Ravulizumab-cwvz (ULTOMIRIS) for Myasthenia Gravis (MG) 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
- ☐ Thymectomy within 12 months
- ☐ Concomitant therapy with rituximab, neonatal Fc receptor antagonists (e.g., efgartigimod), or any other complement inhibitor (e.g., eculizumab)
- ☐ Concomitant chronic therapy with intravenous immunoglobulin or plasma exchange (use of these treatments in exacerbations is reasonable while on ravulizumab-cwvz)

Inclusion Criteria

All of the following must be met:

- ☐ Care provided by a VA/VA Community Care neurology provider or locally designated expert
- ☐ Diagnosis of acetylcholine receptor (AChR) antibody positive generalized myasthenia gravis (gMG)
- ☐ Patient is not a candidate for or has opted against thymectomy.
- ☐ Myasthenia Gravis Foundation of America (MGFA) clinical classification II to IV ^1
- ☐ Myasthenia Gravis-specific Activities of Daily Living scale (MG-ADL) total score ≥ 6 ^2
- ☐ Patient is vaccinated against pneumococcal disease and *Neisseria meningitidis* with both Meningococcal conjugate vaccine (MenACWY) and Meningococcal serogroup B vaccine ^3

Additional Inclusion Criteria

One of the following must be met.

☐ Inadequate symptom control to maximally tolerated pyridostigmine AND at least two immunosuppressive agents separately trialed for at least 6 months each (e.g. azathioprine, cyclosporine, mycophenolate, etc.)
☐ History of intolerance or contraindication preventing trial of immunosuppressive agents (e.g. azathioprine, cyclosporine, mycophenolate, etc.)
☐ Lack of symptom control despite 4 or more courses of plasma exchange, high-dose steroid bursts and/or intravenous immune globulin in a 12 month or less period.

Other Justification

☐_____

Footnotes

1. Myasthenia Gravis Foundation of America (MGFA) Clinical Classification can be found at: https://myasthenia.org/Portals/0/MGFA%20Classification.pdf
2. Myasthenia Gravis Activities of Daily Living (MG-ADL) can be found at: https://myasthenia.org/Portals/0/ADL.pdf
3. In emergent cases where waiting to initiate ravulizumab-cwvz at least two weeks after completion of vaccination is not possible, patients should begin the vaccination series at the time of initial ravulizumab-cwvz dosing and be provided with appropriate prophylaxis.

Prepared: December 2019. Rev March 2023, November 2024 Contact: Natasha Antonovich, PharmD, BCPS, National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services

---