Division: Pharmacy Policy	Subject: State of Florida's Agency for Health Care Administration's Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	June 9, 2021

ULTOMIRIS® (ravulizumab-cwvz)

LENGTH OF AUTHORIZATION: Up to one year

REVIEW CRITERIA:

Required for all indications:

- Documentation of meningococcal vaccine date required. If Patient has not been previously vaccinated, then the patient must receive a meningococcal vaccination at least 2 weeks prior to first dose of Ultomiris®
    - Verify vaccination via CPT codes in medical claims history, physician notes or vaccination records; document verification source in clinical notes.
- Prescribed by, or in consultation with, a hematologist, oncologist, immunologist, genetic specialist or neurologist.

- **Atypical Hemolytic Uremic Syndrome (aHUS)**
    - Patient must be ≥ 1 month of age.
    - Supporting documentation indicating a diagnosis of atypical hemolytic uremic syndrome (aHUS).
    - Patient does not have Shiga toxin Escherichia coli related hemolytic uremic syndrome (STEC-HUS). Lab test confirming the *absence* of Shiga toxin required.
    - Documented baseline values for one or more of the following (necessary for renewal): serum lactate dehydrogenase (LDH), serum creatinine/eGFR, platelet count, and dialysis requirement.
    - Patient shows signs of thrombotic microangiopathy (TMA) (e.g. changes in mental status, seizures, angina, dyspnea, thrombosis, increasing blood pressure, decreased platelet count, increased serum creatinine, increased LDH, etc.).

OR

- **Paroxysmal nocturnal hemoglobinuria (PNH)**
    - Patient must be ≥ 18 years of age.
    - Supporting documentation indicating a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH).
    - Documented baseline values for one or more of the following (necessary for renewal): serum lactate dehydrogenase (LDH), hemoglobin level, and packed RBC transfusion requirement.
    - Patient has one of the following:
        - Presence of a thrombotic event
        - Presence of organ damage secondary to chronic hemolysis
        - Patient is pregnant and potential benefit outweighs potential fetal risk
        - Patient is transfusion dependent
        - Patient has high LDH activity (defined as ≥1.5 x ULN) with clinical symptoms

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DOSING AND ADMINISTRATION:

- Dosage forms: 300 mg/30 mL single-dose vial, 300 mg/3 mL single-dose vial, 1,100 mg/11 mL single-dose vial
- Administer as an intravenous infusion
- Recommended weight-based dosing

Atypical hemolytic uremic syndrome (aHUS) for patients 1 month and older

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	

Paroxysmal Nocturnal Hemoglobinuria (PNH) for patients 18 and older

Body Weight Range (kg)	Loading Dose (mg)	Maintenance Dose (mg) and Dosing Interval	
40 to less than 60	2,400	3,000	Every 8 weeks
60 to less than 100	2,700	3,300	
100 or greater	3,000	3,600	

- Because of the risk of meningococcal infections, Ultomiris® is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Ultomiris REMS. More information is available at www.UltomirisREMS.com or at 1-888-765-4747.