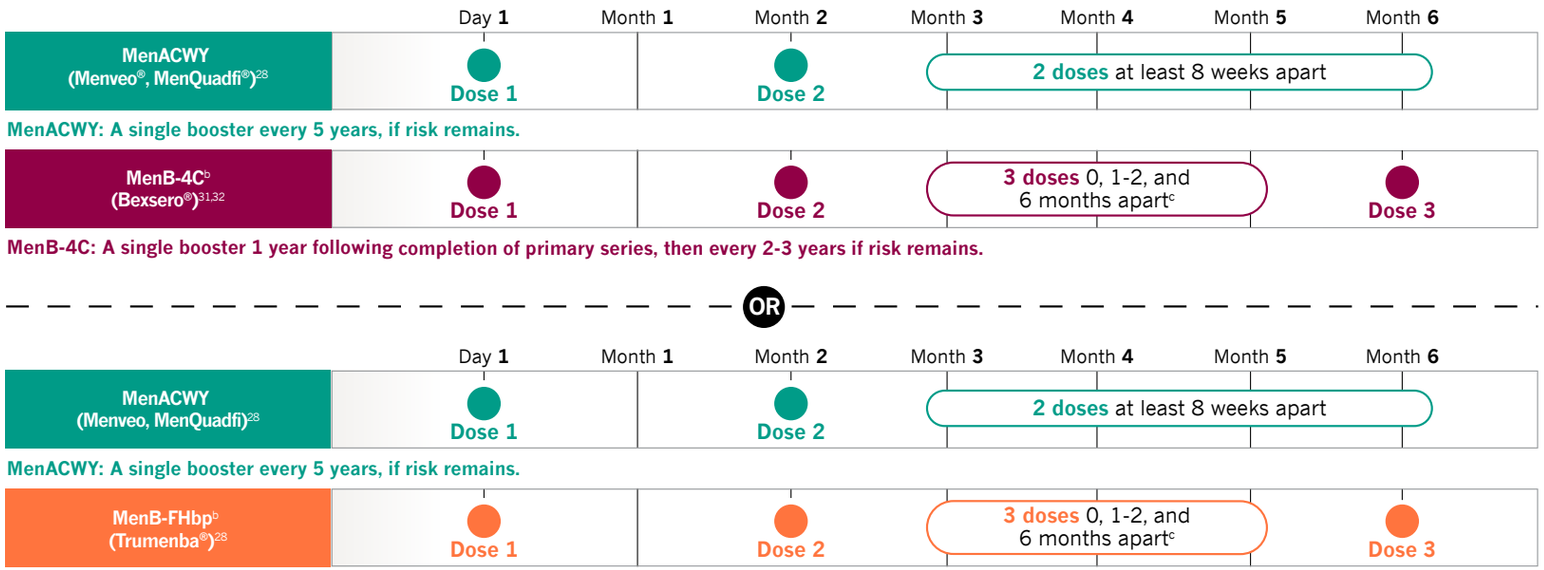
ULTOMIRIS® (ravulizumab-cwvz) injection for intravenous use 300 mg/3 mL vial

Complete or update meningococcal vaccination (for serogroups A, C, W, Y, and B) at least 2 weeks prior to administration of the first dose of ULTOMIRIS®, per the current Advisory Committee on Immunization Practices (ACIP) recommendations for patients receiving a complement inhibitor.[1]

- ACIP recommends that persons using complement inhibitors should complete or update their meningococcal vaccinations at least 2 weeks before complement inhibitor initiation unless the risks of delaying treatment outweigh the risks of developing meningococcal disease[28]
- Revaccinate patients in accordance with ACIP recommendations considering the duration of ULTOMIRIS therapy[1,a]

Required Meningococcal Vaccination Regimen

Your patient must receive both MenACWY and MenB vaccine series. The vaccines may be administered during the same visit but at different injection sites.[29,30]



This list is not exhaustive and is intended to provide an example of most commonly prescribed meningococcal vaccines. The choice of vaccine brand deemed medically appropriate is the decision of the treating HCP.

