Rozanolixizumab-noli (RYSTIGGO) for Myasthenia Gravis
Criteria for Use
March 2025

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

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 rozanolixizumab.

- ☐ Concomitant therapy with other monoclonal antibody or neonatal Fc receptor antagonist (e.g., efgartigimod)
- ☐ Thymectomy within 3 months
- ☐ Intravenous immunoglobulin (IVIG) or plasma exchange within 1 month
- ☐ Untreated hepatitis B, hepatitis C, or HIV with low CD4 count
- ☐ Active, untreated infection (rozanolixizumab may be started / restarted once the infection is controlled)

Inclusion Criteria

All of the following must be met to receive rozanolixizumab.

- ☐ Care provided by a VA/VA Community Care neurologist
- ☐ Acetylcholine receptor (AChR) antibody positive generalized myasthenia gravis or muscle-specific tyrosine kinase (MuSK) antibody positive myasthenia gravis
- ☐ Myasthenia Gravis Foundation of America (MGFA) clinical classification II to IV ^1
- ☐ Myasthenia Gravis-specific Activities of Daily Living scale (MG-ADL) total score ≥ 5 ^2

Additional Inclusion Criteria

One of the following must be met.

- ☐ For bridge therapy: Inadequate symptom control, contraindication, or intolerance to high dose steroid burst, plasma exchange or IVIG
- ☐ For AChR+ chronic therapy: 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.]
- ☐ For MuSK+ chronic therapy: Inadequate symptom control to rituximab trialed for at least 6 months
- ☐ For AChR+ or MuSK+ chronic therapy: History of intolerance or contraindication preventing trial of above immunosuppressive agents

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**

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