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

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.

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 July 2024. 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.

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General Product Information

RYSTIGGO injection is a sterile, preservative-free, clear to slightly opalescent, colorless to pale brownish yellow solution.[1]

The recommended dosage of RYSTIGGO is based on body weight[1]

RYSTIGGO is supplied in single-dose vials

Body weight of patient	Dose	Dosage volume	Package size*	NDC	Vials per cycle
<50 kg	420 mg	3 mL	3-mL, single-dose glass vial in a carton	50474-981-83 50474-0981-83†	6 vials
50 kg to <100 kg	560 mg	4 mL	4-mL, single-dose glass vial in a carton	50474-982-84 50474-0982-84†	6 vials
≥100 kg	840 mg	6 mL	6-mL, single-dose glass vial in a carton	50474-983-86 50474-0983-86†	6 vials

*RYSTIGGO is also available in a 280-mg/2-mL, single-dose vial (NDC 50474-980-79/50474-0980-79†). The 560-mg dose requires two 280-mg/2-mL vials, or 12 vials per cycle. The 840 mg dose requires three 280-mg/2-mL vials, or 18 vials per cycle.[1]
†For certain purposes, including the proper billing of drug products, an 11-digit NDC may be required.

Each vial is for one-time use only. **Discard any remaining solution.**[1]

- The recommended dosage is administered as a subcutaneous infusion using an infusion pump once weekly for 6 weeks[1,‡]
- 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[1,§,¶]
- 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.[1]
The following criteria are recommended for administration of RYSTIGGO[1]:

- Infusion pump occlusion 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

‡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.[1]
§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.[1]
¶In an extension study, the minimum time for initiating subsequent treatment cycles was 63 days from the start of the previous treatment cycle.[1]
NDC=National Drug Code.

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Coding for RYSTIGGO in Adults With gMG

Diagnosis coding

The following list provides ICD-10-CM codes that may relate to the use of RYSTIGGO for its approved indications.[2]

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[1,3,4]

Code type	Code	Definition
HCPCS (J-code)	J9333	Injection, rozanolixizumab-noli, 1 mg
HCPCS modifier	JZ	Zero drug amount discarded/not administered to any patient
NDC	50474-980-79 50474-0980-79*	280-mg/2-mL (140-mg/mL), single-dose vial
	50474-981-83 50474-0981-83*	420-mg/3-mL (140-mg/mL), single-dose vial
	50474-982-84 50474-0982-84*	560-mg/4-mL (140-mg/mL), single-dose vial
	50474-983-86 50474-0983-86*	840-mg/6-mL (140-mg/mL), single-dose vial

*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.

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Coding for RYSTIGGO in Adults With gMG (cont'd)

Other relevant codes (cont'd)

Drug administration codes[5,*]

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)
96371	Additional pump set-up with establishment of new subcutaneous infusion site(s) (list separately in addition to code for primary procedure)
96372[†]	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
96401[†]	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic

*Please contact your payers individually for specific guidance regarding their approved CPT® administration codes for RYSTIGGO.
[†]Either 96372 or 96401 may be required by some payers for infusions with a duration of less than 15 minutes. CPT 96401 should be used only if the payer policy allows for use of this code for administration of a non-chemotherapy "highly complex biologic agent."[6]
CPT=Current Procedural Terminology.

Revenue codes[7,8,‡]

Revenue code[§]	Code description
0250	Pharmacy; General Classification
0636	Pharmacy; 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 July 2024.

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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.

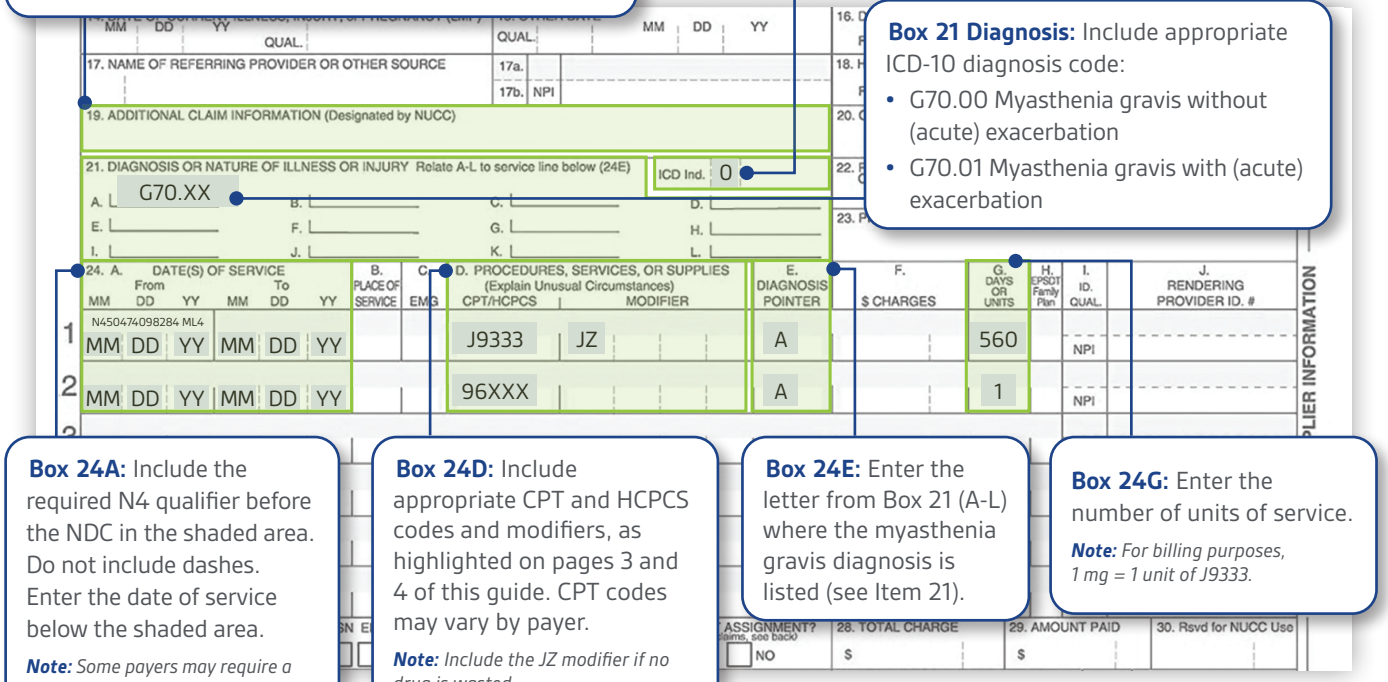
CMS-1500 sample claim form: physician office

Note: *Pending specific payer policy, NDC and quantity information may be required in Box 19.*

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



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 (eg, N450474098284 ML4). 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: *Include the JZ modifier if 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 J9333.*

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.

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Sample Claim Forms (cont'd)

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

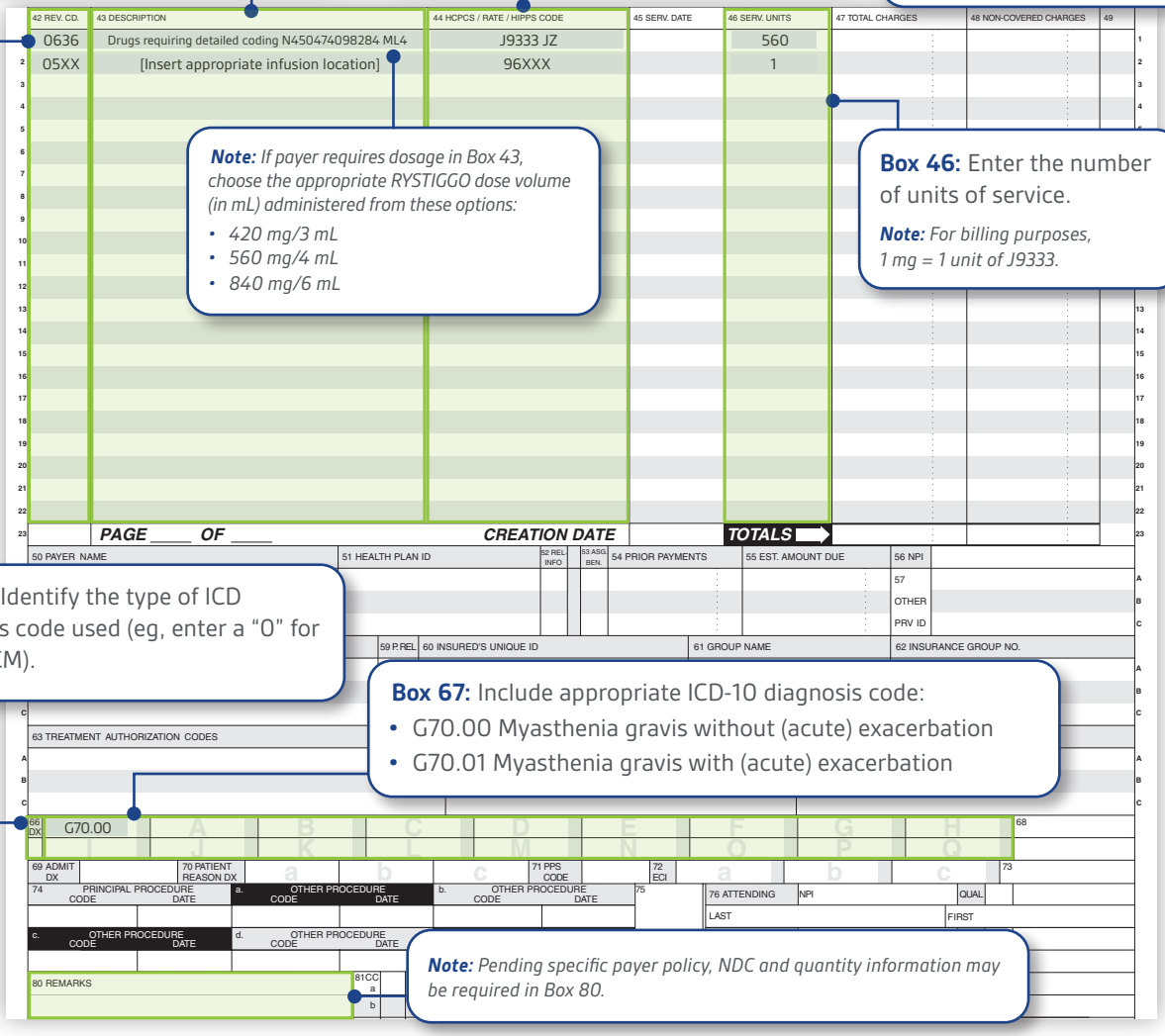
Box 42: Indicate revenue codes.
- 0250 - Pharmacy; General Classification
- 0636 - Pharmacy; Drugs Requiring Detailed Coding
- 05XX - Clinic or outpatient location*

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

Note: *If required based on individual payer policy, 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, N450474098284 ML4).*

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: *Include the JZ modifier if no drug is wasted.*



Note: *If payer requires dosage in Box 43, choose the appropriate RYSTIGGO dose volume (in mL) administered from these options:*
- *420 mg/3 mL*
- *560 mg/4 mL*
- *840 mg/6 mL*

Box 46: Enter the number of units of service.

Note: *For billing purposes, 1 mg = 1 unit of J9333.*

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

Note: *Pending specific payer policy, NDC and quantity information may be required in Box 80.*

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.

For more information about RYSTIGGO, visit RYSTIGGOhcp.com.

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

ucb RRE Rare Reimbursement Executive

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

References: 1. RYSTIGGO [prescribing information]. Smyrna, GA: UCB, Inc. **2.** Centers for Medicare & Medicaid Services. ICD-10-CM tabular list of disease and injuries. Updated April 1, 2024. Accessed June 26, 2024. https://www.cms.gov/medicare/coding-billing/icd-10-codes/2024-icd-10-cm. **3.** Centers for Medicare & Medicaid Services. HCPCS quarterly update. Published July 2024. Accessed June 26, 2024. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update. **4.** American Academy of Professional Coders. HCPCS code for zero drug amount discarded/not administered to any patient JZ. Accessed June 26, 2024. https://www.aapc.com/codes/hcpcs-modifiers/JZ. **5.** American Medical Association. *AMA CPT 2023: Professional Edition*. American Medical Association; 2022. Accessed June 26, 2024. https://aapc.vitalsource.com/books/A23BPL0007. **6.** Centers for Medicare & Medicaid Services. Billing and coding: complex drug administration coding. Updated April 1, 2024. Accessed June 26, 2024. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=58527. **7.** Centers for Medicare & Medicaid Services. Medicare CY 2024 Outpatient Prospective Payment System (OPPS) final rule claims accounting. Accessed June 26, 2024. https://www.cms.gov/files/document/2024-nfrm-opps-claims-accounting.pdf. **8.** Centers for Medicare & Medicaid Services. Billing and coding: hospital outpatient drugs and biologicals under the Outpatient Prospective Payment System (OPPS) (A55913). Updated April 23, 2020. Accessed June 26, 2024. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=55913.

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