Medical Policy

Utilization Management and Clinical Medical Policy

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
Rozanolixizumab-noli (Rystiggo)	MP-RX-FP-168-25	☒ **MMM MA** ☒ **MMM MultiHealth**	**6/19/2025**	**5/6/2026**
			Last Review Date: **5/6/2026**	**Frequently Revision:** **Annual**

Service Category:

- ☐ Anesthesia
- ☐ Surgery
- ☐ Radiology Procedures
- ☐ Pathology and Laboratory Procedures
- ☐ Medicine Services and Procedures
- ☐ Evaluation and Management Services
- ☐ DME/Prosthetics or Supplies
- ☒ Other: Part B Drugs

Service Description:

This document addresses the use of Rozanolixizumab-noli (Rystiggo®) , a drug approved by the Food and Drug Administration (FDA) for the treatment of generalized myasthenia gravis in adult patients who are anti-acetylcholine receptor (AchR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive. Rystiggo subcutaneously administered through an infusion pump by a healthcare professional.

Background Information:

Generalized myasthenia gravis (gMG) is an autoimmune neuromuscular disorder characterized by fluctuating motor weakness causing dyspnea, dysphagia, diplopia, dysarthria, and ptosis. Generalized myasthenia gravis is commonly mediated by IgG autoantibodies directed against the neuromuscular junction. Treatment strategies include symptomatic therapy (with anticholinesterase agents such as pyridostigmine), chronic immunotherapy with steroids or other immunosuppressive drugs (such as azathioprine, cyclosporine, or methotrexate), rapid immunotherapy (with plasmapheresis or IV immune globulin), and/or surgical treatment. Soliris and Ultomiris are immunotherapies which block complement activation triggered by acetylcholine receptor antibodies at the neuromuscular junction. Rystiggo (rozanolixizumab-noli), Vyvgart (efgartigimod alfa-fcab), and Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) reduce autoantibodies by binding to the neonatal Fc receptor (FcRn), but differ in product administration, frequency, and population. Only Rystiggo is additionally approved for MuSK-positive individuals. Myasthenia Gravis Foundation of America (MGFA) international consensus guidelines, published prior to the approval of FcRn inhibitors, recommend immunosuppressive drugs and/or corticosteroids for individuals who have not met treatment goals after an adequate trial of pyridostigmine.

Current published evidence for Rystiggo includes one phase 3, multicenter, randomized, placebo-controlled trial that included individuals with non-ocular symptoms and were on at least one gMG treatment (cholinesterase inhibitors, corticosteroids, or non-steroidal immunosuppressants) prior to screening and throughout the study. Trial inclusion criteria required Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IVa disease and a Myasthenia Gravis Activities of Daily Living (MG-ADL) score of at least 3 or higher (non-ocular symptoms). Individuals with clinically relevant active infection or recent severe infections were excluded. Individuals with either AchR- or MuSK- positive disease were included. Participants in the trial were treated with Rystiggo 7 mg/kg or 10 mg/kg or placebo administered subcutaneously weekly for 6 weeks. The primary endpoint was change from baseline to day 43 in MG-ADL score. Secondary endpoints included MG-ADL response, based on the established clinically meaningful improvement of ≥2 point reduction. Both dosage groups in the trial showed statistically significant improvements in MG-ADL score compared to placebo and a greater proportion of patients in both treatment groups were MG-ADL responders (improvement of ≥2 points). Subsequent treatment cycles were not administered in the clinical trial, but the package insert states that subsequent 6-weeks cycles should be administered based on clinical evaluation, no sooner than 63 days from the start of the previous cycle.

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Approved Indications

A. For the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or antimuscle-specific tyrosine kinase (MuSK) antibody positive.

