# Ravulizumab (Ultomiris®)

**Goal(s):**

- Restrict use to OHP-funded conditions and according to OHP guidelines for use.
- Promote use that is consistent with national clinical practice guidelines and medical evidence.
- Ravulizumab is approved by the FDA for the following indications:
  - The treatment of adults and pediatric patients one month of age and older with paroxysmal nocturnal hemoglobinuria (PNH)
  - Inhibiting complement-mediated thrombotic microangiopathy in adult and pediatric patients one month of age and older with atypical hemolytic uremic syndrome (aHUS)

**Length of Authorization:**

Up to 12 months

**Requires PA:**

- Ultomiris® (Ravulizumab) pharmacy and physician administered claims

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the diagnosis funded by OHP? | **Yes:** Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Is this request for continuation of therapy? | **Yes:** Go to **Renewal Criteria** | **No:** Go to # 4 |
| 4. Has the patient been vaccinated against *Streptococcus pneumoniae, Haemophilus influenzae* type B, and *Neisseria meningitidis serogroups A, C, W, and Y and serogroup B* according to current Advisory Committee on Immunization Practice (ACIP) recommendations for vaccination in patients with complement deficiencies*?*<br><br>Note: Prescribing information recommends vaccination at least 2 weeks prior to starting therapy. If the risk of delaying therapy outweighs the risk of developing a serious infection, a 2 week course of antibiotic prophylaxis must be immediately initiated if vaccines are administered less than 2 weeks before starting complement therapy. | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 5. Is the diagnosis for a patient at least 1 month of age or older and weighs at least 5 kg with atypical Hemolytic Uremic Syndrome (aHUS) or Paroxysmal Nocturnal Hemoglobinuria (PNH) ?<br><br>Note: Ravulizumab is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS). | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness |
| 6. Does the requested dosing align with the FDA- approved dosing (**Table 1**)? | **Yes:** Approve for 12 months | **No:** Pass to RPh. Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 1. Is there objective documentation of treatment benefit from baseline?<br><br>Appropriate measures will vary by indication (e.g., hemoglobin stabilization, decreased transfusions, symptom improvement, functional improvement, etc.). | **Yes:** Approve for 12 months<br><br>Document baseline assessment and physician attestation received. | **No:** Pass to RPh. Deny; medical appropriateness |

**Table 1. FDA-Approved Intravenous Infusion Dosing for Ravulizumab[1]**

| Body Weight | Loading Dose | Maintenance Dose (begins 2 weeks after loading dose) |
|---|---|---|
| 5 to 9 kg | 600 mg | 300 mg every 4 weeks |
| 10 to 19 kg | 600 mg | 600 mg every 4 weeks |
| 20 to 29 kg | 900 mg | 2,100 mg every 8 weeks |
| 30 to 39 kg | 1,200 mg | 2,700 mg every 8 weeks |
| 40 to 59 kg | 2,400 mg | 3,000 mg every 8 weeks |
| 60 to 99 kg | 2,700 mg | 3,300 mg every 8 weeks |
| 100 kg or greater | 3,000 mg | 3,600 mg every 8 weeks |

1. Ultomiris™ (Ravulizumab-cwvz) Solution for Intravenous Infusion Prescribing Information. Boston, MA: Alexion Pharmaceuticals Inc. 6/2021.

*P&T/DUR Review: 12/21 (DM); 4/21 (DM)*
*Implementation: 1/1/22; 5/1/21*