

Rystiggo® (rozanolixizumab-noli)

When requesting Rystiggo® (rozanolixizumab-noli), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indication

Rystiggo is indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.

Coverage Guidelines

Generalized Myasthenia Gravis

The individual must meet ALL of the following criteria for an initial authorization:

- Is 18 years of age or older;
- Has a confirmed diagnosis of anti-acetylcholine receptor antibody-positive generalized myasthenia gravis OR anti-muscle-specific tyrosine kinase (anti-MuSK) antibody-positive generalized myasthenia gravis;
- Has received or is currently receiving pyridostigmine unless contraindication to pyridostigmine OR has anti-MuSK antibody-positive generalized myasthenia gravis;
- Has evidence of unresolved symptoms of generalized myasthenia gravis such as difficulty swallowing, difficulty breathing, or a functional disability resulting in the discontinuation of physical activity (e.g., double vision, talking, impairment of mobility);
- Has Myasthenia Gravis Foundation of America class of II to IV;
- Has Myasthenia Gravis Activities of Daily Living (MG-ADL) score of 3 or greater for non-ocular symptoms;
- Rystiggo is prescribed by or in consultation with a neurologist.

The individual must meet all of the following criteria for re-authorization:

- Is 18 years of age or older;
- Is continuing to receive benefits from Rystiggo treatment (e.g., reductions in exacerbations of myasthenia gravis; improvement in speech, swallowing, mobility, and respiratory function);
- Rystiggo is prescribed by or in consultation with a neurologist;
- Treatment cycles are no more frequent than every 63 days from the start of the previous treatment cycle.

Approval duration (initial): 6 months

Approval duration (renewal): 12 months

Dosing Recommendation

The recommended dosage is administered as a subcutaneous infusion once weekly for 6 weeks based on body weight.

Body Weight of Patient	Dose	Volume to be Infused
Less than 50 kg	420 mg	3 mL
50 kg to less than 100 kg	560 mg	4 mL
100 kg and above	840 mg	6 mL

The subsequent treatment cycle should be administered based on clinical evaluation. The safety of initiating subsequent cycles sooner than 63 days from the start of the previous treatment cycle has not been established.

References

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3. Cleanthous S, Mork AC, Regnault A, et al. Development of the myasthenia gravis (MG) symptoms PRO: a case study of a patient-centred outcome measure in rare disease. *Orphanet J Rare Dis*. 2021;16:457.
4. Rodolico C, Bonanno C, Toscano A, and Vita G. MuSK-associated myasthenia gravis: clinical features and management. *frontiers in Neurology*. 2020;11:660.
5. Bril V, Druzdż A, Grosskreutz J, et al on behalf of the MG0003 study team. Safety and efficacy of rozanolixizumab in patients with generalized myasthenia gravis (MycarinG): a randomized, double-blind, placebo-controlled, adaptive phase 3 study. *Lancet Neurol*. 2023;22:383-394.
6. Sanders DB, Wolfe GI, Benatar M, et al. International Consensus Guidance for Management of Myasthenia Gravis. *Neurology*. 2016;87:419-425.
7. Narayanaswami P, Sanders DB, Wolfe G, et al. International Consensus Guidance for Management of Myasthenia Gravis: 2020 Update. *Neurology*. 2021;96(3):114-122.
8. Rodolico C, Bonanno C, Toscano A, et al. MuSK-associated myasthenia gravis: Clinical features and management. *Front Neurol*. 2020;11:660.