Rystiggo® (rozanolixizumab-noli)
(Subcutaneous)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months.
- Renewal: Prior authorization validity may be renewed every 12 months thereafter.

II. Dosing Limits

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

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

III. Initial Approval Criteria

Target Agent(s) will be approved when ALL of the following are met:

- ONE of the following:
  - The patient has a diagnosis of generalized Myasthenia Gravis (gMG) AND ALL of the following:
    - ONE of the following: (medical records required)
      - The patient has a positive serological test for anti-AChR antibodies; **OR**
      - The patient has a positive serological test for anti-MuSK antibodies; **AND**
    - The patient has a Myasthenia Gravis Foundation of America (MGFA) clinical classification class of II-IVb; **AND**
    - BOTH of the following:
      - The patient has a MG-Activities of Daily Living total score of greater than or equal to 3; **AND**
      - At least 3 points are from non-ocular symptoms; **AND**
    - ONE of the following:
      - The patient'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**
    - ONE of the following:

        - The patient 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 patient 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 patient 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 patient required chronic intravenous immunoglobulin (IVIG); **OR**
        - The patient required chronic plasmapheresis/plasma exchange; **OR**
    - The patient has another FDA labeled indication for the requested agent and route of administration; **AND**
- If the patient has an FDA labeled indication, then ONE of the following:
    - The patient's age is within FDA labeling for the requested indication for the requested agent; **OR**
    - There is support for using the requested agent for the patient's age for the requested indication; **AND**
- The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis; **AND**
- The patient will NOT be using the requested agent in combination with Soliris (eculizumab), Bkemv (eculizumab-aeeb), Epysqli (eculizumab-aagh), Ultomiris (ravulizumab-cwvz), Vyvgart (efgartigimod),Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc), Zilbrysq (zilucoplan), or Imaavy (nipocalimab-aahu); **AND**
- The patient does NOT have any FDA labeled contraindications to the requested agent; **AND**
- The requested quantity (dose) is within FDA labeled dosing for the requested indication

IV. Renewal Criteria

Target Agent(s) will be approved when ALL of the following are met:

- The patient has been previously approved for the requested agent through the plan's Medical Drug Review process (Note: patients not previously approved for the requested agent will require initial evaluation review); **AND**
- The patient has had clinical benefit with the requested agent; **AND**
- The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis; **AND**

- The patient will NOT be using the requested agent in combination with Soliris (eculizumab), Bkemv (eculizumab-aeeb), Epysqli (eculizumab-aagh), Ultomiris (ravulizumab-cwvz), Vyvgart (efgartigimod), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc), Zilbrysq (zilucoplan), or Imaavy (nipocalimab-aahu); **AND**
- The patient does NOT have any FDA labeled contraindications to the requested agent; **AND**
- The requested quantity (dose) is within FDA labeled dosing for the requested indication

V. Dosage/Administration

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.

VI. Billing Code/Availability Information

HCPCS Code:

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

NDC(s):

- Rystiggo 280 mg/2 mL 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

VII. References

1. Rystiggo prescribing information. UCB, Inc. March 2025.
2. National Institute of Neurological Disorders and Stroke. Myasthenia Gravis Fact Sheet. NIH Publication No. 17-768. July 2018.
3. Narayanaswami P, Sanders DB, Wolfe G, et al. International Consensus Guidance for Management of Myasthenia Gravis. *Neurology*. 2021;96(3):114-122. doi:10.1212/wnl.0000000000011124.

4. Wincentsen J. MG Activities of Daily Living (MG-ADL) scale. Conquer Myasthenia Gravis. Published September 29, 2022. https://myastheniagravis.org/mg-activities-of-daily-living-mg-adl-scale/.
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. Alhaidar MK, Abumurad S, Soliven B, Rezania K. Current Treatment of Myasthenia Gravis. J Clin Med. 2022;11(6):1597. Published 2022 Mar 14. doi:10.3390/jcm11061597.
7. Barnett C, Katzberg H, Nabavi M, Bril V. The quantitative Myasthenia gravis score. Journal of Clinical Neuromuscular Disease. 2012;13(4):201-205. doi:10.1097/cnd.0b013e31824619d5.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

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		
Jurisdictio	**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
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
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
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