[a]Note that ACIP recommends an administration schedule in patients receiving complement inhibitors that differs from the administration schedule in the vaccine prescribing information.[1]
[b]MenB vaccines are not interchangeable. Patients must receive the same product for all doses.[29]
[c]For additional information on clinical considerations, refer to the most current ACIP recommendations and CDC immunization schedule.

CDC, Centers for Disease Control and Prevention; MenACWY, meningococcal serogroups A, C, W, and Y; MenB, multicomponent meningococcal serogroup B; MenB-4C, multicomponent meningococcal serogroup B-4C; MenB-FHbp, bivalent factor H-binding protein meningococcal serogroup B.

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

Meningococcal vaccination is part of a risk-mitigation strategy that takes into account how C5 inhibitors work[1,28,29] (continued)

If patients have not been vaccinated and ULTOMIRIS® must be started right away, provide antibacterial drug prophylaxis and administer meningococcal vaccines as soon as possible[1,a]

The benefits and risks of antibiotic prophylaxis for prevention of meningococcal infections in patients receiving ULTOMIRIS have not been established.[1]

Vaccination does not eliminate the risk of meningococcal infections, despite development of antibodies following vaccination.[1]

Please see the respective meningococcal vaccine's Prescribing Information for complete details, including the vaccine's Warnings, Precautions, and Contraindications.

- If your patient received meningococcal vaccines in the past, they might need additional vaccination before starting ULTOMIRIS[29]
- The choice of vaccine deemed medically appropriate is your independent decision
- In most cases, your patients can receive meningococcal vaccines at a physician's office or retail pharmacy
- To help reduce the risk of meningococcal infections, the complete series for the MenACWY and MenB vaccines should be administered[29]

Talk to your Alexion representative to learn about real-world meningococcal infection rates, or view this brochure to learn more

[a]Several antibiotics are available for the treatment of meningococcal disease, including ceftriaxone, cefotaxime, and, when the diagnosis is confirmed, penicillin.[28]

MenACWY, meningococcal serogroups A, C, W, and Y; MenB, multicomponent meningococcal serogroup B.

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

Prophylactic antibiotic use in CHAMPION-MG

In the CHAMPION-MG trial, all patients were required to receive meningococcal vaccine within 3 years prior to or at the time of initiating study treatment. Patients receiving study drug <2 weeks after receiving meningococcal vaccine were required to receive appropriate prophylactic antibiotics until 2 weeks after vaccination.[4]
Alexion does not make recommendations regarding antibiotic regimens; choice of antibiotic regimen and duration are at the discretion of the treating physician.

The following antibiotic use was observed in the CHAMPION-MG study

Antibiotics Used for Prophylaxis in CHAMPION-MG[22]	
Amoxicillin	Ciprofloxacin
Cefcapene	Erythromycin
Cefixime	Phenoxymethylpenicillin
Cefuroxime	

Fluoroquinolone antibiotics and macrolide antibiotics may worsen gMG symptoms.[33]

- The durations and drug regimens for antibacterial drug prophylaxis and their efficacy have not been studied in unvaccinated or vaccinated patients receiving complement inhibitors, including ULTOMIRIS®[1]
- The benefits and risks of treatment with ULTOMIRIS, as well as the benefits and risks of antibacterial drug prophylaxis in unvaccinated or vaccinated patients, must be considered against the known risks for serious infections caused by *Neisseria meningitidis*[1]
- In the CHAMPION-MG study, HCPs were not provided a protocol for antibiotic prophylaxis, allowing them to use their clinical discretion in selecting appropriate antibiotics

gMG, generalized myasthenia gravis.

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

Prophylactic antibiotic use in CHAMPION-MG

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

Consider each patient when starting on ULTOMIRIS®

Complete or update meningococcal vaccination (for serogroups A, C, W, Y, and B) at least 2 weeks prior to administration of the first dose of ULTOMIRIS[1]

NOTE: If the patient's status changes, follow the guidance under "If Urgent" to start ULTOMIRIS sooner.

