Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Rystiggo (rozanolixizumab-noli)

Effective: September 15, 2026

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

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☒ Tufts Health Plan Commercial products; Fax 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☐ Tufts Health Together – MassHealth Accountable Care Partnership Plans; Fax 617-673-0939

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ 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

Food and Drug Administration-Approved Indications

Rystiggo (rozanolixizumab-noli) 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 (rozanolixizumab-noli) for Members when **ALL** of the following criteria are met:

Initial Authorization Criteria

1. Documented diagnosis of generalized myasthenia gravis

AND

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

AND

3. Documentation of Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IVa generalized myasthenia gravis

AND

4. Documentation of Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score of at least 3

AND

5. The prescribing physician is a neurologist

AND

6. Documentation of **one (1)** of the following:
    a. Persistent symptoms that limit function following a previous trial of immunosuppressive therapy consisting of a glucocorticoid in combination with at least one other immunotherapeutic agent (e.g., azathioprine, mycophenolate, cyclosporine, tacrolimus)

b. Ongoing rescue therapy with intravenous immunoglobulin or plasma exchange while receiving immunosuppressive therapy
c. Clinical rationale to avoid immunosuppressive therapy with glucocorticoids and other immunotherapeutic agents (e.g., azathioprine, mycophenolate, cyclosporine, tacrolimus)

Reauthorization Criteria

1. Documented diagnosis of generalized myasthenia gravis

AND

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

AND

3. The prescribing physician is a neurologist

AND

4. Documentation the patient 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 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. Gilhus N, Verschuuren J. Myasthenia gravis: subgroup classification and therapeutic strategies. *Lancet Neurol.* 2015;14(10):1023-36. doi: 10.1016/S1474-4422(15)00145-3.
2. Mantegazza R, et al. When myasthenia gravis is deemed refractory: clinical signposts and treatment strategies. Ther Adv Neurol Disord. 2018;11:1756285617749134.
3. Narayanaswami P, Sanders D, Wolfe G, et al. International Consensus Guidance for Management of Myasthenia Gravis: 2020 Update. *Neurology*. 2021;96(3):114-122.
4. Rystiggo (rozanolixizumab-noll) [package insert]. Smyrna, GA: UCB, Inc.; December 2025.
5. 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:

- January 1, 2024: Administrative updated: Added new J Code J9333 to Medical Necessity Guideline.
- February 13, 2024: Removed Tufts Health Together from the Medical Necessity Guideline effective 3/4/24. Coverage for Tufts Health Together will defer to Unified Medical Policies Medical Necessity Guideline effective 3//2024.
- August 13, 2024: Updated requirements to establish refractory disease (eff 1/1/25).
- September 10, 2024: Updated requirements to establish refractory disease of generalized myasthenia gravis (eff 1/1/25).
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- September 9, 2025: No changes.
- September 15, 2026: Administrative updates: Template updated to remove CareLink from the Medical Necessity Guideline template. Template updated from “Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans” to “Tufts Health Together- MassHealth Accountable Care Partnership Plans.”

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is 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.