Medical Benefit Drug Policy

Ultomiris (ravulizumab-cwvz) injection, for intravenous use

Policy Number: MC/PC 047
Effective Date: June 1, 2026

Instructions for Use

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Related Policies

- n/a

Coverage Rationale

Atypical Hemolytic Uremic Syndrome

For initial coverage of Ultomiris (ravulizumab-cwvz) for Atypical Hemolytic Uremic Syndrome (aHUS), the following will be required:

- Diagnosis of atypical hemolytic uremic syndrome (aHUS) **and**
- Patient is one month of age and older **and**
- Prescribed by or in consultation with one of the following:
  - Hematologist
  - Nephrologist

For reauthorization coverage of Ultomiris (ravulizumab-cwvz) for Atypical Hemolytic Uremic Syndrome (aHUS), the following will be required:

- Patient demonstrates positive clinical response to therapy (e.g., normalization of platelet count, improvement in serum creatinine from baseline)

Generalized Myasthenia Gravis

For initial coverage of Ultomiris (ravulizumab-cwvz) for Generalized Myasthenia Gravis (gMG), the following will be required:

- Diagnosis of generalized myasthenia gravis (gMG) **and**
- Patient is anti-acetylcholine receptor (AChR) antibody positive **and**
- One of the following:
  - Trial and failure, contraindication, or intolerance to two immunosuppressive therapies (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus) **or**
  - Both of the following:

        - Trial and failure, contraindication, or intolerance to one immunosuppressive therapy (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus) **and**
        - Trial and failure, contraindication, or intolerance to one of the following:
            - Chronic plasmapheresis or plasma exchange (PE)
            - Intravenous immunoglobulin (IVIG) **and**
- Prescribed by or in consultation with a neurologist

For reauthorization coverage of Ultomiris (ravulizumab-cwvz) for Generalized Myasthenia Gravis (gMG), the following will be required:

- Patient demonstrates positive clinical response to therapy

Neuromyelitis Optica Spectrum Disorder (NMOSD)

For initial coverage of Ultomiris (ravulizumab-cwvz) for Neuromyelitis Optica Spectrum Disorder (NMOSD), the following will be required:

- Diagnosis of Neuromyelitis Optica Spectrum Disorder (NMOSD) **and**
- Patient is anti-aquaporin-4 (AQP4) antibody positive **and**
- Prescribed by or in consultation with one of the following:
    - Neurologist
    - Ophthalmologist

For reauthorization coverage of Ultomiris (ravulizumab-cwvz) for Neuromyelitis Optica Spectrum Disorder (NMOSD), the following will be required:

- Patient demonstrates positive clinical response to therapy

Paroxysmal Nocturnal Hemoglobinuria

For initial coverage of Ultomiris (ravulizumab-cwvz) for Paroxysmal Nocturnal Hemoglobinuria (PNH), the following will be required:

- Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) **and**
- Patient is one month of age and older **and**
- Prescribed by or in consultation with a Hematologist/Oncologist.

For reauthorization coverage of Ultomiris (ravulizumab-cwvz) for Paroxysmal Nocturnal Hemoglobinuria (PNH), the following will be required:

- Patient demonstrates positive clinical response to therapy (e.g., hemoglobin stabilization, decrease in the number of red blood cell transfusions)

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
J1303	Injection, ravulizumab-cwvz, 10 mg

ICD-10 Code	Description
D59.30	Hemolytic-uremic syndrome, unspecified
D59.32	Hereditary hemolytic-uremic syndrome
D59.39	Other hemolytic-uremic syndrome
D59.5	Paroxysmal nocturnal hemoglobinuria [Marchiafava-Micheli]
G36.0	Neuromyelitis optica [Devic]
G70.0	Myasthenia gravis
G70.00	Myasthenia gravis without (acute) exacerbation
G70.01	Myasthenia gravis with acute exacerbation

Background

Ravulizumab is a long-acting intravenous monoclonal antibody, which inhibits terminal complement-mediated intravascular hemolysis in patients with paroxysmal nocturnal hemoglobinuria and complement-mediated thrombotic microangiopathy (TMA) in patients with atypical hemolytic uremic syndrome. Ravulizumab binds to the complement protein C5 with high affinity, thereby inhibiting its cleavage to C5a (the proinflammatory anaphylatoxin) and C5b (the initiating subunit of the terminal complement complex [C5b-9]) and preventing the generation of the terminal complement complex C5b-9. The presumed mechanism of action of ravulizumab in generalized myasthenia gravis is the reduction of the terminal complement complex C5b-9 deposition at the neuromuscular junction (Clinical Pharmacology 2026).

Clinical Evidence

Atypical Hemolytic Uremic Syndrome (aHUS)

- The efficacy and safety of ravulizumab for the treatment of aHUS were established in two Phase 3, single-arm, multicenter (MC), open-label (OL) trials in 58 adults and 21 children.
    - In the 26-week trial, 53.6% of the complement inhibitor naïve adults with aHUS achieved a complete TMA response, defined as normalization of platelet count (≥ 150 x 10^9/L), LDH (≤ 246 U/L), and ≥ 25% improvement in serum creatinine (SCr) from baseline for ≥ 28 days apart. At the last follow-up, 60.7% of the adults maintained a complete TMA response. The majority of patients achieved normalization of platelet count and lactate dehydrogenase (LDH). A total of 58.9% of adults had ≥ 25% improvement in SCr (Rondeau et al 2020).
    - In the 26-week study enrolling complement inhibitor naïve children with aHUS, TMA response rate at Weeks 26 and 50 were 77.8% and 94.4%. Normalization of platelet count (94.4%), LDH (88.9%), ≥ 25% improvement in SCr (83.3%), and hemoglobin (Hb) (88.9%) were observed following ravulizumab for 26 weeks. Seventeen of eighteen (94.4%) children had normalization of these parameters at Week 50 (Ariceta et al 2020).

Generalized Myasthenia Gravis (gMG)

- A 26-week, double blind (DB), placebo-controlled (PC), MC, randomized control trial (RCT) established the efficacy and safety of ravulizumab-cwvz in 175 adults with anti-AChR antibody positive gMG. Patients were randomized to ravulizumab-cwvz (n = 86) or placebo (n = 89) administered via IV administration and dosed based on body weight. Patients were also treated with acetylcholinesterase inhibitors (80%), corticosteroids (70%), and non-steroidal immunosuppressants (68%) at baseline and continued during the study. The primary endpoint, mean MG-ADL (Myasthenia Gravis Activities of Daily Living) change from baseline at Week 26 was significantly improved with ravulizumab-cwvz (difference, -1.6; 95% confidence interval [CI], -2.6 to -0.7; $p < 0.001$) compared to placebo. Ravulizumab-cwvz also significantly improved the key secondary endpoint, change from baseline in QMG (quantitative myasthenia gravis scores) (difference, -2.0; 95% CI, -3.2 to -0.8; $p < 0.001$).

Serious adverse effects (AEs, i.e., infections, pneumonia) were reported in 23% of patients receiving ravulizumab-cwvz (Ultomiris prescribing information 2024-5).

- Long-term efficacy was demonstrated in an OLE study, which reported sustained improvements across all metrics for up to 60 weeks (Meisel et al 2023).

Neuromyelitis optica spectrum disorder (NMOSD)

The efficacy and safety of ULTOMIRIS in adult patients with anti-AQP4 antibody positive NMOSD was assessed in an open-label multicenter study, Study ALXN1210-NMO-307 (NCT04291262). Patients participating in Study ALXN1210-NMO-307 received ULTOMIRIS intravenously in the Primary Treatment Period that ended when the last enrolled patient completed (or discontinued prior to) 50 weeks on study, representing a median study duration of 73.5 weeks (minimum 13.7, maximum 117.7). Efficacy assessments were based on a comparison of patients in Study ALXN1210-NMO-307 with an external placebo control group from another study (Study ECU-NMO-301, NCT01892345) composed of a comparable population of adult patients with anti-AQP4 antibody positive NMOSD.