If Urgent[1]

1 Start ULTOMIRIS with prophylactic antibiotics[a]

2 Administer meningococcal vaccines as soon as possible

[a]In patients not up to date with meningococcal vaccines according to ACIP recommendations.

CHAMPION-MG did not evaluate antibiotic prophylaxis outcomes. These data should not be used to make any clinical decisions. HCPs can consider consulting an infectious disease specialist for recommendations on antibiotic prophylaxis.

MENINGOCOCCAL INFECTION RISK OVERVIEW:
Because ULTOMIRIS blocks terminal complement activation, patients are at an increased risk of contracting meningococcal infections or other infections caused by *Neisseria meningitidis*. It is important to vaccinate all patients on complement inhibitors against meningococcal disease.[28,29,34]

RECOMMENDED MENINGOCOCCAL VACCINATIONS:
Complete or update meningococcal vaccination (for serogroups A, C, W, Y, and B) ≥2 weeks prior to administration of the first dose of ULTOMIRIS, per the current ACIP recommendations for patients receiving a complement inhibitor.[1]

- Revaccinate patients in accordance with ACIP recommendations considering the duration of ULTOMIRIS therapy[1]

ANTIBACTERIAL DRUG PROPHYLAXIS:
If urgent ULTOMIRIS therapy is indicated in a patient who is not up to date with meningococcal vaccines according to ACIP recommendations, provide the patient with antibacterial drug prophylaxis and administer meningococcal vaccines as soon as possible.[1]

Note that ACIP recommends an administration schedule in patients receiving complement inhibitors that differs from the administration schedule in the vaccine prescribing information.

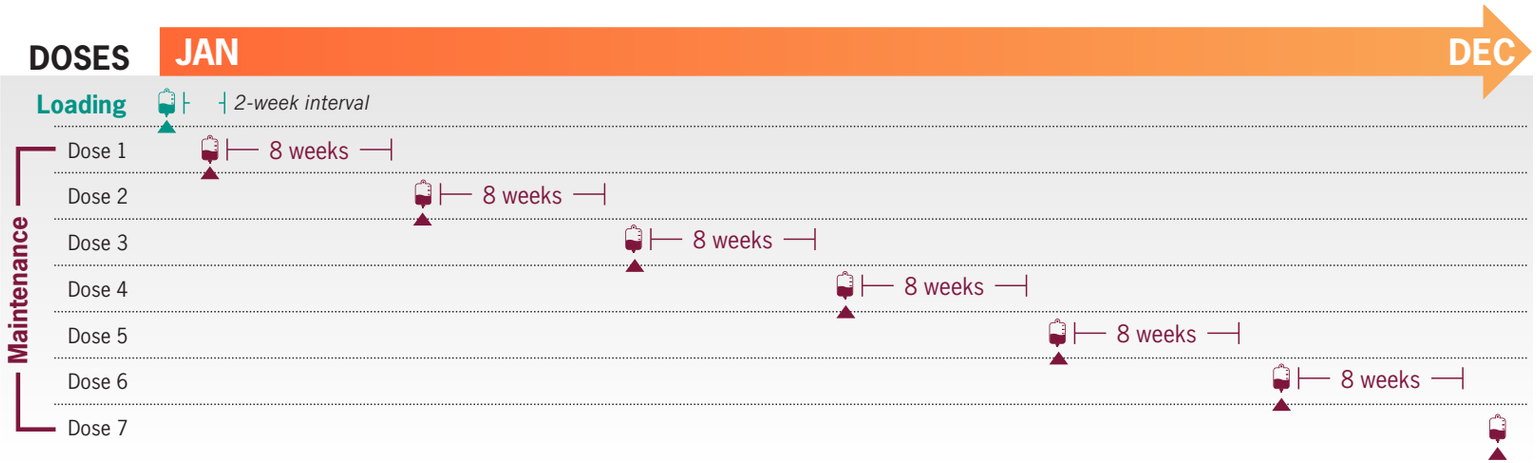
ACIP, Advisory Committee on Immunization Practices.

