Ravulizumab-cwvz (ULTOMIRIS) for Paroxysmal Nocturnal Hemoglobinuria (PNH)
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

☐ *Neisseria meningitidis, Neisseria gonorrhoeae, Haemophilus influenzae,* or *Streptococcus pneumoniae* active infection

Inclusion Criteria

All of the following must be met:

☐ Must be prescribed by or in consultation with a VA or VA Community Care hematology, oncology, immunology 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)

☐ Laboratory-confirmed diagnosis of PNH, as evidenced by detectable GPI-deficient hematopoietic clones (Type III PNH red blood cells (RBC)) via Flow Cytometry. Documentation of Flow Cytometry pathology report must indicate presence of PNH-type RBC ^1,^2

☐ Must have a lactate dehydrogenase (LDH) level of 1.5 times the upper limit of the normal range (unless switching from eculizumab; laboratory results with reference range must be available for review).

Other Justification

☐ _____

Footnotes

1. PNH: paroxysmal nocturnal hemoglobinuria
2. GPI: glycosylphosphatidylinositol

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