CareSource

| PHARMACY POLICY STATEMENT<br>**Ohio Medicaid** | |
|---|---|
| DRUG NAME | Ultomiris (ravulizumab-cwvz) |
| BILLING CODE | J3590 |
| BENEFIT TYPE | Medical |
| SITE OF SERVICE ALLOWED | Home/Office/Outpatient |
| COVERAGE REQUIREMENTS | Prior Authorization Required (Preferred Product)<br>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.

## 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. |

References:


1. Ultomiris [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc., December 2018.
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.


Effective date: 07/01/2019
Revised date: 05/07/2019