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

ULTOMIRIS® provides adult patients with gMG with predictable, once-every-8-week maintenance dosing for lasting symptom control[1,4,a]

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

1 infusion every 8 weeks, starting 2 weeks after a loading dose; 6-7 maintenance infusions per year[1]



Each infusion typically lasts less than 1 hour for the majority of patients. Patients are monitored for at least 1 hour after infusions for signs or symptoms of an infusion-related reaction.[1,a]

- If an adverse reaction occurs during the administration of ULTOMIRIS, the infusion may be slowed or stopped at the discretion of the physician[1]
- The recommended weight-based dosing regimen in adult patients with gMG (≥40 kg [88 lb]) consists of a loading dose followed 2 weeks later by the start of maintenance dosing every 8 weeks. The recommended ULTOMIRIS dosing in adult patients with gMG weighing 40 kg or greater is based on the patients' body weight[1]
- The dosing schedule is allowed to occasionally vary within 7 days of the scheduled infusion day (except for the first maintenance dose of ULTOMIRIS), but subsequent doses should be administered according to the original schedule[1]
- The IV infusion set tubing should be flushed with 0.9% Sodium Chloride Injection, USP at the end of the infusion to ensure the full dose of ULTOMIRIS is administered. This is important for all patients, especially due to the weight-based dosing and small volume (<100 mL) of ULTOMIRIS 100 mg/mL[1]
- Following a missed intravenous ULTOMIRIS dose, the patient should contact their healthcare provider immediately[1]

[a]Minimum infusion time for ULTOMIRIS 100 mg/mL maintenance doses ranges from 30 minutes to less than 1 hour, depending on body weight.[1]
gMG, generalized myasthenia gravis; IV, intravenous; USP, United States Pharmacopeia.

SELECT IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS

Most common adverse reactions in adult patients with gMG (incidence ≥10%) were diarrhea and upper respiratory tract infection. Serious adverse reactions were reported in 20 (23%) of patients treated with ULTOMIRIS and in 14 (16%) patients receiving placebo.

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

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

Doses and infusion times for ULTOMIRIS® 100 mg/mL[1]

Body Weight Range[1,a,b]	Loading Dose[1]	Maintenance Dose[1]	Minimum Infusion Time (loading, maintenance dose)[1]
40 kg (88 lb) to less than 60 kg (132 lb)	2400 mg	3000 mg	48 min, 54 min
60 kg (132 lb) to less than 100 kg (220 lb)	2700 mg	3300 mg	36 min, 42 min
100 kg (220 lb) or greater	3000 mg	3600 mg	24 min, 30 min

If an adverse reaction occurs during the administration of ULTOMIRIS, the infusion may be slowed or stopped at the discretion of the physician. Monitor the patient for at least 1 hour following completion of the infusion for signs or symptoms of an infusion-related reaction.[1]

With a predictable, patient-friendly infusion schedule, ULTOMIRIS **decreases the treatment burden for adult patients with gMG** who are anti-AChR antibody positive. ULTOMIRIS offers **the only once-every-8-week maintenance dosing** schedule[1]

[a]Body weight at time of treatment.[1]
[b]Approximate weight in pounds was calculated using standard weight conversion of 1 kg=2.205 lb.
AChR, acetylcholine receptor; gMG, generalized myasthenia gravis.

SELECT IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS (continued)

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.

