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.
- Restrict use to FDA-approved indications.

Length of Authorization:

- Up to 12 months

Requires PA:

- Ravulizumab (ULTOMIRIS) 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 this an FDA approved indication?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; medical appropriateness.
3. Is the diagnosis funded by OHP?	**Yes:** Go to #5	**No:** For current age ≥ 21 years: Pass to RPh. Deny; not funded by the OHP For current age < 21 years: Go to #4
4. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical necessity.
5. Is this request for continuation of therapy?	**Yes:** Go to **Renewal Criteria**	**No:** Go to # 6

Approval Criteria		
6. 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*?* 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 #7	**No:** Pass to RPh. Deny; medical appropriateness
7. Is the diagnosis for a patient with one of the following indications: • 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) or • an adult with generalized myasthenia gravis (gMG) who is anti-acetylcholine receptor (AchR) antibody positive? Note: Ravulizumab is not indicated for the treatment of patients with Shiga toxin *E. coli* related hemolytic uremic syndrome (STEC-HUS).	**Yes:** Go to #8	**No:** Pass to RPh. Deny; medical appropriateness
8. Is the request for intravenous dosing?	**Yes:** Go to # 9	**No:** Go to # 10
9. Does the requested intravenous dosing align with the FDA- approved dosing (**Table 1**)?	**Yes:** Approve for 12 months	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
10. Is the request for subcutaneous (SC) administration of ravlizumab 490 mg SC once a week in an adult weighing 40 kg or greater with PNH or aHUS? Note: Subcutaneous administration of ravulizumab is not approved for use in pediatric patients.	**Yes:** Approve for 12 months	**No:** Pass to RPh. Deny; medical appropriateness

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

Table 1. FDA-Approved Intravenous Weight-based Infusion Dosing for Ravulizumab in Adults and Pediatric Patients aged 1 month and older with PNH, aHUS, or gMG[1]

Body Weight	Indications	Loading Dose	Maintenance Dose (begins 2 weeks after loading dose)
5 to 9 kg	aHUS and PNH	600 mg	300 mg every 4 weeks
10 to 19 kg	aHUS and PNH	600 mg	600 mg every 4 weeks
20 to 29 kg	aHUS and PNH	900 mg	2,100 mg every 8 weeks
30 to 39 kg	aHUS and PNH	1,200 mg	2,700 mg every 8 weeks
40 to 59 kg	aHUS, gMG, and PNH	2,400 mg	3,000 mg every 8 weeks
60 to 99 kg	aHUS, gMG, and PNH	2,700 mg	3,300 mg every 8 weeks
100 kg or greater	aHUS, gMG, and PNH	3,000 mg	3,600 mg every 8 weeks
Abbreviations: aHUS = atypical hemolytic uremic syndrome; gMG = generalized myasthenia gravis; PNH = paroxysmal nocturnal hemoglobinuria			

1. ULTOMIRIS (Ravulizumab-cwvz) Solution for Intravenous Infusion Prescribing Information. Boston, MA: Alexion Pharmaceuticals Inc. 7/2022.