

Ultomiris® (ravulizumab-cwvz) (Intravenous/Subcutaneous)

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I. Length of Authorization

Coverage will be provided for twelve (12) months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Ultomiris 10 mg/mL** – 30 mL SDV: 10 vials on day zero followed by 13 vials starting on day 14 and every 8 weeks thereafter
- Ultomiris 100 mg/mL – 3 mL SDV: 10 vials on day zero followed by 13 vials starting on day 14 and every 8 weeks thereafter
- Ultomiris 100 mg/mL – 11 mL SDV: 3 vials on day zero followed by 3 vials starting on day 14 and every 8 weeks thereafter
- Ultomiris 245 mg/3.5 mL single-dose cartridge on-body delivery system: 2 on-body delivery systems weekly

B. Max Units (per dose and over time) [HCPCS Unit]:

- Ultomiris IV
 - PNH/aHUS/gMG: 300 units on Day 0 followed by 360 units on Day 14 and every 8 weeks thereafter
- Ultomiris SQ
 - PNH/aHUS: 49 units weekly

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

- Patient is at least 1 month of age (*unless otherwise specified*); AND
- Prescriber is enrolled in the Ultomiris Risk Evaluation and Mitigation Strategy (REMS) program; AND

Universal Criteria ¹

- Patients must be administered a meningococcal vaccine at least two weeks prior to initiation of therapy and will continue to be revaccinated according to current medical guidelines for vaccine use (*If urgent Ultomiris therapy is indicated in an unvaccinated patient, administer meningococcal vaccine(s) as soon as possible and provide patients with two weeks of antibacterial drug prophylaxis.*) **AND**
- Will not be used in combination with other immunomodulatory biologic therapies (i.e., efgartigimod, eculizumab, pegcetacoplan, satralizumab, inebilizumab, etc.); **AND**

Paroxysmal Nocturnal Hemoglobinuria (PNH) † Φ 1,4,8,9,18

- Used as switch therapy; **AND**
 - Patient is currently receiving treatment with Soliris and has shown a beneficial disease response and absence of unacceptable toxicity while on therapy; **OR**
- Patient is complement inhibitor treatment-naïve; **AND**
 - Diagnosis must be accompanied by detection of PNH clones of at least 5% by flow cytometry diagnostic testing; **AND**
 - Demonstrate the presence of at least 2 different glycosylphosphatidylinositol (GPI) protein deficiencies (e.g., CD55, CD59, etc.) within at least 2 different cell lines (e.g., granulocytes, monocytes, erythrocytes); **AND**
 - Patient has laboratory evidence of significant intravascular hemolysis (i.e., LDH $\geq 1.5 \times$ ULN) with symptomatic disease and at least one other indication for therapy from the following (regardless of transfusion dependence):
 - Patient has symptomatic anemia (i.e., hemoglobin < 7 g/dL or hemoglobin < 10 g/dL, in at least two independent measurements in a patient with cardiac symptoms)
 - Presence of a thrombotic event related to PNH
 - Presence of organ damage secondary to chronic hemolysis (i.e., renal insufficiency, pulmonary insufficiency/hypertension)
 - Patient is pregnant and potential benefit outweighs potential fetal risk
 - Patient has disabling fatigue
 - Patient has abdominal pain (requiring admission or opioid analgesia), dysphagia, or erectile dysfunction; **AND**
 - Documented baseline values for one or more of the following (necessary for renewal): serum lactate dehydrogenase (LDH), hemoglobin level, and packed RBC transfusion requirement, history of thrombotic events

Atypical Hemolytic Uremic Syndrome (aHUS) † 1,5,7

- Used as switch therapy; **AND**
 - Patient is currently receiving treatment with Soliris and has shown a beneficial disease response and absence of unacceptable toxicity while on therapy; **OR**

