

**RYSTIGGO**<sup>®</sup>  
(rozanolixizumab-noli)  
Injection For Subcutaneous Use  
280 mg/2 mL vial

# Coding and Billing Guide

For the use of RYSTIGGO (rozanolixizumab-noli) in adult patients with generalized myasthenia gravis (gMG)

**This guide summarizes coding and billing information required for the administration of RYSTIGGO in the healthcare provider setting (eg, physician office, infusion center, or hospital outpatient clinic) and in the patient's home by an authorized home care partner.**

## 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.

**Please refer to page 7 for additional Important Safety Information.**

**Please refer to the full Prescribing Information provided by the UCB representative and visit [RYSTIGGOhcp.com](https://www.rystiggohcp.com).**

UCB, Inc. has developed this resource to provide objective and publicly available coding and billing information. The information contained in this guide is for educational purposes only and is intended to assist healthcare professionals in understanding the reimbursement process for RYSTIGGO when appropriately prescribed or administered. The information is not intended to provide specific guidance on how to code, bill, or charge for any product or service. Any determination regarding if and how to seek reimbursement should be made by the appropriate members of the healthcare provider's office and in consideration of the specific patient. It is the sole responsibility of the healthcare professional to select the proper code and ensure the accuracy of all claims used in seeking reimbursement. Coding, coverage, and reimbursement may vary significantly by the payer, plan, patient, and setting of care. Healthcare professionals should contact insurers to verify coverage and correct coding procedures prior to submitting claims, as information on coverage and coding is subject to change without notice. The information in this guide is current as of [Month 2023]. The information contained in this guide represents no statement, promise, or guarantee by UCB, Inc. concerning reimbursement of RYSTIGGO and administration, and UCB, Inc. does not recommend or endorse the use of any particular diagnosis or procedure code.



RYSTIGGO injection is a sterile, preservative-free, clear to slightly opalescent, colorless to pale brownish yellow solution.<sup>1</sup>

RYSTIGGO is supplied as one (1) 280 mg/2 mL (140 mg/mL) single-dose glass vial per carton (NDC 50474-980-79/50474-0980-79\*).<sup>1</sup>

## The recommended dosage of RYSTIGGO is based on body weight<sup>1</sup>

RYSTIGGO is supplied in 280 mg/2 mL single-dose vials

Body weight of patient	Dose	Dosage volume	Total vials used	Vials per dosage	Vials per cycle
<50 kg	420 mg	3 mL	1.5 vials	2 vials	12 vials
≥50 kg to <100 kg	560 mg	4 mL	2 vials	2 vials	12 vials
≥100 kg	840 mg	6 mL	3 vials	3 vials	18 vials

Each vial is for one-time use only. **Discard any remaining solution.**<sup>1</sup>

- The recommended dosage is administered as a subcutaneous infusion using an infusion pump once weekly for 6 weeks<sup>1,†</sup>
- Subsequent treatment cycles may be administered based on clinical evaluation. The safety of initiating subsequent cycles sooner than 63 days from the start of the previous treatment cycle has not been established<sup>1,‡,§</sup>
- RYSTIGGO is administered under the medical benefit

## RYSTIGGO infusions can be administered in different settings

RYSTIGGO should be administered using an infusion pump at a constant flow rate up to 20 mL/hr.

The following criteria are recommended for administration of RYSTIGGO<sup>1</sup>:

- Infusion pump alarm limits should be at maximum setting
- Administration tubing length should be 61 cm or shorter
- Infusion set with a needle of 26 gauge or larger should be used

## RYSTIGGO should only be prepared and infused by a healthcare professional



**Physician office  
infusion site**



**Independent  
infusion center**



**Hospital outpatient  
department**



**Home infusion**

\*For certain purposes, including the proper billing of drug products, an 11-digit NDC may be required.

†If a scheduled infusion is missed, RYSTIGGO may be administered up to 4 days after the scheduled time. Thereafter, resume the original dosing schedule until the treatment cycle is completed.<sup>1</sup>

‡The average number of treatment cycles initiated per year was 4. The median time between start of treatment cycles was 98 days for patients who initiated 4 cycles.<sup>1</sup>

§In an extension study, the minimum time for initiating subsequent treatment cycles was 63 days from the start of the previous treatment cycle.<sup>1</sup>

Please refer to page 7 for Important Safety Information.

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## Diagnosis coding

The following list provides ICD-10-CM codes that may relate to the use of RYSTIGGO for its approved indications.<sup>3</sup>

ICD-10-CM code	ICD-10-CM code description
G70.00	Myasthenia gravis without (acute) exacerbation
G70.01	Myasthenia gravis with (acute) exacerbation

ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification.

