Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	June 9, 2021 October 14, 2022, May 11, 2023

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 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 ≥ 1 month of age.
    - Supporting documentation indicating a diagnosis of 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

*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.

- Patient is transfusion dependent
- Patient has high LDH activity (defined as ≥1.5 x ULN) with clinical symptoms

OR

- **Generalized myasthenia gravis (gMG)**
  - Patient must be ≥ 18 years of age.
  - Supporting documentation indicating a diagnosis of gMG who are anti-acetylcholine receptor (AChR) antibody-positive.
  - Documented Myasthenia Gravis Foundation of America (MGFA) clinical classification class II to IV and Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score ≥ 6.

CONTINUATION OF THERAPY

- Patient met initial review criteria.
- Documentation of improved clinical response.
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/.
- Available as 300 mg/30 mL single-dose vial, 300 mg/3 mL single-dose vial, 1,100 mg/11 mL single-dose vial and 245 mg/3.5 mL single-dose prefilled cartridge for use with on-body injector.

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