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

ULTOMIRIS® 100 mg/mL dosing at a glance[1]

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

	Body Weight Range[a,b]	ULTOMIRIS Volume		Volume of 0.9% of NaCl[c]		Total Volume (dose)	Minimum Infusion Time[d]	Maximum Infusion Rate	ULTOMIRIS Vial Combinations	
									1100 mg/ 11 mL	300 mg/ 3 mL
Loading Dose Administration	40 kg (88 lb) to <60 kg (132 lb)	24 mL	+	24 mL	=	48 mL (2400 mg)	48 min	60 mL/hr	—	8
	60 kg (132 lb) to <100 kg (220 lb)	27 mL	+	27 mL	=	54 mL (2700 mg)	36 min	90 mL/hr	—	9
	100 kg (220 lb) or greater	30 mL	+	30 mL	=	60 mL (3000 mg)	24 min	150 mL/hr	—	10
Maintenance Dose Administration	40 kg (88 lb) to <60 kg (132 lb)	30 mL	+	30 mL	=	60 mL (3000 mg)	54 min	67 mL/hr	—	10
	60 kg (132 lb) to <100 kg (220 lb)	33 mL	+	33 mL	=	66 mL (3300 mg)	42 min	95 mL/hr	3	—
	100 kg (220 lb) or greater	36 mL	+	36 mL	=	72 mL (3600 mg)	30 min	144 mL/hr	3	1

Concomitant use of ULTOMIRIS with PE, PP, or IVIg treatment can reduce serum ULTOMIRIS concentrations and requires a supplemental dose of ULTOMIRIS.[1]

[a]Body weight at time of treatment.[1]
[b]Approximate weight in pounds was calculated using standard weight conversion of 1 kg=2.205 lb.
[c]Dilute ULTOMIRIS only using 0.9% Sodium Chloride Injection, USP.[1]
[d]Minimum infusion time for ULTOMIRIS 100 mg/mL maintenance doses ranges from 30 minutes to less than 1 hour, depending on body weight.[1]
IVIg, intravenous immunoglobulin; NaCl, sodium chloride; PE, plasma exchange; PP, plasmapheresis; USP, United States Pharmacopeia.

SELECT IMPORTANT SAFETY INFORMATION
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.

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

Supplemental dosing of ULTOMIRIS® after PE, PP, or IVIg[1]

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

Body Weight Range[a]	Most Recent ULTOMIRIS Dose	Supplemental Dose Following Each PE or PP Intervention	Supplemental Dose Following Completion of an IVIg Cycle
40 kg (88 lb) to <60 kg (132 lb)	2400 mg	1200 mg	600 mg
	3000 mg	1500 mg	
60 kg (132 lb) to <100 kg (220 lb)	2700 mg	1500 mg	600 mg
	3300 mg	1800 mg	
100 kg (220 lb) or greater	3000 mg	1500 mg	600 mg
	3600 mg	1800 mg	
Timing of ULTOMIRIS supplemental dose		Within 4 hours following each PE or PP intervention	Within 4 hours following completion of an IVIg cycle

[a]Body weight at time of treatment.[1]
IVIg, intravenous immunoglobulin; PE, plasma exchange; PP, plasmapheresis.

SELECT IMPORTANT SAFETY INFORMATION
DRUG INTERACTIONS (continued)

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 additional Important Safety Information throughout and full Prescribing Information for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

Count on OneSource™ for comprehensive support along the way

ONESOURCE® Personalized Patient Support from Alexion

OneSource is a comprehensive, complimentary, and personalized patient support program offered by Alexion to help with a variety of your patients' needs from diagnosis through treatment.

We can help make sense of health insurance coverage, answer questions about treatment with ULTOMIRIS®, and foster connections to community resources. With our experience and resources, we're here to help you and your patients feel supported every step of the way.

Alexion OneSource Specialists assist with:

Education
- Providing your patients with educational resources and materials related to generalized myasthenia gravis (gMG)
- Helping to answer your patients' questions about the disease or treatment logistics
- Providing information about meningococcal vaccinations and can help your patients locate a vaccination center

Health insurance navigation
- Helping your patients understand ULTOMIRIS health insurance coverage
- Exploring alternative funding options and financial resources

Ongoing support
- Personalized support for your patients in maintaining therapy during their major life events, such as a change in job, insurance status, provider, or relocation

Community connections
- Providing information to patients regarding in-person and online meetings and events
- Connecting patients with other people living with gMG