- Patient is complement inhibitor treatment-naïve; **AND**
 - Patient shows signs of thrombotic microangiopathy (TMA) (e.g., changes in mental status, seizures, angina, dyspnea, thrombosis, increasing blood pressure, decreased platelet count, increased serum creatinine, increased LDH, etc.); **AND**
 - Thrombotic Thrombocytopenic Purpura (TTP) has been ruled out by evaluating ADAMTS-13 level (ADAMTS-13 activity level $\geq 10\%$); **AND**
 - Shiga toxin *E. coli* related hemolytic uremic syndrome (STEC-HUS) has been ruled out; **AND**
 - Other causes have been ruled out such as coexisting diseases or conditions (e.g., bone marrow transplantation, solid organ transplantation, malignancy, autoimmune disorder, drug-induced, malignant hypertension, HIV infection, Streptococcus pneumoniae sepsis or known genetic defect in cobalamin C metabolism, etc.); **AND**
 - Documented baseline values for one or more of the following (necessary for renewal): serum lactate dehydrogenase (LDH), serum creatinine/eGFR, platelet count, and dialysis requirement

Generalized Myasthenia Gravis (gMG) † Φ 1,11,12-17

- Used as switch therapy; **AND**
 - Patient is at least 18 years of age; **AND**
 - Patient is currently receiving treatment with Soliris and has shown a beneficial disease response and absence of unacceptable toxicity while on therapy; **OR**
- Patient is complement inhibitor treatment-naïve; **AND**
 - Patient is at least 18 years of age; **AND**
 - Patient has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II to IV disease §; **AND**
 - Patient has a positive serologic test for anti-acetylcholine receptor (AChR) antibodies; **AND**
 - Patient has had a thymectomy (*Note: Applicable only to patients with thymomas OR non-thymomatous patients who are 50 years of age or younger*); **AND**
 - Physician has assessed objective signs of neurological weakness and fatigability on a baseline neurological examination (e.g., including, but not limited to, the Quantitative Myasthenia Gravis (QMG) score, etc.); **AND**
 - Patient has a MG-Activities of Daily Living (MG-ADL) total score of ≥ 6 ; **AND**
 - Patient will avoid or use with caution medications known to worsen or exacerbate symptoms of MG (e.g., certain antibiotics, beta-blockers, botulinum toxins, hydroxychloroquine, etc.); **AND**
 - Patient had an inadequate response after a minimum one-year trial with two (2) or more immunosuppressive therapies (e.g., corticosteroids plus an immunosuppressant such as azathioprine, cyclosporine, mycophenolate, etc.); **OR**

- Patient required chronic treatment with plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG) in addition to immunosuppressant therapy

§ Myasthenia Gravis Foundation of America (MGFA) Disease Clinical Classification ¹⁴:

- **Class I**: Any ocular muscle weakness; may have weakness of eye closure. All other muscle strength is normal.
- **Class II**: Mild weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity.
 - **IIa**. Predominantly affecting limb, axial muscles, or both. May also have lesser involvement of oropharyngeal muscles.
 - **IIb**. Predominantly affecting oropharyngeal, respiratory muscles, or both. May also have lesser or equal involvement of limb, axial muscles, or both.
- **Class III**: Moderate weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity.
 - **IIIa**. Predominantly affecting limb, axial muscles, or both. May also have lesser involvement of oropharyngeal muscles.
 - **IIIb**. Predominantly affecting oropharyngeal, respiratory muscles, or both. May also have lesser or equal involvement of limb, axial muscles, or both.
- **Class IV**: Severe weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity.
 - **IVa**. Predominantly affecting limb, axial muscles, or both. May also have lesser involvement of oropharyngeal muscles.
 - **IVb**. Predominantly affecting oropharyngeal, respiratory muscles, or both. May also have lesser or equal involvement of limb, axial muscles, or both.
- **Class V**: Defined as intubation, with or without mechanical ventilation, except when employed during routine postoperative management. The use of a feeding tube without intubation places the patient in class IVb.

