Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs

Rystiggo® (rozanolixizumab-noli)

Effective: January 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Public Plans Products

☒ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☒ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☒ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☒ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Myasthenia gravis (MG) is an autoimmune disorder characterized by muscle weakness and fatigue. There are two classifications of MG: ocular and general. The degree of muscle weakness can fluctuate and vary in severity from person to person; however, it will generally improve with rest and worsen with physical activity. Most patients with MG develop autoantibodies that attack the acetylcholine receptor (AChR), blocking or destroying the receptors, which prevents muscles from contracting. Treatment decisions for generalized myasthenia gravis (gMG) are based on knowledge of the natural history of disease in each patient and the predicted response to a specific form of therapy. Goals are individualized based on disease severity, patient age and sex, and the degree of functional impairment.

Approval of Rystiggo (rozanolixizumab-noli) is based on the MycarinG Phase 3 trial, in which 200 patients were randomly assigned to receive subcutaneous infusions of Rystiggo 7 mg/kg, Rystiggo 10 mg/kg, or placebo once a week for 6 weeks. Patients generalized myasthenia gravis diagnosis was confirmed by a positive record of autoantibodies against AChR or MuSK at screening. In addition, patients had a MGFA Clinical Classification Class II to Iva, MG-ADL total score of at least 3. Patients were on a stable dose of myasthenia gravis therapy prior to screening that included AChE inhibitors, steroids, or NSISTs, either in combination or alone. Treatment with Rystiggo resulted in a greater reduction in the Myasthenia Gravis Activities of Daily Living (MG-ADL) total score at Day 43 than placebo (-3.4 vs -0.8 points).

Food and Drug Administration-Approved Indications

Rystiggo is a neonatal Fc receptor blocker 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.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Rystiggo for Members when **ALL** of the following criteria are met:

Initial Authorization Criteria

1. Documented diagnosis of generalized myasthenia gravis

AND

2. The prescribing physician is a neurologist

AND

3. Documentation of a positive serologic test for **one (1)** of the following:
    a. Anti-acetylcholine antibodies
    b. Anti-muscle-specific tyrosine kinase antibodies

Reauthorization Criteria

1. Documented diagnosis of generalized myasthenia gravis

AND

2. The prescribing physician is a neurologist

AND

3. Documentation of a positive serologic test for **one (1)** of the following:
    a. Anti-acetylcholine antibodies
    b. Anti-muscle-specific tyrosine kinase antibodies

AND

4. Documentation the Member has experienced a therapeutic response as defined by an improvement of Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score from baseline

Limitations

- Initial coverage of Rystiggo for generalized myasthenia gravis will be authorized for 6 months. Reauthorization of Rystiggo will be provided for 12-month intervals,
- Members new to the plan stable on Rystiggo should be reviewed against Reauthorization Criteria.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J9333	Injection, rozanolixizumab-noli, 1 mg

References

1. Rystiggo (rozanolixizumab-noli) [package insert]. Smyrna, GA: UCB, Inc.; June 2023.
2. Narayanaswami P, et al. International Consensus Guidance for Management of Myasthenia Gravis. 2020 Update. Neurology. 2021;96:114-122.
3. Bril V, et al. Safety and efficacy of rozanolixizumab in patients with generalised myasthenia gravis (MycarinG): a randomised, double-blind, placebo-controlled, adaptive phase 3 study. Lancet Neurol. 2023;22(5):383–394.
4. Jaretzki A 3rd, et al. Myasthenia gravis: recommendations for clinical research standards. Task Force of the Medical Scientific Advisory Board of the Myasthenia Gravis Foundation of America. Neurology. 2000;55(1):16–23.
5. Lazaridis K, et al. Autoantibody specificities in myasthenia gravis; implications for improved diagnostics and therapeutics. Front Immunol. 2020;11(212):1–13.
6. Schneider-Gold C, et al. Understanding the burden of refractory myasthenia gravis. Therapeutic Advances in Neurological Disorders. 2019;12:1–16.
7. Mantegazza R, et al. When myasthenia gravis is deemed refractory: clinical signposts and treatment strategies. Ther Adv Neurol Disord. 2018;11:1756285617749134.
8. Silvestri NJ, et al. Treatment-refractory myasthenia gravis. J Clin Neuromuscul Dis. 2014;15(4):167.

Approval And Revision History

September 12, 2023: Reviewed by Pharmacy and Therapeutics Committee (P&T).

Subsequent endorsement date(s) and changes made:

- September 2023: Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024.
- November 2023: Administrative Update in support of calendar year 2024 Medicare Advantage and PDP Final Rule.
- August 13, 2024: No changes (eff 10/1/2024).
- September 2024: Joint Medical Policy and Health Care Services UM Committee review (eff 10/1/24).
- June 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template
- December 9, 2025: No changes (eff 1/1/26)
- December 2025: Joint Medical Policy and Health Care Services UM Committee review (effective 1/1/26)

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or

drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guidelines not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.