VACCINATION SUPPORT

- Educating patients/caregivers about meningococcal vaccines
- Assisting patients in finding a local vaccination solution
- Providing VaxFirst, a complimentary program to help eligible patients access meningococcal vaccinations to ensure compliance with FDA-mandated REMS (Risk Evaluation and Mitigation Strategies) requirements and help reduce the risk of infections caused by *Neisseria meningitidis,* which can increase a patient's susceptibility to serious, life-threatening, or fatal infections
- Arranging the required meningococcal vaccinations
- Locating infusion centers or other nearby options

OneSource will help eligible patients find the appropriate vaccine options for each individual patient. Contact OneSource for more information at 1-888-765-4747.

For more information, please visit:
AlexionOneSource.com | UltomirisHCP.com/gMG

With your experience and the expertise of OneSource, patients can feel supported at every step

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

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

Resources to help you navigate financial access for your patients

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 in generalized myasthenia gravis (gMG), including:

- ULTOMIRIS Access & Reimbursement Guide
- ULTOMIRIS gMG Common Prior Authorization Criteria
- ULTOMIRIS gMG Appeal Letter

Visit alexionaccessnavigator.com/ULTOMIRIS for more information

Our team is ready to help you and your patients navigate patient access for ULTOMIRIS. Your dedicated Field Reimbursement Manager (FRM) can provide the following:

- HCP Office Access and Reimbursement Education
- Case-Specific Prior Authorization Education
- Product Acquisition and Claims Support
- Prior Authorization Denial Educational Support

Visit alexionaccessnavigator.com/connect-with-an-frm to get in touch with an FRM

As low as $0 out-of-pocket treatment costs for eligible patients[a]

The Alexion OneSource CoPay Program provides financial assistance by covering up to $15,000 US dollars per calendar year for eligible patients' out-of-pocket medication and infusion costs associated with ULTOMIRIS.

[a]Additional eligibility requirements apply; see Terms and Conditions at qr.short.az/TermsConditions

