Neighborhood Health Plan OF RHODE ISLAND™
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Rystiggo® (rozanolixizumab-noli)
(Subcutaneous)

Effective Date: 08/01/2024
Review Date: 05/08/2024, 10/28/2025, 04/07/2026
Scope: Medicaid, Commercial, Medicare

I. Length of Authorization [1]

Initial coverage will be provided for 16 weeks. Coverage may be renewed every 6 months thereafter.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 840 billable units (840 mg) weekly for 6 doses per 63 days (5040 billable units per 63 days)

III. Summary of Evidence

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 (Ab+). Rystiggo's approval is based on a Phase 3, multi-center, randomized, double-blind, placebo-controlled study (MycarinG), which enrolled 200 adult patients with gMG who were anti-AChR Ab+ or anti-MuSK Ab+ with a Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score of at least 3 (with at least 3 points from non-ocular symptoms). At baseline, median MG-ADL total score was 8, and the median Quantitative Myasthenia Gravis (QMG) total score was 15. Patients were randomly assigned (1:1:1) to receive SC infusions of Rystiggo 7 mg/kg, Rystiggo 10 mg/kg, or placebo once a week for 6 weeks. 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 for both strengths of Rystiggo versus -0.8 points for placebo ($p<0.001$). Adverse effects include headache, increased risk of infection, diarrhea, pyrexia, hypersensitivity reactions, and nausea.

IV. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

Medicare members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

Universal Criteria [1,3]

- Member is at least 18 years of age; **AND**
- Will not be used in combination with other immunomodulatory biologic therapies (e.g., Imaavy (nipocalimab), Vyvgart (efgartigimod), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase),

Soliris/Epysqli/Bkemv (eculizumab), Ultomiris (ravulizumab), Uplizna (inebilizumab), Zilbrysq (zilucoplan), etc.); **AND**

- The member does NOT have any FDA labeled contraindications to the requested agent

Generalized Myasthenia Gravis (gMG) † Φ [1,3-6,8]

- Submission of medical records (e.g., chart notes, laboratory values, etc.) to support the diagnosis of generalized myasthenia gravis (gMG); AND
- Prescribed by, or in consultation with, a neurologist; AND
- Member has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II to IVb disease §; **AND**
- Member has a positive serologic test for anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibodies; **AND**
- Physician has assessed objective signs of neurological weakness and fatiguability on a baseline neurological examination (e.g., including, but not limited to, the Quantitative Myasthenia Gravis (QMG) score, etc.); **AND**
- Member has a baseline MG-Activities of Daily Living (MG-ADL) total score of at least 3 **AND** at least 3 points are from non-ocular symptoms; **AND**
- The member meets one of the following:
    - The member has tried and had an inadequate response to at least ONE conventional agent used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide); **OR**
    - The member has an intolerance or hypersensitivity to ONE conventional agent used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide); **OR**
    - The member has an FDA labeled contraindication to ALL conventional agents used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide); **OR**
    - The member required chronic intravenous immunoglobulin (IVIG); **OR**
    - The member required chronic plasmapheresis/plasma exchange; **AND**
- The member's current medications have been assessed and any medications known to exacerbate myasthenia gravis (e.g., beta blockers, procainamide, quinidine, magnesium, anti-programmed death receptor-1 monoclonal antibodies, hydroxychloroquine, aminoglycosides) have been discontinued **OR** discontinuation of the offending agent is NOT clinically appropriate; **AND**
- The member must have an inadequate response, intolerance, or FDA-labeled contraindication to Uplizna (inebilizumab) [medical documentation required]; **AND**
- Prescribed dose provided, and in accordance with FDA-approved labeling based on current documented weight.

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); **Φ** Orphan Drug

§ Myasthenia Gravis Foundation of America (MGFA) Disease Clinical Classification: [5,6]

– **Class I**: Any ocular muscle weakness; may have weakness of eye closure. All other muscle strength is normal.
– **Class II**: Mild weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity.
  - **IIa**. Predominantly affecting limb, axial muscles, or both. May also have lesser involvement of oropharyngeal muscles.
  - **IIb**. Predominantly affecting oropharyngeal, respiratory muscles, or both. May also have lesser or equal involvement of limb, axial muscles, or both.
– **Class III**: Moderate weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity.
  - **IIIa**. Predominantly affecting limb, axial muscles, or both. May also have lesser involvement of oropharyngeal muscles.
  - **IIIb**. Predominantly affecting oropharyngeal, respiratory muscles, or both. May also have lesser or equal involvement of limb, axial muscles, or both.
– **Class IV**: Severe weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity.
  - **IVa**. Predominantly affecting limb, axial muscles, or both. May also have lesser involvement of oropharyngeal muscles.
  - **IVb**. Predominantly affecting oropharyngeal, respiratory muscles, or both. May also have lesser or equal involvement of limb, axial muscles, or both.
– **Class V**: Defined as intubation, with or without mechanical ventilation, except when employed during routine postoperative management. The use of a feeding tube without intubation places the member in class IVb.