- Study ALXN1210-NMO-307 enrolled 58 adult patients with NMOSD who had a positive serologic test for anti-AQP4 antibodies, at least 1 relapse in the last 12 months prior to the Screening Period, and an Expanded Disability Status Scale (EDSS) score ≤ 7. In the external placebo control group, eligibility criteria were similar except patients were required to have at least 2 relapses in last 12 months or 3 relapses in the last 24 months with at least 1 relapse in the 12 months prior to screening. Prior treatment with immunosuppressant therapies (ISTs) was not required for enrollment. However, patients on selected ISTs (i.e., corticosteroids, azathioprine, mycophenolate mofetil, methotrexate, and tacrolimus) were permitted to continue on therapy, with a requirement for stable dosing until they reached Week 106 in the Study. Similar IST use was permitted in the external placebo control group.
- The demographics were similar between the ULTOMIRIS treatment group from Study ALXN1210-NMO-307 and the placebo treatment group from Study ECU-NMO-301 (including age [median of 46.0 years for ULTOMIRIS versus 44.0 years for placebo] and sex [89.7% female for ULTOMIRIS versus 89.4% female for placebo]). The majority of patients were White or Asian. The median time from diagnosis to first dose was 0.9 years for ULTOMIRIS and 2.0 years for placebo. The median annualized relapse rate (ARR) in the last 24 months was 1.4 for ULTOMIRIS versus 1.9 for placebo, and the median number of historical relapses was 2 for ULTOMIRIS versus 4 for placebo. The median baseline EDSS score was 3.3 for ULTOMIRIS versus 4.0 for placebo. At baseline, 48% of patients in the ULTOMIRIS group received concomitant IST, including corticosteroids, versus 72% of subjects in the placebo group.
- The primary endpoint of Study ALXN1210-NMO-307 was the time to first adjudicated on-trial relapse as determined by an independent adjudication committee. No adjudicated on-trial relapses were observed in ULTOMIRIS-treated patients during the Primary Treatment Period, representing a statistically significant difference between the ULTOMIRIS and placebo treatment arms in time to first adjudicated on-trial relapse ($p < 0.0001$). The hazard ratio (95% confidence interval [CI]) for ULTOMIRIS compared with placebo was 0.014 (0.000, 0.103), representing a 98.6% reduction in the risk of relapse. ULTOMIRIS-treated patients experienced similar improvement in time to first adjudicated on-trial relapse with or without concomitant treatment (Ultomiris prescribing information 2025).

Paroxysmal Nocturnal Hemoglobinuria (PNH)

- Efficacy and safety of ravulizumab was first established in the Phase 3, OL, noninferiority RCTs CHAMPION-301 and CHAMPION-302. Results from these studies support the noninferiority of ravulizumab vs eculizumab with respect to efficacy, safety, Quality of Life (QoL) improvement, and survival benefit. Ravulizumab was also evaluated in pediatrics with PNH.
    - The 56-week CHAMPION-301 study randomized complement-naïve patients 1:1 to weight-based ravulizumab (n = 125) or eculizumab (n = 121). After 26 weeks of treatment, ravulizumab was non-inferior (NI) to eculizumab with respect to transfusion avoidance (TA) and lactate dehydrogenase (LDH) normalization (OR, 1.19; NI) (Lee et al 2019).
    - The 52-week CHAMPION-302 study randomized complement-experienced patients 1:1 to weight-based ravulizumab (n = 97) or eculizumab (n = 95). At study end, ravulizumab was NI to eculizumab with

respect to LDH % Complement Factor B (CFB) (-0.8% vs + 8.4%; NI), TA, breakthrough hemolysis (BTH), and hemoglobin (Hb) (Kulasekararaj et al 2019).
    - Extension data from CHAMPION-301, CHAMPION-302, and a Phase 1/2 pilot (N = 475) evaluated 1479 patient-years of follow-up data to conclude an estimated 0.8 deaths per 100 patient-years in patients with PNH treated with ravulizumab (Kulasekararaj et al 2022 [abstract]).

