ravulizumab-cwvz (Ultomiris)

Commercial Medical Benefit Drug Policy

Place of Service

Home Infusion Administration
Infusion Center Administration
Office Administration
Outpatient Facility Administration

Drug Details

USP Category: IMMUNOLOGICAL AGENTS
Mechanism of Action: Complement inhibitor
HCPCS:
J1303:Injection, ravulizumab-cwvz, 10 mg
How Supplied:

- 300 mg/30 mL (10 mg/mL) solution in a single-dose vial
- 300 mg/3 mL (100 mg/mL) solution in a single-dose vial
- 1,100 mg/11 mL (100 mg/mL) solution in a single-dose vial

Condition(s) listed in policy *(see coverage criteria for details)*

- Atypical Hemolytic Uremic Syndrome (aHUS)
- Generalized Myasthenia Gravis (gMG)
- Neuromyelitis Optica Spectrum Disorder (NMOSD)
- Paroxysmal Nocturnal Hemoglobinuria (PNH)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct)** may be required to have their medication administered at a preferred site of service, including the home, a physician's 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 THIS DRUG 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 doses of 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.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Atypical Hemolytic Uremic Syndrome (aHUS)

Meets medical necessity if all the following are met:

Initial

1. ***Effective 2/1/2026 and after:*** Prescribed by or in consultation with a hematologist or nephrologist
2. ***Effective 2/1/2026 and after:*** Not being used for Shiga E. coli related hemolytic uremic syndrome (STEC-HUS)

Reauthorization

1. ***Effective 2/1/2026 and after:*** Prescribed by or in consultation with a hematologist or nephrologist
2. Patient has continued to respond to therapy (e.g. reduction of plasma exchanges, reduction in dialysis, increased platelet count, reduction of hemolysis)

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:
one year

ICD-10:
D59.3

Generalized Myasthenia Gravis (gMG)
Meets medical necessity if all the following are met:
Initial

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

Reauthorization

1. One of the following (a or b):
   a. Improvement of at least 2 points (reduction in score) in MG-ADL total score
   b. Reduction in signs and symptoms of myasthenia gravis

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: one year

ICD-10:
G70.00, G70.01

Neuromyelitis Optica Spectrum Disorder (NMOSD)
Meets medical necessity if all the following are met:
Initial

1. Prescribed by or in consultation with a neurologist
2. Patient is anti-aquaporin-4 (AQP4) antibody positive

3. Not being used in combination with another drug therapy for NMOSD (e.g., rituximab, inebilizumab, satralizumab)
4. Meets ONE of the following:
   a. Patient has had an inadequate response or intolerance to rituximab
   b. Patient has not been treated with rituximab and has a contraindication to Ruxience and Truxima

Reauthorization
1. Documented reduction in frequency of NMO attacks from baseline
2. ***Effective 2/1/2026 and after:*** Prescribed by or in consultation with a neurologist
3. ***Effective 2/1/2026 and after:*** Not being used in combination with another drug therapy for NMOSD (e.g. rituximab, inebilizumab, satralizumab)

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:
one year

ICD-10:
G36.0

Paroxysmal Nocturnal Hemoglobinuria (PNH)
Meets medical necessity if all the following are met:
Initial
1. ***Effective 2/1/2026 and after:*** Prescribed by or in consultation with a hematologist or oncologist
2. ***Effective 2/1/2026 and after:*** Not being used in combination with another complement C3 inhibitor, complement factor B inhibitor or complement C5 inhibitor

Reauthorization
1. ***Effective 2/1/2026 and after:*** Prescribed by or in consultation with a hematologist or oncologist
2. Clinical response from baseline (e.g. increased or stabilization of hemoglobin levels, reduction in transfusions, improvement in hemolysis, decrease in LDH, etc)
3. ***Effective 2/1/2026 and after:*** Not being used in combination with another complement C3 inhibitor, complement factor B inhibitor or complement C5 inhibitor

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:
one year

ICD-10:
D59.5

References

1. AHFS. Available by subscription at http://www.lexi.com
2. American Academy of Allergy Asthma and Immunology. Guidelines for the Site of Care for Administration of IGIV Therapy. December 2011.
3. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
4. MCG Care Guidelines, 19th edition, 2015, Home Infusion Therapy, CMT: CMT-0009(SR)
5. Ultomiris (ravulizumab) [prescribing information]. Alexion Pharmaceuticals, Boston, MA: September 2025.

Review History

Date of Last Annual Review: 4Q2025
Changes from previous policy version:

- aHUS: Added specialist requirement, clarified combination use restriction
- PNH/NMOSD: Added specialist requirement, clarified reauthorization requirements, and combination use restriction

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee