Generic Name: rozanolixizumab-noli

Applicable Drugs: Rystiggo®

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/14/2025

Date Last Reviewed / Revised: 2/14/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met)

I. Documented diagnosis of one of the following conditions AND must meet ALL criteria listed:
   a. Generalized Myasthenia Gravis (gMG)
      i. MGFA clinical classification class II, III, or IVa.
      ii. Documentation of a serologic test confirming the presence of acetylcholine receptor antibodies (AchR-Ab+) or antimuscle-specific tyrosine kinase (MuSK) antibodies.
      iii. Baseline Myasthenia Gravis-specific Activities of Daily Living scale (MG-ADL) total score of ≥ 5, with at least 3 points from non-ocular symptoms. See Other Criteria for MG-ADL scale criteria.
      iv. Member has documented treatment failure, intolerance, or contraindication to **both** of the following (1 and 2):
         1. Corticosteroids (at least 3 months of treatment)
         2. Nonsteroidal immunosuppressive therapy (at least one agent for at least 3 months of treatment) (e.g. azathioprine, cyclosporine, methotrexate, mycophenolate, etc.)

II. Patient is 18 years of age or older.

III. Treatment must be prescribed by or in consultation with a neurologist.

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- MGFA class I
- Active infection or sepsis
- Untreated hepatitis B, hepatitis C, or HIV with low CD4 count

- Coadministration with other immunomodulatory biologic therapies (e.g. rituximab, eculizumab, efgartigimod, zilucoplan, etc.)
- Coadministration with live vaccines
- Pregnancy
- Subsequent cycles initiated sooner than 63 days from the start of the previous treatment cycle.
- More than six treatment cycles per year

OTHER CRITERIA

- The time between treatment cycles is customized based on patient response and clinical evaluation. Treatment cycles may not be more frequent than six (6) cycles per year and a subsequent cycle may not be initiated sooner than 63 days from the start of the previous treatment cycle.
- MG-ADL Scoring Template:

Grade	0	1	2	3	Score
Talking	Normal	Intermittent slurring or nasal speech	Constant slurring or nasal, but can be understood	Difficult to understand speech	
Chewing	Normal	Fatigue with solid food	Fatigue with soft food	Gastric tube	
Swallowing	Normal	Rare episode of choking	Frequent choking necessitating changes in diet	Gastric tube	
Breathing	Normal	Shortness of breath with exertion	Shortness of breath at rest	Ventilator dependence	
Impairment of ability to brush teeth or comb hair	None	Extra effort, but no rest periods needed	Rest periods needed	Cannot do one of these functions	
Impairment of ability to arise from a chair	None	Mild, sometimes uses arms	Moderate, always uses arms	Severe, requires assistance	
Double vision	None	Occurs, but not daily	Daily, but not constant	Constant	
Eyelid droop	None	Occurs, but not daily	Daily, but not constant	Constant	
				Total Score:	

Wolfe GI, Herbelin L, Nations SP, Foster B, Bryan WW, Barohn RJ. Neurology 1999;52(7):1487-9

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Six vials (volume varies based on vial dose) per 42-day cycle

- For approved requests, quantity and supply limits will account for the time between treatment cycles. For example, if a patient's treatment plan includes a six-week cycle followed by a six-week break, the quantity and days supply limit will be calculated per 84-day period.

APPROVAL LENGTH

- **Authorization:** 6 months
- **Re-Authorization:** 6 months, with an updated letter of medical necessity or progress notes showing clinically significant improvement or maintenance with treatment and that the patient is adherent to treatment and the medication is tolerated. Clinical improvement or maintenance may be demonstrated by a ≥ 2-point reduction in MG-ADL score from baseline or by physician attestation that patient is continuing to derive benefit from treatment (as evidenced by reductions in exacerbations, improvements in speech, swallowing, mobility, or respiratory function, etc.)

APPENDIX

N/A

REFERENCES

1. Rystiggo™ [Package Insert], Smyrna, GA; UCB, Inc.; June 2024. https://www.ucb-usa.com/RYSTIGGO-prescribing-information.pdf
2. Bril V, Drużdż A, Grosskreutz J, et al. Safety and efficacy of rozanolixizumab in patients with generalised myasthenia gravis (MycarinG): a randomised, double-blind, placebo-controlled, adaptive phase 3 study [published correction appears in Lancet Neurol. 2023 Oct;22(10):e11]. *Lancet Neurol*. 2023;22(5):383-394. doi:10.1016/S1474-4422(23)00077-7
3. Narayanaswami P, International Consensus Guidance for Management of Myasthenia Gravis 2020 Update. *Neurology*. 2021; 96:114-122. doi:10.1212/WNL.0000000000011124
4. Tice JA, The effectiveness and value of eculizumab and efgartigimod for generalized myasthenia gravis. *J Manag Care Spec Pharm*. 2022;28(1):119-124. doi:10.18553/jmcp.2022.28.1.119
5. Muppidi S, Utilization of MG-ADL in myasthenia gravis clinical research and care. *Muscle Nerve*. 2022;65(6):630-639. doi:10.1002/mus.27476