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

Guide to Writing a Letter of Appeal*

When a patient's health plan denies a PA (prior authorization) request for RYSTIGGO (rozanolixizumab-noli), you can submit a letter of appeal in response to the official denial letter. In the letter of appeal, you can explain your clinical rationale for prescribing RYSTIGGO, provide supporting documentation that addresses the reason(s) given for the denial, and request approval.

This resource provides information on the process and a checklist to follow when drafting a letter of appeal. In addition, this document includes a sample letter with information health plans often require.

Preparing an Effective Letter of Appeal

✓ **Refer to the health plan's specific appeals process, as there may be varying processes**

- Some health plans may require you to use their specific appeal form; if not, draft the letter on your letterhead

✓ **Confirm the health plan's time frame for submitting an appeal**

- If appropriate, mark the appeal request "urgent" based on the patient's needs and the health plan's timelines

✓ **Understand the reason for denial and include why you believe the decision should be reconsidered**

- If the denial was for inaccurate or incomplete information, correct or update the discrepancies
- Include specific and relevant medical information that, in your independent clinical judgment, supports the use of RYSTIGGO for your patient in accordance with the health plan's criteria
- Directly address any specific rationale cited by the health plan for the denial

✓ **Include all required information. Information recommended for a letter of appeal typically includes:**

- Patient's full name, plan identification number, gender, date of birth, and case identification number (if available)
- Patient's medical history, diagnosis (including ICD-10 code), prior treatments (including start/stop dates and reason(s) for discontinuation, if applicable), and any other patient characteristics and/or clinical considerations relevant to RYSTIGGO therapy
- Summary of your treatment recommendations
- Any additional enclosures to be submitted at the same time as the letter of appeal and in the correct order indicated in the health plan's appeal instructions. Additional enclosures typically include:
  - Letter of Medical Necessity
  - A copy of the health plan's denial letter
  - Relevant patient documentation, such as physician notes, lab results, and medical records
  - Clinical support, including trial data or relevant peer-reviewed articles (as applicable)

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).

HCP=healthcare professional; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; NPI=National Provider Identifier.

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.

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

Sample Letter of Appeal

This sample letter of appeal may be used as a starting point to address the health plan's specific reasons for denial and help reinforce your reasoning for why RYSTIGGO is medically necessary for your patient. The content of the letter of appeal should be personalized based on your patient's medical information and the health plan's denial response. Always exercise independent medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition. It is recommended you use your 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 or Pharmacy Benefit Manager]
[Address]
[City, State Zip Code]
Date(s) of service: [Date(s)]

Re: [First/Second]-Level Appeal for Coverage Denial of RYSTIGGO® (rozanolixizumab-noli) Injection For Subcutaneous Use[: Request for Expedited Review Due to Medical Urgency]

Date of Denial Letter: [MM-DD-YEAR]
Denial Reference Number: [Denial Reference Number]
Insured: [Full name of patient]; Date of Birth: [MM-DD-YEAR]; Policy Number: [Number]; Group Number: [Number]

Dear [Name of Contact]:

I am writing on behalf of my patient, [full name of patient], to appeal the coverage denial for treatment with RYSTIGGO for [anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK)] antibody positive generalized myasthenia gravis (gMG). The aforementioned letter of denial stated [list reasons for denial] as the reason for coverage denial. This appeal letter 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-AChR or anti-MuSK] antibody positive gMG on [date of diagnosis MM-DD-YEAR].

[Provide summary of rationale for treatment with RYSTIGGO for this patient based on your independent clinical assessment and medical opinion. Address the reason for denial directly. 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.]

Summary
Considering the patient's medical information provided and the supporting documentation enclosed, I believe RYSTIGGO is indicated and medically necessary for [full name of patient], and, as such, the coverage decision should be reversed. 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.

[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, Letter of Medical Necessity, copy of health plan's denial letter, etc.]

Download a copy of the full Prescribing Information.

Directly address the reason for denial and include relevant medical information that, in your clinical judgment, supports your patient's appropriate use in accordance with the health plan's criteria. See next page for specific examples of patient medical history to consider including.

Confirm that the documents are listed and attached in the order specified by the health plan.

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

Examples of Medical History for a Letter of Appeal

- **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.

Frequent Reasons for Denial

Listed below are some of the most common reasons why a health plan may initially deny coverage of RYSTIGGO that can be addressed in a letter of appeal, using the patient's medical history and your clinical judgment.

- Unclear understanding of RYSTIGGO indication
- Lack of information regarding previous treatments, including those required for initiation of RYSTIGGO
- Confusion regarding patient's participation in Rituximab clinical trial (if applicable)
- Missing clinical information to support initiation of RYSTIGGO, including MG-ADL score, QMG score, antibody testing results, and the patients' vaccination records

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†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; IVIg=intravenous immunoglobulin; MG-ADL=Myasthenia Gravis Activities of Daily Living scale; 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.
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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.

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