Place in therapy

aHUS
The 2024 Kidney Disease: Improving Global Outcomes (KDIGO) Controversies Conference report on the role of complement in kidney disease emphasizes that C5 inhibition (e.g., eculizumab or ravulizumab) is the gold-standard therapy for complement-mediated aHUS. It further highlights that early initiation of complement blockade is critical to optimizing both short- and long-term outcomes. Given the persistent diagnostic complexity of aHUS, treatment decisions should be guided by clinical suspicion and should not be delayed while awaiting genetic testing results (Vivarelli et al 2024)

MG
International consensus guidance for the management of MG recommends pyridostigmine as initial symptomatic treatment in most patients with MG. Corticosteroids and/or other immunosuppressive therapy (e.g., azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus) may be used in patients who have not met treatment goals after an adequate trial of pyridostigmine. Patients with refractory MG may require chronic IVIG or PE, cyclophosphamide, or rituximab; complement inhibition with eculizumab should be considered in severe refractory MG (Narayanaswami et al 2020).

NMOSD
The Neuromyelitis Optica Study Group (NEMOS) recommends eculizumab, ravulizumab, inebilizumab, rituximab, or satralizumab for first-line treatment and azathioprine, mycophenolate mofetil, or tocilizumab for second-line treatment. Third-line therapy may include a combination of a monoclonal antibody plus a classical immunosuppressive therapy (e.g., azathioprine or mycophenolate mofetil) (Kumpfel et al 2024).

The European Federation of Neurological Societies (EFNS) guideline for the prevention of NMO relapses recommends oral azathioprine plus prednisone or rituximab as first-line therapy (Sellner et al 2010). Other groups recommend mycophenolate mofetil plus prednisone as an additional first-line choice. Other treatment options include oral methotrexate, mitoxantrone, IV cyclophosphamide, IVIG, or PLEX (Kimbrough et al 2012, Sellner et al 2010).

PNH
There are currently no U.S. consensus guidelines for the treatment of PNH. **Expert Consensus** panels (Bodó et al 2023, Risitano and Peffault de Latour 2022, Oliver and Patriquin 2023) recommend:

- Approach to PNH therapy depends on severity of symptoms and degree of hemolysis. Asymptomatic patients should be monitored every 6 to 12 months for changes. Symptomatic patients should be treated with a complement inhibitor. Due to the preponderance of evidence, C5 inhibitors are considered first-line (eculizumab or ravulizumab).
    - Patients with BMF who present with significant PNH clone size and active hemolysis should be started on a C5 inhibitor. In such patients, PNH manifestations and/or thrombosis may worsen.
    - Response to therapy should be monitored via regular assessment of Hb, LDH, and ARC.
    - Switching between C5 inhibitors is unlikely to improve response unless the patient is experiencing pharmacodynamic BTH. Ravulizumab is preferred in this situation due to extended half-life.
- Up to 40% of patients on C5 inhibitor therapy will experience an inadequate response and persistent EVH. C5-experienced patients that may benefit from a switch to a C3 inhibitor (ie, pegcetacoplan) include those with frequent BTH, evidence of residual EVH, or unprovoked TEs despite ≥ 3 months of treatment with a C5 inhibitor.
- Patients with BMF and moderate-severe aplastic anemia are unlikely to benefit from complement inhibitor therapy and should be evaluated for HSCT. Those resistant to C5 therapy or thromboprophylaxis should also be evaluated.

