CareSource

PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Ultomiris (ravulizumab-cwvz)
BILLING CODE	J3590
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Home/Freestanding facility or clinic
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.

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