HIGHMARK HEALTH OPTIONS

Updated: 07/2024
Approved: 12/2023

Request for Prior Authorization for Rystiggo (rozanolixizumab-noli)
Website Form – www.wv.highmarkhealthoptions.com
Submit request via: Fax - 1-833-547-2030.

All requests for Rystiggo (rozanolixizumab-noli) require a Prior Authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Rystiggo (rozanolixizumab-noli) Prior Authorization Criteria:

Coverage may be provided with a diagnosis of **generalized Myasthenia Gravis (gMG)** and the following criteria is met:

- Medication is prescribed by, or in consultation with, a neurologist
- Documentation of a positive serologic test for one of the following:
  - anti-acetylcholine antibodies
  - anti-muscle specific tyrosine kinase (MUSK)
- Documentation the member meets the following Myasthenia Gravis Foundation of America Clinical Classification Class
  - Rystiggo (rozanolixizumab-noli)
    - II to IVa
- Documentation the member has a Myasthenia Gravis-Specific Activities of Daily Living (MG-ADL) total score of one of the following:
  - Rystiggo (rozanolixizumab-noli)
    - ≥ 3 (with at least 3 points from non-ocular symptoms)
- Documentation of a baseline Quantitative Myasthenia Gravis (QMG) scale score
- Laboratory testing demonstrating IgG levels of the following:
  - Rystiggo (rozanolixizumab-noli)
    - at least 5.5 g/L
- Documentation of at least one of the following:
  - Failed treatment over 1 year or more with 2 or more immunosuppressive therapies either in combination or as monotherapy (e.g. azathioprine, cyclophosphamide, methotrexate)
  - Failed treatment over 1 year or more with at least 1 immunosuppressive therapy while on chronic plasmapheresis or plasma exchange (PE)
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- Must be age-appropriate according to FDA-approved labeling, nationally recognized compendia, or evidence-based practice guidelines
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**
  - First reauthorization criteria (member on therapy for 0 to 6 months)
    - Documentation from the provider that the member had a positive clinical response and tolerates therapy supported by at least one of the following:
      - A 2 point improvement in the member's total MG-ADL score
      - A 3 or more point improvement in QMG total score
  - Subsequent reauthorization criteria (member on therapy ≥ 6 months)

  - Documentation from the prescriber indicating stabilization or improvement in condition.
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

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RYSTIGGO (ROZANOLIXIZUMAB-NOLI) PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX: (833)-547-2030.**
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: 1-844-325-6251 Mon – Fri 8 am to 7 pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Directions:	Quantity:	Refills:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:	

Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No

Billing Information

This medication will be billed: ☐ at a pharmacy **OR** ☐ medically, JCODE: _____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis:	ICD Code:

Does the member have anti-acetylcholine antibodies? ☐ Yes ☐ No
Does the member have anti-muscle specific tyrosine kinase? ☐ Yes ☐ No
What is the member's Myasthenia Gravis Foundation of America Clinical Classification? _____
Is there documentation of the member's baseline MG-ADL and QMG scores? ☐ Yes , please document below ☐ No

- MG-ADL score _____ QMG score _____
- What is the member's baseline IgG level _____

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

First reauthorization: Has the member had at least a 2 point improvement in their MG-ADL score or a 3 point improvement in their QMG score ? (please provide supporting documentation) ☐ Yes ☐ No

Subsequent reauthorization: Has the member had a stabilization or improvement in their condition? ☐ Yes ☐ No

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date