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); ☐ Orphan Drug

IV. Renewal Criteria ¹

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: serious meningococcal infections (septicemia and/or meningitis), infusion-related reactions, other serious infections, thrombotic microangiopathy (TMA) complications, etc.; **AND**

Paroxysmal Nocturnal Hemoglobinuria (PNH) ^{1,4,8,18}

- Patient has not developed severe bone marrow failure syndrome (i.e., aplastic anemia or myelodysplastic syndrome) OR experienced a spontaneous disease remission OR received curative allogeneic stem cell transplant; **AND**
- Disease response indicated by one or more of the following:
 - Decrease in serum LDH from pretreatment baseline Stabilization/improvement in hemoglobin level from pretreatment baseline
 - Decrease in packed RBC transfusion requirement from pretreatment baseline (i.e., reduction of at least 30%)

- Reduction in thromboembolic events

Atypical Hemolytic Uremic Syndrome (aHUS) ^{1,5,7}

- Disease response indicated by one or more of the following:
 - Decrease in serum LDH from pretreatment baseline
 - Stabilization/improvement in serum creatinine/eGFR from pretreatment baseline
 - Increase in platelet count from pretreatment baseline
 - Decrease in plasma exchange/infusion requirement from pretreatment baseline

Generalized Myasthenia Gravis (gMG) ^{1,11-17}

- Patient experienced an improvement (i.e., reduction) of at least 3-points from baseline in the Myasthenia Gravis-Specific Activities of Daily Living scale (MG-ADL) total score; **OR**
- Patient experienced an improvement of at least 5-points from baseline in the Quantitative Myasthenia Gravis (QMG) total score

Switch therapy from Soliris to Ultomiris

- Refer to Section III for criteria

V. Dosage/Administration ¹

Indication	Dose				
Paroxysmal nocturnal hemoglobinuria (PNH); Atypical Hemolytic Uremic Syndrome (aHUS); Generalized Myasthenia Gravis (gMG)	<u>IV Dosing for Complement-Inhibitor Therapy Naïve*</u>				
	Administer the INTRAVENOUS doses based on the patient’s body weight. Starting 2 weeks after the loading dose, begin maintenance doses once every 4 weeks or every 8 weeks (depending on body weight)				
	Indications	Body Weight Range	Loading Dose (mg)	Maintenance Dose (mg)	Dosing Interval
	PNH, aHUS	≥5 kg - <10 kg	600	300	Every 4 weeks
		≥10 kg - <20 kg	600	600	Every 4 weeks
		≥20 kg - <30	900	2,100	Every 8 weeks
		≥30 kg - <40 kg	1,200	2,700	Every 8 weeks
	PNH, aHUS, gMG	≥40 kg - <60 kg	2,400	3,000	Every 8 weeks
		≥60 kg - <100 kg	2,700	3,300	Every 8 weeks
		≥100 kg	3,000	3,600	Every 8 weeks
<u>IV Dosing for Switch Therapy from Eculizumab OR Ultomiris SQ to Ultomiris IV*</u>					
Population	Weight-based Ultomiris IV Loading Dose		Time of First Ultomiris IV Weight-based Maintenance Dose		
Currently treated with eculizumab	At time of next scheduled eculizumab dose		2 weeks after Ultomiris IV loading dose		
Currently treated with Ultomiris SQ	Not applicable		1 week after last Ultomiris SQ maintenance dose		

