Ravulizumab-cwvz (Ultomiris™)	Place of Service Office Administration Home Infusion Administration Infusion Center Administration Outpatient Facility Administration* [*Prior authorization required – see section (1)] HCPCS: J1303 per 10 mg

Conditions listed in policy (*see criteria for details*)

- Atypical hemolytic uremic syndrome
- Generalized myasthenia gravis (gMG)
- Paroxysmal nocturnal hemoglobinuria (PNH)

AHFS therapeutic class: Complement inhibitor

Mechanism of action: Complement inhibitor

(1) Special Instructions and pertinent Information

Please submit clinical information for prior authorization review.

Members with the following plans: **PPO, Direct Contract HMO and when applicable, ASO/Shared Advantage/HMO (non-direct contract)** may be required to have their medication administered at a preferred site of service, including the home, a physicians' office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

****CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION ****

MCG™ Care Guidelines, 19th edition, 2015

ADMINISTRATION OF ULTOMIRIS IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (Supporting Documentation must be submitted)

1. **Patient is receiving their first 2 infusions of Ultomiris or is being re-initiated on Ultomiris after at least 6 months off therapy.** *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

Or

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. **Patient has experienced a previous severe adverse event on Ultomiris based on documentation submitted.**

3. **Patient continues to experience moderate to severe adverse events on Ultomiris based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.**

4. **Patient is clinically unstable based on documentation submitted.**

5. Patient is physically or cognitively unstable based on documentation submitted.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Ultomiris™ (ravulizumab-cwvz) must be sent for clinical review and receive authorization prior to drug administration or claim payment

Atypical hemolytic uremic syndrome (aHUS)

Covered Doses

Body Weight Range (kg)	IV Loading Dose (mg)	IV Maintenance Dose (mg) and Interval. Maintenance dosing starts 2 weeks after the loading dose.	
5 to less than 10	600	300	Every 4 weeks
10 to less than 20	600	600	
20 to less than 30	900	2,100	Every 8 weeks
30 to less than 40	1,200	2,700	
40 to less than 60	2,400	3,000	
60 to less than 100	2,700	3,300	
100 or greater	3,000	3,600	

Coverage Period

Initial: 1 year

Reauthorization: Cover yearly based upon patient's continued response to therapy

ICD-10: D59.3

Generalized myasthenia gravis (gMG)

1. Prescribed by or in consultation with a neurologist, **AND**
2. Positive serologic test for anti-AChR antibodies, **AND**
3. Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score ≥6, **AND**
4. Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV, **AND**
5. Inadequate response to at least one first-line therapy [i.e., acetylcholinesterase inhibitors, corticosteroids, or non-steroidal immunosuppressive therapies (NSISTs)]

Covered Doses

Body Weight Range (kg)	IV Loading Dose (mg)	IV Maintenance Dose (mg) and Interval. Maintenance dosing starts 2 weeks after the loading dose.	
40 to less than 60	2,400	3,000	Every 8 weeks
60 to less than 100	2,700	3,300	
100 or greater	3,000	3,600	

Coverage Period

Initial: 6 months
Reauthorization: Yearly, based upon patient's continued response to therapy as shown by one of the following:

1. Improvement of at least 2 points (reduction in score) in MG-ADL total score, OR
2. Reduction in signs and symptoms of myasthenia gravis

ICD-10:
G70.00, G70.01

Paroxysmal nocturnal hemoglobinuria (PNH)

Covered Doses

Body Weight Range (kg)	IV Loading Dose (mg)	IV Maintenance Dose (mg) and Interval. Maintenance dosing starts 2 weeks after the loading dose.	
5 to less than 10	600	300	Every 4 weeks
10 to less than 20	600	600	
20 to less than 30	900	2,100	Every 8 weeks
30 to less than 40	1,200	2,700	
40 to less than 60	2,400	3,000	
60 to less than 100	2,700	3,300	
100 or greater	3,000	3,600	

Coverage Period
Initial: 1 year
Reauthorization: Cover yearly based upon patient's continued response to therapy

ICD-10:
D59.5

(3) The following condition(s) DO NOT require Prior Authorization/Preservice
All requests for Ultomiris™ (ravulizumab-cwvz) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)
Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information
How Supplied:
300 mg/30mL (10 mg/mL) single-dose vial

(6) References

- AHFS®. Available by subscription at http://www.lexi.com

- American Academy of Allergy Asthma and Immunology. Guidelines for the Site of Care for Administration of IGIV Therapy. December 2011.
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- MCG™ Care Guidelines, 19th edition, 2015, Home Infusion Therapy, CMT: CMT-0009(SR)
- Ultomiris® (ravulizumab-cwvz) [Prescribing Information]. Boston, MA: Alexion, Inc.; 7/2022.

(7) Policy Update

Date of last revision: 1Q2024
Date of next review: 3Q2024
Changes from previous policy version:

- Generalized myasthenia gravis: Clarified reauthorization requirement to include clinical response (i.e., MG-ADL total score, signs and symptoms). *Rationale: Published literature supports MG-ADL score to assess clinical treatment response in myasthenia gravis.*

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee