RYSTIGGO®
(rozanolixizumab-noli)
Injection For Subcutaneous Use
140 mg/mL

Guide to Writing a Letter of Medical Necessity*

A health plan may request a letter of medical necessity to support coverage of RYSTIGGO (rozanolixizumab-noli). A letter of medical necessity helps explain the physician's rationale and clinical decision-making in choosing therapy for a specific patient and may include supporting documentation (eg, medical records, clinical treatment history, prescribing information, and peer-reviewed literature). The letter may be submitted as part of the prior authorization (PA) process, with the claim form, as part of an appeal, or in response to a health plan's request for additional documentation.

This resource provides information on the process of drafting a letter of medical necessity. Included below is a checklist that can be followed when creating a letter of medical necessity. In addition, attached to this document is a sample letter that includes information health plans often require.

Preparing an Effective Letter of Medical Necessity

✓ **When requesting treatment for your patient, follow the patient's plan requirements, which may require specific forms for documenting a letter of medical necessity; otherwise, treatment may be delayed**

✓ **Provide complete, comprehensive information regarding your patient's condition and the clinical rationale for treatment. Information recommended for a letter of medical necessity typically includes:**

- **Patient information**
  - Full name
  - Date of birth
  - Case ID number (if available)
  - Insurance ID/group number
  - Diagnosis, including ICD-10 CM code(s)
- **Summary of previous treatments**
  - Medication
  - Clinical outcomes
  - Treatment duration
  - Discontinuation rationale (if applicable)
- **Current condition and severity**
  - Current symptoms
  - MGFA classification
  - MG-ADL and QMG score
- **Clinical rationale for treatment**
  - Medical history
  - Physical examination
  - Trial data
  - Dosing and administration
- **Summary of your recommendations**

✓ **Attach documentation that supports your recommendations (as applicable):**

- **Additional rationale for treatment**
  - Prescribing information
  - Clinical trial data
  - Peer-reviewed literature
  - FDA approval letter
- **Additional patient information**
  - Patient medical records
  - Clinical notes
  - Lab results

INDICATION

RYSTIGGO (rozanolixizumab-noli) is 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.

IMPORTANT SAFETY INFORMATION

RYSTIGGO is associated with important warnings and precautions, including increased risk of infection, drug-induced aseptic meningitis, and hypersensitivity reactions. The most common adverse reactions (≥10%) in patients with gMG are headache, infections, diarrhea, pyrexia, hypersensitivity reactions, and nausea.

*__Use of the information in this letter does not guarantee that the health plan will provide reimbursement for RYSTIGGO. The information in this letter is not intended to be a substitute for, or an influence on, your independent medical judgment.__ It is presented for informational purposes only and is not intended to provide reimbursement or legal advice. HCPs are encouraged to contact third-party payers for specific information on their current coverage policies. For other questions, please call ONWARD™ at 1-844-ONWARD-1 (1-844-669-2731).

FDA=Food and Drug Administration; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; ID=identification; MG-ADL=Myasthenia Gravis-Activities of Daily Living; MGFA=Myasthenia Gravis Foundation of America; QMG=Quantitative Myasthenia Gravis.

Please refer to page 4 for additional Important Safety Information.
Please refer to the full Prescribing Information provided by the UCB representative and visit RYSTIGGOhcp.com.

RYSTIGGO®
(rozanolixizumab-noli)
Injection For Subcutaneous Use

Guide to Writing a Letter of Medical Necessity* (cont'd)

Sample Letter of Medical Necessity

Below is a sample letter of medical necessity that may be used as a starting point to describe your reasoning for why the treatment you prescribed is medically necessary for your patient. The content of the letter of medical necessity should be personalized based on your patient's medical information. Always exercise your independent medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition. It is recommended you use your institution's letterhead for the final draft that you submit to the health plan.

SAMPLE ONLY
UPDATE AND PLACE ON YOUR LETTERHEAD

[Date]

[Contact Name]
[Title]
[Name of Health Insurance Company]
[Address]
[City, State Zip Code]
Insured: [Full name of patient]; Date of Birth: [MM-DD-YEAR]; Policy Number: [Number]; Group Number: [Number]
Date(s) of service: [Date(s)]

Re: Coverage for RYSTIGGO® (rozanolixizumab-noli) for [Full name of patient]

Dear [Name of Contact]:
I am writing on behalf of my patient, [full name of patient], to provide information supporting medical necessity for treatment with RYSTIGGO (rozanolixizumab-noli). This letter of medical necessity provides information regarding my patient's medical history and diagnosis, and my treatment rationale for the use of RYSTIGGO.

Patient History and Diagnosis
[Full name of patient] is a[n] [age]-year-old [male/female] born [MM-DD-YEAR] who was diagnosed with [anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK)] antibody positive generalized myasthenia gravis (gMG) on [date of diagnosis MM-DD-YEAR].

[Provide a summary of rationale for treatment with RYSTIGGO for this patient based on your independent clinical assessment and medical opinion. Include a description of the patient's relevant gMG clinical signs and symptoms, disease progression, history of prior treatments, as well as specific clinical presentations and relevant patient-specific clinical scenarios demonstrating medical necessity.]

If Policy Requires Step Therapy/Trial or Failure of Branded Therapy (OPTIONAL)
Your policy requires a step edit through [branded therapy per clinical policy]. In my medical opinion, [branded therapy per clinical policy] is not an appropriate step for my patient. [Discuss rationale for using RYSTIGGO. Include your professional opinion of your patient's likely prognosis or disease progression without treatment. Consider citing any clinical evidence or lack of clinical evidence (head-to-head clinical studies, treatment guidelines, etc.), regarding use of one branded therapy or one class over another.]

Summary
Considering the patient's medical information provided and the supporting documentation enclosed, I believe RYSTIGGO is indicated and medically necessary for this patient. If you have any further questions, please feel free to call me at [prescriber's telephone number] to discuss. Thank you kindly for your prompt attention to this request.

Sincerely,
[Physician's Name, Credentials]
[Physician's Identification Number]
[Physician's Practice Name]
[Physician's Phone Number]
[Physician's Fax Number]
[Physician's Email]

Enclosures: [Clinical documentation, Prescribing Information, clinical notes and medical records, FDA approval letter for RYSTIGGO in gMG, etc.]

Consider submitting a letter of medical necessity, even if it is not requested, to avoid delay.

See the next page for specific examples of patient medical history you may consider including here.

If you are unsure, confirm with the payer what specific documentation needs to be submitted alongside your letter.

*Use of the information in this letter does not guarantee that the health plan will provide reimbursement for RYSTIGGO. The information in this letter is not intended to be a substitute for, or an influence on, your independent medical judgment. It is presented for informational purposes only and is not intended to provide reimbursement or legal advice. HCPs are encouraged to contact third-party payers for specific information on their current coverage policies. For other questions, please call ONWARD at 1-844-ONWARD-1 (1-844-669-2731).

Please refer to page 4 for Important Safety Information.
Please refer to the full Prescribing Information provided by the UCB representative and visit RYSTIGGOhcp.com.

RYSTIGGO®
(rozanolixizumab-noli)
Injection For Subcutaneous Use

Guide to Writing a Letter of Medical Necessity* (cont'd)

Examples of Medical History for a Letter of Medical Necessity

- **Documented diagnosis** of gMG[1]
- Positive record of **autoantibodies against AChR or MuSK**,[1] including laboratory results, date, and additional relevant context
- **MGFA Clinical Classification** status based on the Myasthenia Gravis Foundation of America disease scale[2]
  - Class I-V. Note: Only Class II-IVa studied in Phase 3 MycarinG clinical trial[1,3]
- **MG-ADL total score**,[2] including related case notes and clinical impressions
  - Only patients with MG-ADL scores of ≥3 were studied in the MycarinG clinical trial population[1,3]
- **Previous gMG treatment** including AChE inhibitors, corticosteroids, NSISTs, IVIg, SCIg, PLEX, eculizumab, ravulizumab-cwvz, and/or efgartigimod alfa-fcab[4,5]
  - Include treatment name(s), dosage, frequency, duration (with specific start/stop dates, if applicable), and clinical impact, including any inadequate response or intolerance to such treatments
- **Contraindications and potential drug interactions** with other agents used in the treatment of gMG[1]
- **History of complications, exacerbations, or myasthenic crises**,[2] which may result in ER visits, hospital admissions, and/or ICU stays
- **Record of signs and symptoms** describing patient's clinical presentation, such as[6,†]
  - Ocular: ptosis, diplopia
  - Bulbar: dysarthria, dysphagia, dysphonia, masticatory weakness
  - Facial: eyelid closure, drooling
  - Limb muscles: commonly proximal, symmetric; arms more affected than legs
  - Axial muscles: neck flexion; neck extension
  - Respiratory muscles: exertional dyspnea, orthopnea, tachypnea, respiratory failure

Note: This is not an all-inclusive list of potential gMG clinical signs and symptoms. Please always use your independent clinical judgment when deciding what to include for review.

*__Use of the information in this letter does not guarantee that the health plan will provide reimbursement for RYSTIGGO. The information in this letter is not intended to be a substitute for, or an influence on, your independent medical judgment.__ It is presented for informational purposes only and is not intended to provide reimbursement or legal advice. HCPs are encouraged to contact third-party payers for specific information on their current coverage policies. For other questions, please call ONWARD at 1-844-ONWARD-1 (1-844-669-2731).

†This list is not inclusive of all gMG clinical signs and symptoms.

AChE=acetylcholinesterase; AChR=acetylcholine receptor; ER=emergency room; FcRn=neonatal Fc receptor; gMG=generalized myasthenia gravis; ICU=intensive care unit; IV=intravenous; IVIg=intravenous immunoglobulin; MG-ADL=Myasthenia Gravis Activities of Daily Living; MGFA=Myasthenia Gravis Foundation of America; MuSK=muscle-specific tyrosine kinase; NSIST=Non-steroidal immunosuppressive therapy; PLEX=plasma exchange; QMG=Quantitative Myasthenia Gravis; SCIg=subcutaneous immunoglobulin.

Please refer to page 4 for Important Safety Information.
Please refer to the full Prescribing Information provided by the UCB representative and visit RYSTIGGOhcp.com.

RYSTIGGO®
(rozanolixizumab-noli)
Injection For Subcutaneous Use

Guide to Writing a Letter of Medical Necessity (cont'd)

Patient Support

If you have questions about getting your RYSTIGGO patients started in the ONWARD™ Patient Support Program, please visit ucbONWARD.com to access resources for healthcare professionals or contact your Rare Reimbursement Executive for assistance.

ONWARD
SUPPORT FOR RARE DISEASE MADE SIMPLE

ONWARD is provided as a service of UCB and is intended to support the appropriate use of UCB medicines. ONWARD may be amended or canceled at any time without notice. Some program and eligibility restrictions may apply.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Infections: RYSTIGGO may increase the risk of infection. Delay RYSTIGGO administration in patients with an active infection until the infection is resolved. During treatment with RYSTIGGO, monitor for clinical signs and symptoms of infection. If serious infection occurs, administer appropriate treatment and consider withholding RYSTIGGO until the infection has resolved.

Immunization

Immunization with vaccines during RYSTIGGO treatment has not been studied. The safety of immunization with live or live-attenuated vaccines and the response to immunization with any vaccine are unknown. Because RYSTIGGO causes a reduction in IgG levels, vaccination with live-attenuated or live vaccines is not recommended during treatment with RYSTIGGO. Evaluate the need to administer age-appropriate vaccines according to immunization guidelines before initiation of a new treatment cycle with RYSTIGGO.

Aseptic Meningitis: Serious adverse reactions of aseptic meningitis (also called drug-induced aseptic meningitis) have been reported in patients treated with RYSTIGGO. If symptoms consistent with aseptic meningitis develop, diagnostic workup and treatment should be initiated according to the standard of care.

Hypersensitivity Reactions: Hypersensitivity reactions, including angioedema and rash, were observed in patients treated with RYSTIGGO. Management of hypersensitivity reactions depends on the type and severity of the reaction. Monitor patients during treatment with RYSTIGGO and for 15 minutes after for clinical signs and symptoms of hypersensitivity reactions. If a reaction occurs, institute appropriate measures if needed.

ADVERSE REACTIONS

In a placebo-controlled study, the most common adverse reactions (reported in at least 10% of RYSTIGGO-treated patients) were headache, infections, diarrhea, pyrexia, hypersensitivity reactions, and nausea. Serious infections were reported in 4% of patients treated with RYSTIGGO. Three fatal cases of pneumonia were identified, caused by COVID-19 infection in two patients and an unknown pathogen in one patient. Six cases of infections led to discontinuation of RYSTIGGO.

Please refer to the full Prescribing Information provided by the UCB representative and visit RYSTIGGOhcp.com.

For more information about RYSTIGGO, visit RYSTIGGOhcp.com.

For additional information, contact UCBCares® at 1-844-599-CARE (2273).

References: 1. RYSTIGGO [prescribing information]. Smyrna, GA: UCB, Inc. **2.** Barnett C, Herbelin L, Dimachkie MM, Barohn RJ. Measuring clinical treatment response in myasthenia gravis. *Neurol Clin*. 2018;36(2):339-353. **3.** Bril V, Drużdż A, Grosskreutz J, et al. 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; 22(5):383-394. **4.** Farmakidis C, Pasnoor M, Dimachkie MM, Barohn RJ. Treatment of myasthenia gravis. *Neurol Clin*. 2018;36(2):311-337. **5.** Menon D, Bril V. Pharmacotherapy of generalized myasthenia gravis with special emphasis on newer biologicals. *Drugs*. 2022;82(8):865-887. **6.** Meriggioli MN, Sanders DB. Autoimmune myasthenia gravis: emerging clinical and biological heterogeneity. *Lancet Neurol*. 2009;8(5):475-490.

US-RZ-2400229 | July 2024