- In patients that develop a TE, therapeutic anticoagulation for 3 to 6 months is recommended.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Ultomiris is a complement inhibitor indicated for:

- The treatment of adult and pediatric patients one month of age and older with paroxysmal nocturnal hemoglobinuria (PNH).
- The treatment of adult and pediatric patients one month of age and older with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy (TMA).
- The treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody-positive.
- The treatment of adult patients with neuromyelitis optica spectrum disorder (NMOSD) who are antiaquaporin-4 (AQP4) antibody-positive.

Limitations of Use: Ultomiris is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).

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Policy History/Revision Information

Date	Summary of Changes
10/18/2023	Approved by OptumRx P&T Committee
3/20/2024	Annual Review. Updated references. Change wording for reauthorization criteria.
4/16/2025	Annual Review. Updated references. Addition of Neuromyelitis Optica Spectrum Disorder (NMOSD) indication, ICD-10 code, and clinical evidence to policy.
05/14/2026	Annual Review. Updated background, clinical guidelines and references.

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. The insurance reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

OptumRx may also use tools developed by third parties to assist us in administering health benefits. OptumRx Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Nondiscrimination & Language Access Policy

Discrimination is Against the Law. Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex, (including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation, gender identity and sex stereotypes), consistent with the scope of sex discrimination described at 45 CFR § 92.101(a)(2). Aspirus Health Plan, Inc. does not exclude people or treat them less favorably because of race, color, national origin, age, disability, or sex.

Aspirus Health Plan, Inc.:
Provides people with disabilities reasonable modifications and free appropriate auxiliary aids and services to communicate effectively with us, such as:

- Qualified sign language interpreters.
- Written information in other formats (large print, audio, accessible electronic formats, other formats).

Provides free language assistance services to people whose primary language is not English, which may include:

- Qualified interpreters.
- Information written in other languages.

If *you* need reasonable modifications, appropriate auxiliary aids and services, or language assistance services, contact the Nondiscrimination Grievance Coordinator at the address, phone number, fax number, or email address below.

If *you* believe that Aspirus Health Plan, Inc. has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, *you* can file a *grievance* with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1890
Southampton, PA 18966-9998
Phone: 1-866-631-5404 (TTY: 711)
Fax: 763-847-4010
Email: customerservice@aspirushealthplan.com

You can file a *grievance* in person or by mail, fax, or email. If *you* need help filing a *grievance*, the Nondiscrimination Grievance Coordinator is available to help *you*.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1.800.368.1019, 800.537.7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html. This notice is available at Aspirus Health Plan, Inc.'s website: https://aspirushealthplan.com/webdocs/70021-AHP-NonDiscrim_Lang-Assist-Notice.pdf.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë.Telefononi në 1-800-332-6501 (TTY: 711).

Arabic تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن اعلى رقم الهاتف1-800-332-6501(رقم هاتف الصم والبك : 711)

French: ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1-800-332-6501 (ATS: 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zurVerfügung. Rufnummer: 1-800-332-6501 (TTY: 711).

Hindi: _यान द_: य_द आप ि हंदी बोलते ह_ तो आपके ि लए मु_त म_ भाषा सहायता सेवाएं उपल_ध ह_।1-800-332-6501 (TTY: 711) पर कॉल कर_।

Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1-800-332-6501 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다.1-800-332-6501 (TTY: 711)번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer1-800-332-6501 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода.Звоните 1-800-332-6501 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al1-800-332-6501 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1-800-332-6501 (TTY: 711).

Traditional Chinese: 注意：如果您使用繁體中文， 您可以免費獲得語言援助服務。請 致電 1-800-332-6501 (TTY: 711)

Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-800-332-6501 (TTY: 711).

Pennsylvania Dutch: Wann du Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1-800-332-6501 (TTY: 711).

Lao: ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ,ໂດຍບໍ່ເສັງຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1-800-332-6501 (TTY: 711).