CareSource

PHARMACY POLICY STATEMENT
Ohio Medicaid

DRUG NAME	Ultomiris (ravulizumab-cwvz)
BILLING CODE	J1303
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Home/Office/Outpatient
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product) QUANTITY LIMIT— see **Dosage allowed** below
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Ultomiris (ravulizumab-cwvz) is a **preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

ATYPICAL HEMOLYTIC UREMIC SYNDROME (aHUS)

For **initial** authorization:

1. Member has diagnosis of aHUS and it is **not** due to any of the following:
   a) Disintegrin and metalloproteinase with a thrombospondin type 1 motif;
   b) Member 13 (ADAMTS13) deficiency;
   c) Shiga toxin Escherichia coli related hemolytic uremic syndrome (STEC-HUS);
   d) Genetic defect in cobalamin C metabolism; AND
2. Member has ALL of the following documented in chart notes:
   a) Platelet count ≤ 150 x 10^9/L;
   b) Evidence of hemolysis (e.g., an elevation in serum Lactic Acid Dehydrogenase (LDH));
   c) Chronic kidney disease (CKD) OR medical history of kidney transplant OR currently on dialysis; AND
3. Member has received vaccination against Neisseria meningitidis (i.e., Menactra®, Menveo®, MenHibrix®); AND
4. Member does **not** have ANY of the following:
   a) Infection-related or identified drug exposure-related hemolytic-uremic syndrome (HUS);
   b) Bone marrow transplant (BMT)/hematopoietic stem cell transplant (HSCT) within last 6 months;
   c) HUS related to known genetic defects of cobalamin C metabolism;
   d) Systemic sclerosis (scleroderma), systemic lupus erythematosus (SLE), or antiphospholipid antibody positivity or syndrome;
   e) Chronic dialysis (defined as dialysis on a regular basis as renal replacement therapy for ESKD).
5. **Dosage allowed:** Weight-based dosing regimen, please see prescribing information for details.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has an increase in mean platelet counts from baseline and signs of complement-mediated thrombotic microangiopathy (TMA) activity were reduced with Ultomiris therapy.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (PNH)

For **initial** authorization:

1. Member with diagnosis of PNH as confirmed by flow cytometry (PNH type III red cells or GPI-AP-deficient polymorphonuclear cells (PMNs)); AND
2. Medication is prescribed by a hematologist or nephrologist; AND
3. Member has received vaccination against Neisseria meningitidis (i.e., Menactra®, Menveo®, MenHibrix®); AND
4. Member has LDH levels > 1.5 times the upper limit of normal documented in chart notes; AND
5. Member has one or more of the following documented in chart notes:
   a) History of at least 1 blood transfusion within the past 24 months due to anemia or anemia related symptoms or personal beliefs precluding transfusion;
   b) Presence of organ damage due to chronic hemolysis.
6. **Dosage allowed:** Administered as an IV infusion. Body weight < 60-40kg: loading dose 2,400 mg, maintenance dose 3,000 mg; body weight < 100-60 kg: loading dose 2,700 mg, maintenance dose 3,300 mg; body weight ≥ 100 mg: loading dose 3,000 mg, maintenance dose 3,600 mg.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member is stable and has shown improvement on Ultomiris.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Ultomiris (ravulizumab-cwvz) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS)**.**

DATE	ACTION/DESCRIPTION
05/07/2019	New policy for Ultomiris created.
10/26/2019	New diagnosis of aHUS added.

References:

1. Ultomiris [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc., October 2019.
2. ClinicalTrials.gov. Identifier: NCT02946463. ALXN1210 (Ravulizumab) Versus Eculizumab in Complement Inhibitor Treatment-Naïve Adult Participants With Paroxysmal Nocturnal Hemoglobinuria (PNH). Available at: https://clinicaltrials.gov/ct2/show/NCT02946463?term=ravulizumab&rank=2.
3. ClinicalTrials.gov. Identifier: NCT03056040. ALXN1210 Versus Eculizumab in Adult Participants With Paroxysmal Nocturnal Hemoglobinuria (PNH) Currently Treated With Eculizumab. Available at: https://clinicaltrials.gov/ct2/show/NCT03056040?term=ravulizumab&rank=3.
4. Lee JW, et al. Ravulizumab (ALXN1210) vs eculizumab in adult patients with PNH naive to complement inhibitors: the 301 study. Blood. 2019;133(6):530.
5. ClinicalTrials.gov Identifier: NCT02949128. Single Arm Study of ALXN1210 in Complement Inhibitor Treatment-Naïve Adult and Adolescent Patients With Atypical Hemolytic Uremic Syndrome (aHUS). Available at: https://clinicaltrials.gov/ct2/show/NCT02949128?term=ALXN1210-aHUS-311&draw=1&rank=1.
6. ClinicalTrials.gov Identifier: NCT03131219. Study of ALXN1210 in Children and Adolescents With Atypical Hemolytic Uremic Syndrome (aHUS). Available at: https://clinicaltrials.gov/ct2/show/NCT03131219?term=ALXN1210-aHUS-312&draw=1&rank=1.

7. Kaplan BS, Ruebner RL, Spinale JM, Copelovitch L. Current treatment of atypical hemolytic uremic syndrome. Intractable Rare Dis Res. 2014;3(2):34-35. Doi: 10.5582/irdr.2014.01001.
8. Cheong H, Jo SK, Yoon SS, et. al. Clinical practice guidelines for the management of atypical hemolytic uremic syndrome in Korea. J Korean Med Sci. 2016;31:1516-1528. Doi: 10.3346/jkms.2016.31.10.1516.

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