	on-body delivery system§											
<u>SQ Dosing for Complement-Inhibitor Therapy Naïve §</u>												
PNH & aHUS (adult patients weighing ≥40 kg ONLY): 490 mg SQ via on-body injector once weekly starting 2 weeks after the initial IV weight-based loading dose (<i>see IV weight-based dosing table above</i>)												
<u>SQ Dosing for Switch Therapy from Eculizumab OR Ultomiris IV to Ultomiris SQ §</u>												
<table><tr><th>Population</th><th>Weight-based Ultomiris IV Loading Dose</th><th>Time of First Ultomiris SQ Maintenance Dose</th></tr><tr><td>Currently treated with eculizumab</td><td>At time of next scheduled eculizumab dose</td><td>2 weeks after Ultomiris IV loading dose</td></tr><tr><td>Currently treated with Ultomiris IV</td><td>Not applicable</td><td>8 weeks after last Ultomiris IV maintenance dose</td></tr></table>				Population	Weight-based Ultomiris IV Loading Dose	Time of First Ultomiris SQ Maintenance Dose	Currently treated with eculizumab	At time of next scheduled eculizumab dose	2 weeks after Ultomiris IV loading dose	Currently treated with Ultomiris IV	Not applicable	8 weeks after last Ultomiris IV maintenance dose
Population	Weight-based Ultomiris IV Loading Dose	Time of First Ultomiris SQ Maintenance Dose										
Currently treated with eculizumab	At time of next scheduled eculizumab dose	2 weeks after Ultomiris IV loading dose										
Currently treated with Ultomiris IV	Not applicable	8 weeks after last Ultomiris IV maintenance dose										
<i>§ Adult patients with PNH and aHUS only</i>												
<i>*Note: For Supplemental Dose Therapy after plasma exchange (PE), plasmapheresis (PP), and intravenous immunoglobulin (IVIg), please refer to the package insert for appropriate dosing.</i>												

VI. Billing Code/Availability Information

HCPCS Code:

- J1303 – Injection, ravulizumab-cwvz, 10 mg; 1 billable unit = 10 mg

NDC(s):

- Ultomiris 300 mg/3 mL single-dose vials for injection: 25682-0025-xx
- Ultomiris 300 mg/30 mL single-dose vials for injection: 25682-0022-xx**
- Ultomiris 1100 mg/11 mL single-dose vials for injection: 25682-0028-xx
- Ultomiris 245 mg/3.5 mL single-dose cartridge on-body subcutaneous delivery system: 25682-0031-xx

****Note:** This NDC has been discontinued as of 06/11/2021.

VII. References

- Ultomiris [package insert]. Boston, MA; Alexion Pharmaceuticals, Inc; July 2022. Accessed July 2022.
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15. Gronseth GS, Barohn R, Narayanaswami P. Practice advisory: Thymectomy for myasthenia gravis (practice parameter update): Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. *Neurology.* 2020;94(16):705. Epub 2020 Mar 25.
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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
D59.32	Hereditary hemolytic-uremic syndrome
D59.39	Other hemolytic-uremic syndrome
D59.5	Paroxysmal nocturnal hemoglobinuria [Marchiafava-Micheli]
G70.00	Myasthenia gravis without (acute) exacerbation
G70.01	Myasthenia gravis with (acute) exacerbation

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Articles (LCAs) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

Nondiscrimination & Language Access Policy

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, sex, sexual orientation, or gender identity. We do not exclude people or treat them differently because of race, color, national origin, age, disability, sex, sexual orientation, or gender identity.

We will:

Provide free aids and services to people with disabilities to communicate effectively with us, such as:

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

Provide free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact us at the phone number shown on the inside cover of this contract, your id card, or aspirushealthplan.com.

If you believe that we have failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, sex, sexual orientation, or gender identity, you can file a grievance with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1062
Minneapolis, MN 55440
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>.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë. Telefononi në 1.866.631.5404 (TTY: 711).

Arabic: تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن اعلی رقم الهاتف 1.866.631.5404 (رقم هاتف الصم والبك : 711)

French: ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelezle 1.866.631.5404 (ATS : 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.866.631.5404 (TTY: 711).

Hindi: _यान द_ : य_द आप िहंदी बोलते ह_ तो आपके िलए मु_त म_ भाषा सहायता सेवाएं उपल_ध ह_। 1.866.631.5404 (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 1.866.631.5404 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.866.631.5404 (TTY: 711)번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1.866.631.5404 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.866.631.5404 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.866.631.5404 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1.866.631.5404 (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 1.866.631.5404 (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 1.866.631.5404 (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 1.866.631.5404 (TTY: 711).

Lao: ໄປດຊາຍ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທ 1.866.631.5404 (TTY: 711).