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

References: 1. ULTOMIRIS. Prescribing Information. Alexion Pharmaceuticals, Inc. **2.** Vu T, Meisel A, Mantegazza R, et al. *NEJM Evid.* 2022;1(5):1-22. **3.** Muppidi S, et al; MG Composite and MG-QOL15 Study Group. *Muscle Nerve.* 2011;44(5):727-731. **4.** Meisel A, Annane D, Vu T, et al. *J Neurol.* 2023;270(8):3862-3875. **5.** Gilhus NE, et al. *Nat Rev Dis Primers.* 2019;5(1):30. **6.** Johnson S, et al. *Med Sci Monit.* 2021;27:e933296. **7.** Sanders DB, et al. *Neurology.* 2016;87(4):419-425. **8.** Mahic M, et al, *Muscle Nerve.* 2023;67(4):297-305. **9.** Harris L, et al. *BMC Neurol.* 2022;22(1):172. **10.** Kusner LL, et al. *Ann N Y Acad Sci.* 2012;1274(1):127-132. **11.** Meriggioli MN, et al. *Lancet Neurol.* 2009;8(5):475-490. **12.** Conti-Fine BM, et al. *J Clin Invest.* 2006;116(11):2843-2854. **13.** Howard JF Jr. *Ann N Y Acad Sci.* 2018;1412(1):113-128. **14.** Engel AG, et al. *Mayo Clin Proc.* 1977;52(5):267-280. **15.** Sahashi K, et al. *J Neuropathol Exp Neurol.* 1980;39(2):160-172. **16.** Kulasekararaj AG, et al. *Blood.* 2019;133(6):540-549. **17.** Lee JW, et al. *Blood.* 2019;133(6):530-539. **18.** Murphy K, et al. *Janeway's Immunobiology.* 9th ed. Garland Science, Taylor & Francis Group, LLC. 2017:37-76. **19.** Rother RP, et al. *Nat Biotechnol.* 2007;25(11):1256-1264. **20.** Vu T, et al. *NEJM Evid.* Appendix Supplement. 2022;1(5):1-44. **21.** Myasthenia Gravis Foundation of America. Accessed June 2, 2025. https://myasthenia.org/Portals/0/ADL.pdf **22.** Data on file. Alexion Pharmaceuticals, Inc. **23.** Myasthenia Gravis Foundation of America. Accessed June 2, 2025. https://myasthenia.org/Portals/O/QMG.pdf **24.** Vu T, et al. Presentation presented at: AAN Annual Meeting; April 13-18, 2024; Denver, CO. **25.** Vu TH, Mantegazza R, Annane D, et al. *Eur J Neurol.* 2025;32(4):e70158. **26.** Howard JF, Vu T, Mantegazza R, et al. *Muscle Nerve.* 2024;69(5):556-565. **27.** Vissing J, Mozaffar T, Mantegazza R, et al. Poster presented at: 2024 Muscular Dystrophy Association (MDA) Clinical & Scientific Conference; March 3-6, 2024; Orlando, FL. **28.** Mbaeyi SA, et al. *MMWR Recomm Rep.* 2020;69(9):1-41. **29.** Centers for Disease Control and Prevention. Adult immunization schedule notes. Published November 21, 2024. Accessed June 2, 2025. https://www.cdc.gov/vaccines/hcp/imz-schedules/adult-notes.html#note-mening **30.** Centers for Disease Control and Prevention. Clinical guidance for managing meningococcal disease risk in patients receiving complement inhibitor therapy. Meningococcal Disease. Published November 26, 2024. Accessed June 2, 2025. https://www.cdc.gov/meningococcal/hcp/clinical-guidance/complement-inhibitor.html **31.** Centers for Disease Control and Prevention. ACIP recommendations. Published May 15, 2025. Accessed June 2, 2025. https://www.cdc.gov/acip/vaccine-recommendations/index.html **32.** Centers for Disease Control and Prevention. Administering meningococcal vaccines. Reviewed November 20, 2023. Accessed June 2, 2025. https://www.cdc.gov/vaccines/vpd/mening/hcp/administering-vaccine.html#print **33.** Ahmed A, Simmons Z. et al. *Internet J Neurol.* 2008;10(2):1-8. **34.** Uria MJ, Zhang Q, Li Y, et al. *J Exp Med.* 2008;205(6):1423-1434.

Meet Madison, a 32-year-old recently diagnosed with gMG and experiencing breakthrough symptoms[a]

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

Madison

Age: 32
Profession: Social worker
Length of Disease: 8 months; treatment initiated upon diagnosis
Location: Cleveland, Ohio

Medical history

- Madison has no significant medical history except for a diagnosis of anti-AChR antibody-positive gMG 8 months ago
- Madison has a family history of osteoporosis and diabetes mellitus

History of present illness

- Madison's disease progressed from oMG to gMG quickly, requiring a steroid and IST for management
- MGFA class IIIa
- MG-ADL total score: 7
- Madison initially experienced an incomplete response on low-dose steroids and azathioprine, requiring an escalation to prednisone 60 mg per day
  - Madison experienced weight gain and acne requiring a steroid reduction to 20 mg per day

Current medications

- Prednisone 20 mg once daily
- Azathioprine 150 mg once daily
- Pyridostigmine 60 mg four times daily

Current chief complaints

- Madison has an incomplete response to current therapies and is experiencing breakthrough symptoms of intermittent slurring of speech, increased shortness of breath upon exertion, and lower limb paresis
- Madison is experiencing adverse reactions including weight gain and increased acne
- Madison is concerned about the increased risk of comorbidities and serious adverse reactions associated with long-term steroid use and ISTs

[a]Patient case is fictitious and intended only for discussion about patient experiences. Patient case is not intended for diagnosis or treatment purposes.