Other Uses

A. None.

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Medical Necessity Guidelines:

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Rozanolixizumab-noli (Rystiggo®)

A. Criteria For Initial Approval (*Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

i. Individual is 18 years of age or older; **AND**
ii. Individual has a diagnosis of generalized myasthenia gravis (gMG); **AND**
iii. Documentation is provided that individual has one of the following:
    A. A positive serologic test for the presence of anti-acetylcholine receptor antibodies (AchR-Ab+)*;* **OR**
    B. A positive serologic test for the presence of anti-muscle-specific tyrosine kinase (MuSK) antibodies; **AND**
iv. Individual has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IVa disease (Bril 2023); **AND**
v. Documentation is provided that individual has a Myasthenia Gravis Activities of Daily Living (MG-ADL) score of at least 3 or higher (Bril 2023); **AND**
vi. Documentation is provided that individual meets both of the following (A and B):
    A. Individual has had a trial and inadequate response or intolerance to an acetylcholinesterase inhibitor; **OR**
        1. Individual is on a stable dose of an acetylcholinesterase inhibitor; **OR**
        2. Individual has a contraindication to acetylcholinesterase inhibitors; **AND**
    B. Individual has had a trial and inadequate response or intolerance to one or more immunosuppressive agents (including but not limited to systemic corticosteroids or non-steroidal immunosuppressants); **OR**
        1. Individual is on a stable dose of one or more immunosuppressive agents (including but not limited to systemic corticosteroids or non-steroidal immunosuppressants); **OR**
        2. Individual has a contraindication to systemic corticosteroids and non-steroidal immunosuppressants;

B. Criteria For Continuation of Therapy

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Requests for continued use of Rystiggo (rozanolixizumab-noli) may be approved if the following criteria are met:

i. Individual has experienced a prior clinical response to rozanolixizumab-noli treatment as defined by the following:
   A. Reduction in signs or symptoms that impact daily function; **AND**
   B. Documentation is provided of at least a 2-point reduction in MG-ADL total score from pre-treatment baseline; **AND**

ii. Individual requires continued treatment to maintain response or to regain clinically meaningful response.

C. Authorization Duration

i. Initial Approval Duration: 26 weeks
ii. Reauthorization Approval Duration: 1 year

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

i. Individual is using in combination with maintenance immunoglobulin treatment, eculizumab, ravulizumab, efgartigimod-alfa, zilucoplan, or rituximab; **OR**

ii. If the above criteria are not met and for all other indications.

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Limits or Restrictions:

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Drug	Limit
Rystiggo (rozanolixizumab-noli) 280mg/2 mL (140mg/mL) single dose vial	840 mg or 6 mL (3 vials) once weekly for 6 weeks (6 weeks = 1 cycle)*
Rystiggo (rozanolixizumab-noli) 420mg/3 mL (140mg/mL) single dose vial	3 mL (1 vial) once weekly for 6 weeks (6 weeks= 1 cycle)*
Rystiggo (rozanolixizumab-noli) 560mg/4 mL (140mg/mL) single dose vial	4 mL (1 vial) once weekly for 6 weeks (6 weeks = 1 cycle)*
Rystiggo (rozanolixizumab-noli) 840mg/6 mL (140mg/mL) single dose vial	6 mL (1 vial) once weekly for 6 weeks (6 weeks = 1 cycle)*
Exceptions	
*May approve for additional treatment cycles (6 weeks = 1 cycle) based on clinical relapse/response, but no sooner than 63 days from the start of the previous treatment cycle.	

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Codes Information:

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

ICD-10 Diagnostic Codes:

Codes	Description
G70.00	Myasthenia gravis without (acute) exacerbation
G70.01	Myasthenia gravis with (acute) exacerbation

HCPCS Codes:

Codes	Description
J9333	Injection, rozanolixizumab-noli, 1 mg [Rystiggo]

CPT Codes:

Codes	Description
XW013TB	Introduction of Rozanolixizumab-noli Monoclonal Antibody into Subcutaneous Tissue, Percutaneous Approach, New Technology Group 11

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Reference Information:

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Type of Review	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Annual Review	Updated policy description. Coding Update: Added ICD-10 Procedure XW013TB.Adinistrative update to incorporate new template.	5/1/2026	5/6/2026
Policy Inception	Elevance Health's Medical Policy adoption.	6/9/2025	6/19/2025