

Clinical Oversight Review Board (CORB) Criteria for Prescribing Ravulizumab-cwvz (Ultomiris)

Notes:

- **Transfusion dependent = hemoglobin 7 g/dL or less, OR hemoglobin less than or equal to 9 g/dL and patient is experiencing symptomatic anemia requiring transfusion

Non-Formulary **ravulizumab-cwvz (Ultomiris)** requires a clinical review. Appropriateness of therapy will be based on the following criteria:

Initiation (new start) criteria: Non-formulary **ravulizumab-cwvz (Ultomiris)** will be covered on the prescription drug benefit when the following criteria are met:

1. Patient has diagnosis of Paroxysmal Nocturnal Hemoglobinuria (PNH)

- Prescribed by hematologist with specialty in benign hematology
- Prescriber enrolled in Ultomiris Risk Evaluation and Mitigation Strategy (REMS) program
- Diagnosis of PNH on problem list
- Patient meets one of the following:
 - Transfusion dependent**
 - Documented history of major adverse vascular events from thromboembolism

2. Patient has diagnosis of Atypical Hemolytic Uremic Syndrome (aHUS)

- Prescribed by nephrologist
- Prescriber enrolled in Ultomiris Risk Evaluation and Mitigation Strategy (REMS) program
- Diagnosis of aHUS on problem list
- Negative test result for shiga toxin
- Negative test result for ADAMTS13 deficiency