AChR, acetylcholine receptor; gMG, generalized myasthenia gravis; IST, immunosuppressive therapy; MG-ADL, Myasthenia Gravis Activities of Daily Living; MGFA, Myasthenia Gravis Foundation of America; oMG, ocular myasthenia gravis.

SELECT IMPORTANT SAFETY INFORMATION

USE IN SPECIFIC POPULATIONS

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to ULTOMIRIS during pregnancy.

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

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

Meet Jacob, a 55-year-old father with gMG worried about treatment burden[a]

Jacob

Age: 55
Profession: Grocery clerk
Length of Disease: 2 years
Location: Boston, Massachusetts

Medical history
- Jacob has no significant medical history except for a diagnosis of anti-AChR antibody-positive gMG 2 years ago

History of present illness
- He has been on an infusion therapy with concomitant steroids for the past 6 months
- MGFA class IIa
- His daily medication regimen previously included azathioprine, which was discontinued because he could not tolerate it
- He was still experiencing gMG symptoms, which prompted more frequent doses of infusion therapy

Current medications
- Intravenous immunoglobulin
- Prednisone 20 mg once daily

Current chief complaints
- Despite more frequent infusions, Jacob is still experiencing fluctuating and unpredictable symptoms between treatment doses, making it difficult to drive to work and keep up with his children's extracurricular activities
- Jacob has concerns about his current treatment regimen due to its unpredictable infusion schedules and frequent lengthy infusion center visits
- Based on conversations with his doctor, Jacob is interested in a treatment option that can help decrease his gMG symptoms, which were evaluated during his MG-ADL assessment

[a]Patient case is fictitious and intended only for discussion about patient experiences. Patient case is not intended for diagnosis or treatment purposes.

AChR, acetylcholine receptor; gMG, generalized myasthenia gravis; MG-ADL, Myasthenia Gravis Activities of Daily Living; MGFA, Myasthenia Gravis Foundation of America.

SELECT IMPORTANT SAFETY INFORMATION

USE IN SPECIFIC POPULATIONS (continued)

Pregnancy Exposure Registry (continued)

Healthcare providers and patients may call 1-833-793-0563 or go to www.UltomirisPregnancyStudy.com to enroll in or to obtain information about the registry.

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.

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

INDICATION & IMPORTANT SAFETY INFORMATION

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

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)*].

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.

Please see full Prescribing Information for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

INDICATION & IMPORTANT SAFETY INFORMATION (continued)

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

WARNINGS AND PRECAUTIONS (continued)

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.

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

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 to 7% of patients, including lower back pain, abdominal pain, muscle spasms, drop or elevation in blood pressure, rigors, limb discomfort, drug hypersensitivity (allergic reaction), and dysgeusia (bad taste). These reactions did not require discontinuation of ULTOMIRIS. If signs of cardiovascular instability or respiratory compromise occur, interrupt ULTOMIRIS 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.

USE IN SPECIFIC POPULATIONS

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to ULTOMIRIS during pregnancy. Healthcare providers and patients may call 1-833-793-0563 or go to www.UltomirisPregnancyStudy.com to enroll in or to obtain information about the registry.

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.

Please see full Prescribing Information for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

ULTOMIRIS® offers adult patients:

- **More than 2x greater improvement in MG-ADL** total score from baseline at Week 26 vs placebo (-3.1 vs -1.4, respectively [*P*<0.001])[1,2,a]
- **Predictable, once-every-8-week maintenance dosing,** 2 weeks after an initial loading dose[1]
- **Most common adverse reactions occurring in ≥10% of patients** taking ULTOMIRIS were diarrhea and upper respiratory tract infection[1]
- **Comprehensive, personalized support through the Alexion OneSource™ program**

[a]**Based on the MG-ADL, a categorical scale that assesses the impact on daily function of 8 signs or symptoms that are typically affected in gMG.**

gMG, generalized myasthenia gravis; MG-ADL, Myasthenia Gravis Activities of Daily Living.

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

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 additional Important Safety Information throughout and full Prescribing Information for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

ALEXION
AstraZeneca Rare Disease

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