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**
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. Medication is prescribed by or in consultation with a hematologist or nephrologist; AND
2. Member has a diagnosis of aHUS supported by ALL of the following:
   a) Thrombocytopenia (platelet count < 150 x 10^9/L),
   b) Evidence of hemolysis i.e. elevated lactate dehydrogenase (LDH), low haptoglobin count, or presence of fragmented red blood cells or schistocytes on blood smear,
   c) Evidence of renal impairment (e.g. raised SCr or low eGFR); AND
3. Shiga toxin-producing E. coli related HUS (STEC-HUS) has been ruled out; AND
4. ADAMTS13 activity level is > 5% (to rule out TTP); AND
5. Member has received meningococcal vaccine.
6. **Dosage allowed:** Administered by IV infusion; loading dose followed by maintenance doses starting 2 weeks later, based on body weight, per prescribing information. See appendix at end of policy.

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

For **reauthorization**:

1. Chart notes must demonstrate hematologic normalization as evidenced by increased platelet count or LDH maintained below upper limit of normal; AND
2. Improved or preserved kidney function.

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. Medication is prescribed by or in consultation with a hematologist; AND
2. Member has a diagnosis of PNH as confirmed by flow cytometry; AND
3. Member has a lactate dehydrogenase (LDH) level >1.5x upper limit of normal (ULN); AND
4. Member has received meningococcal vaccine.
5. **Dosage allowed:** Administered by IV infusion; loading dose followed by maintenance doses starting 2 weeks later, based on body weight, per prescribing information. See appendix at end of policy.

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

For **reauthorization**:

1. Clinical evidence of positive response to therapy such as increased hemoglobin level, decreased need for transfusions, normalized LDH levels, improved fatigue.

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 diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
05/07/2019	New policy for Ultomiris created.
10/26/2019	New diagnosis of aHUS added.
06/03/2021	aHUS: Updated references. Added specialist requirement. Revised diagnostic parameters. Summarized excluded causes. Removed list of restrictions from clinical trials. Revised renewal criteria. PNH: Updated references. Removed nephrology as specialist. Removed transfusion and organ damage requirements. Updated dosing information. Reduced initial approval duration from 12 months to 6 months. Revised renewal criteria.

References:

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APPENDIX:

Table 1: ULTOMIRIS Weight-Based Dosing Regimen - PNH and aHUS

Body Weight Range (kg)	Loading Dose (mg)	Maintenance Dose (mg) and Dosing Interval	
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	

Effective date: 01/01/2022
Revised date: 06/03/2021