## Other relevant codes

The following codes may be relevant when filing claims for RYSTIGGO.

### Drug/biologic codes<sup>1,4-6</sup>

Code type	Code	Definition
HCPCS (J-code)	[J3590/JXXXX]*	[Unclassified biologics/Approved J-code definition TK]
HCPCS modifier	JW <sup>†</sup>	Drug amount discarded/not administered to any patient
	JZ <sup>†</sup>	Zero drug amount discarded/not administered to any patient
NDC	50474-980-79 50474-0980-79 <sup>‡</sup>	280 mg/2 mL single-dose vial

[\*It is expected that RYSTIGGO will have a permanent J-code in (Month Year).] [\*A permanent product-specific J-code was issued as of (Month Year).]

<sup>†</sup>Available on January 1, 2023, but required as of July 1, 2023.

<sup>‡</sup>For certain purposes, including the proper billing of drug products, an 11-digit NDC may be required.

HCPCS=Healthcare Common Procedure Coding System; NDC=National Drug Code.

Note: While we have provided a sample of potential ICD-10-CM and HCPCS codes for billing as they pertain to the approved indications for RYSTIGGO treatment, the ultimate responsibility for correct coding lies with the service provider. The codes included in this chart are not intended to encourage or suggest use of any drug that is inconsistent with US Food and Drug Administration (FDA)-approved indications and usage. The codes provided are not intended to be exhaustive and are subject to change. Please consult your code book for a detailed list of codes and additional information, including dosing information, which may vary by indication and patient demographic. Also, please contact your payers individually for specific guidance regarding their implementation of the new code set and any coding requirements (procedure codes, payer's use of modifiers, etc.) that might pertain uniquely to their organization.

**Please refer to page 7 for Important Safety Information.**

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## Other relevant codes (cont'd)

### Drug administration codes<sup>7,\*</sup>

CPT code	Code description
96369	Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); initial, up to 1 hour, including pump setup and establishment of subcutaneous infusion site(s)
96370	Each additional hour (list separately in addition to code for primary procedure)
96371	Additional pump set-up with establishment of new subcutaneous infusion site(s) (list separately in addition to code for primary procedure)

\*Please contact your payers individually for specific guidance regarding their approved CPT administration codes for RYSTIGGO.

CPT=Current Procedural Terminology.

### Revenue codes<sup>8,9,†</sup>

Revenue code <sup>‡</sup>	Code description
[0250]	[Pharmacy; General Classification]
[0636]	[Pharmacy, 025X Extension; Drugs Requiring Detailed Coding]

†A revenue code is used in a CMS-1450/UB-04 claim form to indicate the inpatient department or place in which a procedure or treatment is performed (eg, emergency room, operating room, or some other department).

‡Additional appropriate revenue codes may be added.

CMS=Centers for Medicare & Medicaid Services.

**Note:** The information contained in this guide is for educational purposes only. It is intended to assist healthcare professionals in understanding the reimbursement process for RYSTIGGO when appropriately prescribed or administered. Any determination regarding if and how to seek reimbursement should be made by the appropriate members of the healthcare provider's office and in consideration of the specific patient. The individual patient's plan details dictate coverage of the individual patient's health care.

The information contained in this guide represents no statement, promise, or guarantee by UCB, Inc. concerning reimbursement of RYSTIGGO and administration, and UCB, Inc. does not recommend or endorse the use of any particular diagnosis or procedure code. Importantly, payer coverage, reimbursement codes, and payment are subject to continual change; information contained in this guide is current as of [Month 2023].

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# Sample Claim Forms

Sample CMS-1500 and CMS-1450/UB-04 forms are provided below as general examples of the application of various codes. Remember, if claim forms are not accurately completed, there is a risk of denial or delay in payment for RYSTIGGO and its administration.

## CMS-1500 sample claim form: physician office

**Box 19:** Enter drug-identifying information as required by the payer (eg, drug name, strength, dosage administered, route of administration, 11-digit NDC with N4 qualifier).

**Note:** When using code J3590, include the amount of drug administered and wasted, if applicable. Choose the appropriate RYSTIGGO dose administered from these options:

- 420 mg/3 mL
- 560 mg/4 mL
- 840 mg/6 mL

**Box 21 ICD Indicator:** Identify the type of ICD diagnosis code used (eg, enter "0" for ICD-10-CM).

**Box 21 Diagnosis:** Include appropriate ICD-10 diagnosis code:

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

24. A. DATE(S) OF SERVICE				B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances)		E. DIAGNOSIS POINTER	F. \$ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #	
From	To				CPT/HCPCS	MODIFIER								
MM	DD	YY	MM	DD	YY									
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC) 50474-0980-79 Rozanolixizumab-noli 560 mg/4 mL SC infusion														
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. 0														
A. L. G70.XX								A			1			
B. L.														
C. L.														
D. L.														
E. L.														
F. L.														
G. L.														
H. L.														
I. L.														
J. L.														
K. L.														
L. L.														
1								J3590 JZ			1			
2								96XXX			1			
3														
4														
5														
ASSIGNMENT? (circle one) NO														
28. TOTAL CHARGE \$														
29. AMOUNT PAID \$														
30. Rsvd for NUCC Use														

**Box 24A:** Include the required N4 qualifier before the NDC in the shaded area. Do not include dashes. Enter the date of service below the shaded area.

**Note:** Some payers may require a Unit of Measure (UOM) and dose administered for each NDC to be provided immediately after without spaces (eg, N450474098079UN1). Double check payer requirements and format for reporting the UOM.

**Box 24D:** Include appropriate CPT and HCPCS codes and modifiers, as highlighted on pages 3 and 4 of this guide. CPT codes may vary by payer.

**Note:** When billing for the 420-mg dose, include a second line item using J3590 with the JW modifier to report amount of drug discarded. Do not include the JZ modifier for the first line. When billing for the 560-mg and 840-mg doses, include the JZ modifier since no drug is wasted.

**Box 24E:** Enter the letter from Box 21 (A-L) where the myasthenia gravis diagnosis is listed (see Item 21).

**Box 24G:** Enter the number of units of service.  
**Note:** For billing purposes, "1 unit" is typically reported when using code J3590.

CMS=Centers for Medicare & Medicaid Services; CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; NDC=National Drug Code; SC=subcutaneous.

Please refer to page 7 for Important Safety Information.

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# Sample Claim Forms

Sample CMS-1500 and CMS-1450/UB-04 forms are provided below as general examples of the application of various codes. Remember, if claim forms are not accurately completed, there is a risk of denial or delay in payment for RYSTIGGO and its administration.

## CMS-1500 sample claim form: physician office

**Box 19:** Enter drug-identifying information as required by the payer (eg, drug name, strength, dosage administered, route of administration, 11-digit NDC with N4 qualifier).

**Note:** If payer requires dosage, choose the appropriate RYSTIGGO dose administered from these options:

- 420 mg/3 mL
- 560 mg/4 mL
- 840 mg/6 mL

**Box 21 ICD Indicator:** Identify the type of ICD diagnosis code used (eg, enter "0" for ICD-10-CM).

**Box 21 Diagnosis:** Include appropriate ICD-10 diagnosis code:

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

24. A. DATE(S) OF SERVICE			B. PLACE OF SERVICE	C. D. PROCEDURES, SERVICES, OR SUPPLIES		E. DIAGNOSIS POINTER	F. \$ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
From	To		EMG	CPT/HCPCS	MODIFIER						
N450474098079UN560				[JXXXX]	JZ	A		[560]		NPI	
				96XXX		A		1		NPI	

**Box 24A:** Include the required N4 qualifier before the NDC in the shaded area. Do not include dashes. Enter the date of service below the shaded area.

**Note:** Some payers may require a Unit of Measure (UOM) and dose administered for each NDC to be provided immediately after without spaces (eg, N450474098079UN560). Double check payer requirements and format for reporting the UOM.

**Box 24D:** Include appropriate CPT and HCPCS codes and modifiers, as highlighted on pages 3 and 4 of this guide. CPT codes may vary by payer.

**Note:** When billing for the 420-mg dose, include a second line item using [JXXXX] with the JW modifier to report amount of drug discarded. Do not include the JZ modifier for the first line. When billing for the 560-mg and 840-mg doses, include the JZ modifier since no drug is wasted.

**Box 24E:** Enter the letter from Box 21 (A-L) where the myasthenia gravis diagnosis is listed (see Item 21).

**Box 24G:** Enter the number of units of service.

**Note:** For billing purposes, [1 mg = 1 unit of drug, and] 1 unit = 1 subcutaneous infusion.

CMS=Centers for Medicare & Medicaid Services; CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; NDC=National Drug Code; SC=subcutaneous.

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# Sample Claim Forms (cont'd)

## CMS-1450/UB-04 sample claim form: hospital clinic or facility

**Box 42:** Indicate revenue codes.

- [0250 - Pharmacy; General Classification]
- [0636 - Pharmacy, 025X Extension; Drugs Requiring Detailed Coding]
- 05XX - Clinic or outpatient location\*

**Box 43:** Describe the procedure according to the revenue code selected in Box 42.

*Note:* If code reported in Box 44 is a J code, include the N4 qualifier and the NDC in Box 43. Some payers may require a Unit of Measure (UOM) and dose administered for each NDC to be provided immediately after without spaces (eg, N450474098079UN560).

**Box 44:** Include appropriate CPT and HCPCS codes and modifiers, as highlighted on pages 3 and 4 of this guide. CPT codes may vary by payer.

*Note:* When billing for the 420-mg dose, include a second line item using J3590 with the JW modifier to report amount of drug discarded. Do not include the JZ modifier for the first line. When billing for the 560-mg and 840-mg doses, include the JZ modifier since no drug is wasted.

**Box 46:** Enter the number of units of service.

*Note:* For billing purposes, [1 mg = 1 unit of drug, and] 1 unit = 1 subcutaneous infusion.

**Box 66:** Identify the type of ICD diagnosis code used (eg, enter a "0" for ICD-10-CM).

**Box 67:** Include appropriate ICD-10 diagnosis code:

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

**Box 74:** Include appropriate CPT procedure code (see page 4 of this guide) and date of administration.

68 DX	69 ADMIT DX	70 PATIENT REASON DX	71 PPS	72	73
G70.00					
	96XXX	DD/MM/YYYY			

These CMS-1500 and CMS-1450/UB-04 sample claim forms are intended solely as a resource tool to assist billing staff regarding reimbursement issues. Any determination about if and how to seek reimbursement should be made only by the appropriate members of the physician's office, in consultation with the physician and in consideration of the procedure performed or therapy provided to a specific patient. Required codes for RYSTIGGO may vary by payer. We recommend verifying a health plan's coding policies. For more information on specific policies and other questions, contact the health plan.

**Note:** The coding information contained herein is gathered from various resources and is subject to change. Healthcare professionals should select the most appropriate codes with the highest level of detail to describe the patient's condition and the services rendered to the patient. It is the healthcare professional's sole responsibility to determine and submit appropriate codes. Healthcare professionals should contact insurers to verify coverage and correct coding procedures prior to submitting claims, as information on coverage and coding is subject to change without notice.

\*Infusion locations may include hospital outpatient department, ambulatory infusion center, and patient's home. Select appropriate revenue code based on the patient's infusion site.

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## 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](https://www.ucb.com/RYSTIGGOhcp.com).**

**For more information about RYSTIGGO, visit [RYSTIGGOhcp.com](https://www.ucb.com/RYSTIGGOhcp.com).**

**For additional information, contact UCBCares<sup>®</sup> at 1-844-599-CARE (2273).**



**If you have questions or for more information, please contact your RRE.**

**References:** **1.** RYSTIGGO [prescribing information]. Smyrna, GA: UCB, Inc. **2.** Data on file. UCB, Inc., Smyrna, GA. **3.** Centers for Medicare & Medicaid Services. ICD-10-CM tabular list of disease and injuries. Accessed May 15, 2023. <https://www.cms.gov/files/zip/2023-code-tables-tabular-and-index-updated-01/11/2023.zip>. **4.** Centers for Medicare & Medicaid Services. List of CPT/HCPCS codes. Accessed May 15, 2023. <https://www.cms.gov/apps/ama/license.asp?file=/files/zip/list-codes-effective-january-1-2023-published-december-1-2022.zip>. **5.** American Academy of Professional Coders. HCPCS code for drug amount discarded/not administered to any patient JW. Accessed May 15, 2023. <https://www.aapc.com/codes/hcpcs-modifiers/JW>. **6.** American Academy of Professional Coders. HCPCS code for zero drug amount discarded/not administered to any patient JZ. Accessed May 15, 2023. <https://www.aapc.com/codes/hcpcs-modifiers/JZ>. **7.** American Medical Association. *AMA CPT 2023: Professional Edition*. American Medical Association; 2022. Accessed May 15, 2023. <https://aapc.vitalsource.com/books/A23BPL0007>. **8.** Centers for Medicare & Medicaid Services. Medicare CY 2023 Outpatient Prospective Payment System (OPPS) Final Rule Claims Accounting. Accessed May 15, 2023. <https://www.cms.gov/files/document/2023-nfrm-opps-claims-accounting.pdf>. **9.** Cigna. Revenue code list-CPT-HCPCS. Accessed May 15, 2023. <https://static.cigna.com/assets/chcp/pdf/resourceLibrary/medical/revenue-code-list-requiring-cpt-and-hcpcs-codes-for-outpatient-facility-claims.pdf>.



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