# 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 ( $\geq$ 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<sup>TM</sup> 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 <u>RYSTIGGOhcp.com</u>.

## RYSTIGG<sup>O®</sup> (rozanolixizumab-noli)

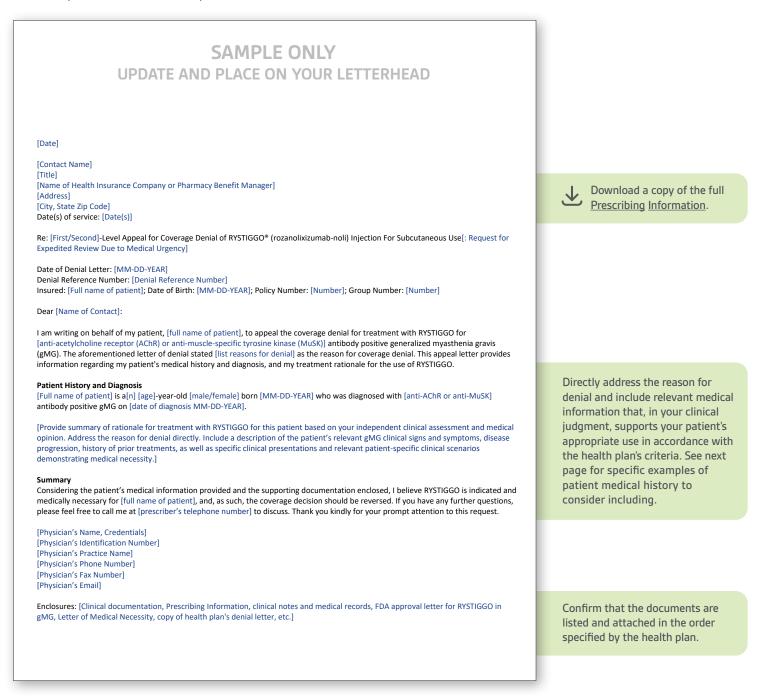
Injection For Subcutaneous Use

## 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.

Guide to Writing a

Letter of Appeal\* (cont'd)



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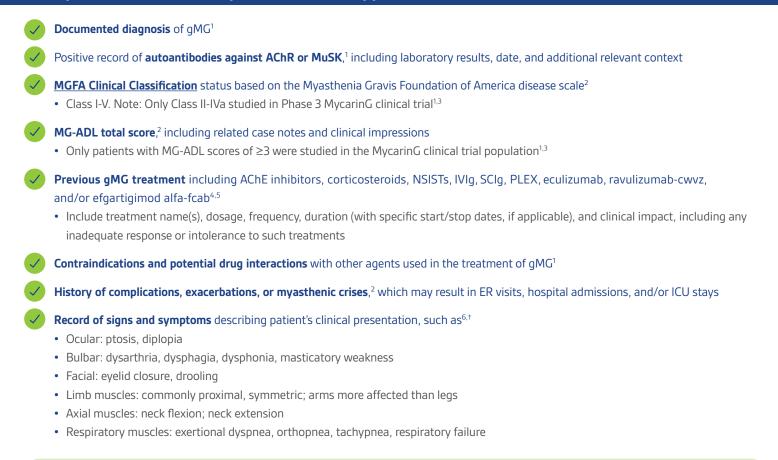
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# Guide to Writing a Letter of Appeal\* (cont'd)

## Examples of Medical History for a Letter of Appeal



**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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<sup>†</sup>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.

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

## **Patient Support**

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

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 <u>RYSTIGGOhcp.com</u>. For more information about RYSTIGGO, visit <u>RYSTIGGOhcp.com</u>. For additional information, contact UCBCares<sup>®</sup> 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.