V. Renewal Criteria [1]

Coverage can be renewed based upon the following criteria:

- The member has been previously approved for the requested agent through the plan's Medical Drug Review process (Note: members not previously approved for the requested agent will require initial evaluation review); **AND**
- Prescribed by, or in consultation with, a neurologist; **AND**
- The member will NOT be using the requested agent in combination with other immunomodulatory biologic therapies (e.g., Imaavy (nipocalimab), Vyvgart (efgartigimod), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase), Soliris/Epysqli/Bkemv (eculizumab), Ultomiris (ravulizumab), Uplizna (inebilizumab), Zilbrysq (zilucoplan), etc.); **AND**
- The member does NOT have any FDA labeled contraindications to the requested agent; **AND**
- Prescribed dose provided, and in accordance with FDA-approved labeling based on current documented weight.
- Member has had an improvement (i.e., reduction) of at least 2-points from baseline in the Myasthenia Gravis-Specific Activities of Daily Living scale (MG-ADL) total score sustained for at least 4 weeks **Δ**; **AND**
- Improvement in muscle strength testing with fatigue maneuvers as evidenced on neurologic examination when compared to baseline; **AND**
- Member requires continuous treatment, after an initial beneficial response, due to new or worsening disease activity *(Note: a minimum of 63 days must have elapsed from the start of the previous treatment cycle)*

(Δ May substitute an improvement of at least 3-points from baseline in the Quantitative Myasthenia Gravis (QMG) total score sustained for at least 4 weeks, if available)

VI. Dosage/Administration [1]

Indication	Dose
Generalized Myasthenia Gravis (gMG)	Administer the recommended dose subcutaneously, via an infusion pump at a rate of up to 20 mL/hour, once weekly for 6 weeks. – <50 kg: 420 mg (3 mL) – 50 kg to <100 kg: 560 mg (4 mL) – ≥100 kg: 840 mg (6 mL) Rystiggo is to be administered by a healthcare professional only. Administer subsequent treatment cycles 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.

VII. Billing Code/Availability Information

HCPCS Code:

- J9333 – Injection, rozanolixizumab-noli, 1 mg; 1 billable unit = 1 mg

NDC:

- Rystiggo 280mg/2mL solution in a single-dose vial: 50474-0980-xx
- Rystiggo 420 mg/3 mL solution in a single-dose vial: 50474-0981-xx
- Rystiggo 560 mg/4 mL solution in a single-dose vial: 50474-0982-xx
- Rystiggo 840 mg/6 mL solution in a single-dose vial: 50474-0983-xx

VIII. References

1. Rystiggo [package insert]. Smyrna, GA; UCB, Inc., December 2025. Accessed March 2026.
2. Sussman J, Farrugia ME, Maddison P, et al. Myasthenia gravis: Association of British Neurologists' management guidelines. Pract Neurol 2015; 15: 199-206.
3. Narayanaswami P, Sanders D, Wolfe G, Benatar M, et al. International consensus guidance for management of myasthenia gravis, 2020 update. Neurology® 2021;96:114-122. doi:10.1212/WNL.0000000000011124.
4. Bril V, Drużdż A, Grosskreutz J, and MG0003 study team. 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 May;22(5):383-394. doi: 10.1016/S1474-4422(23)00077-7. PMID: 37059507. https://pubmed.ncbi.nlm.nih.gov/37059507

5. Jayam-Trouth A, Dabi A, Solieman N, Kurukumbi M, Kalyanam J. Myasthenia gravis: a review. *Autoimmune Dis*. 2012;2012:874680. doi:10.1155/2012/874680
6. Bril V, Druzdz A, Grosskreutz J, et al. Long-term Efficacy and Safety of Symptom-driven Cyclic Rozanolixizumab Treatment in Patients with Generalized Myasthenia Gravis: A Pooled Analysis of a Phase 3 Study and Two Open-label Extension Studies (P1-5.012). Neurology Apr 2023, 100 (17 Supplement 2) 3747; DOI: 10.1212/WNL.0000000000203497
7. Guidon AC, Muppidi S, Nowak RJ, et al. Telemedicine visits in myasthenia gravis: expert guidance and the Myasthenia Gravis Core Exam (MG-CE). Muscle Nerve 2021; 64:270-276
8. Gronseth GS, Barohn R, Narayanaswami P. Practice advisory: Thymectomy for myasthenia gravis (practice parameter update): Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Neurology. 2020;94(16):705. Epub 2020 Mar 25.
9. Bril V, Benatar M, Andersen H, MG0002 Investigator Study Group, et al. Efficacy and Safety of Rozanolixizumab in Moderate to Severe Generalized Myasthenia Gravis A Phase 2 Randomized Control Trial. Neurology Feb 2021, 96 (6) e853-e865; DOI: 10.1212/WNL.0000000000011108.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
G70.00	Myasthenia gravis without (acute) exacerbation
G70.01	Myasthenia gravis with (acute) exacerbation

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

Policy Rationale:

Rystiggo was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Rystiggo according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For Medicare members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.