

Ravulizumab-cwvz (ULTOMIRIS) for Atypical Hemolytic Uremic Syndrome (aHUS) Criteria for Use December 2024

VA Pharmacy Benefits Management Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National Formulary Committee Monograph on this drug at the [PBM INTRANet](#) site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive ravulizumab-cwvz

- Shiga toxin E. coli-related hemolytic uremic syndrome (STEC-HUS)
- Neisseria meningitidis*, *Neisseria gonorrhoeae*, *Haemophilus influenzae*, or *Streptococcus pneumoniae* active infection
- Concomitant therapy with rituximab or any other complement inhibitor such as eculizumab
- Concomitant chronic therapy with plasma exchange

Inclusion Criteria

All of the following must be met:

- Must be prescribed by or in consultation with a VA or VA Community Care nephrology or hematology provider or locally designated expert
- Patient is vaccinated against pneumococcal disease
- Patient is vaccinated with BOTH the protein conjugate ACWY meningococcal vaccine and the type B meningococcal vaccine (in emergent cases begin vaccination series at initial dosing and provide antibiotic prophylaxis until 2 weeks after vaccination)

Additional Inclusion Criteria

One of the following must be met:

- Patient requires treatment of aHUS and there is documentation ruling out Shiga toxin E. coli-related hemolytic uremic syndrome (STEC-HUS) and thrombotic thrombocytopenia purpura (TTP) (e.g. clinical evaluation and/or rule out of ADAMTS13 deficiency) ^1
- Patient requires prophylaxis in renal transplant to ensure aHUS does not recur in the transplanted kidney

Updated version may be found at [PBM INTRANet](#)

Other Justification



Footnote

1. aHUS: atypical hemolytic uremic syndrome

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