

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

Fulfillment Resource Guide

A guide to help your office navigate the access and reimbursement process for RYSTIGGO (rozanolixizumab-noli)

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.

The information provided in this guide is of a general nature and for informational purposes only. It is intended to assist healthcare professionals in understanding the reimbursement process for RYSTIGGO when appropriately prescribed or administered.

Coverage policies change periodically and often without warning. The responsibility to determine coverage and reimbursement parameters, and appropriate coding for a particular patient and/or procedure, is always the responsibility of the provider or physician. The information provided in this guide in no way represents a statement, promise, or guarantee by UCB, Inc. concerning reimbursement of RYSTIGGO and administration services, and UCB, Inc. does not recommend or endorse the use of any particular diagnosis or procedure code.

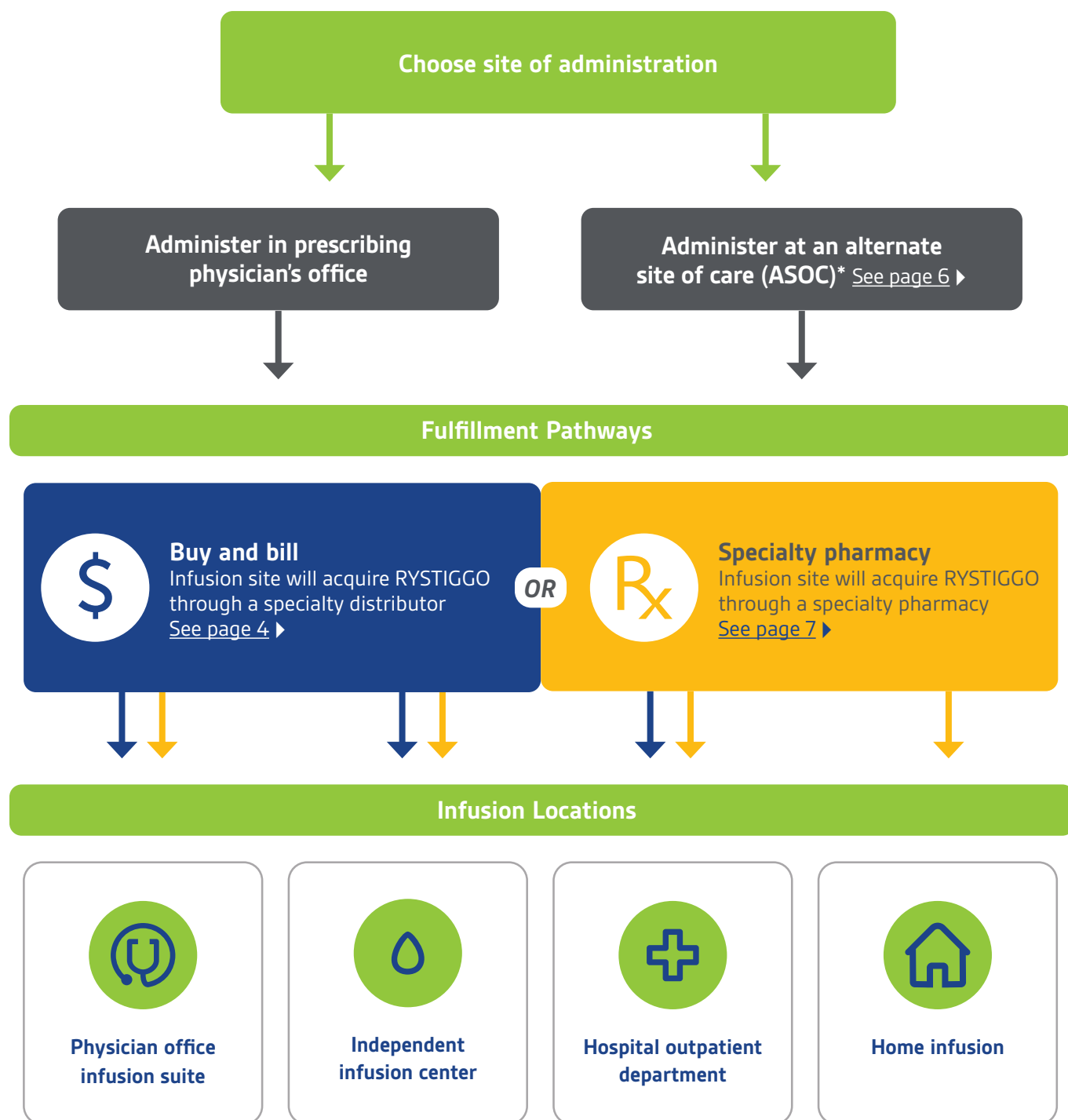
Please refer to page 20 for additional Important Safety Information.
Please refer to the full Prescribing Information provided by the
UCB representative and visit [RYSTIGGOhcp.com](https://www.rystiggohcp.com).

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CMS=Centers for Medicare & Medicaid Services.

Please refer to page 20 for Important Safety Information.
Please refer to the full Prescribing Information provided by the UCB representative and visit [RYSTIGGOhcp.com](https://www.rystiggohcp.com).

In this guide, you'll find the steps to obtaining RYSTIGGO through each of the fulfillment pathways after a prescribing decision has been made. RYSTIGGO can be acquired through 2 pathways and administered by a healthcare professional (HCP) in 4 different locations.



*ASOCs include physician office infusion suites, independent infusion centers, hospital outpatient departments, and home infusion.

Please refer to page 20 for Important Safety Information.

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

RYSTIGGO can be acquired through a specialty distributor. Use this checklist to help navigate the buy and bill fulfillment pathway.

Please note: The prescribing physician's office is responsible for all steps **only** if they are the site of care where RYSTIGGO is administered. Steps 3 to 6 are completed if an alternate site of care (ASOC) is selected and the ASOC chooses to acquire RYSTIGGO through buy and bill.*

1 Verify benefits

- ☐ Contact your patient's health plan to confirm your patient's benefits
- ☐ Collect information that may be required by your patient's health plan before approving RYSTIGGO (eg, copy of your patient's insurance cards, appropriate HCPCS code [J-code], ICD-10-CM diagnosis code(s), documented prescription/medication order, use of prior medications)
- ☐ Review coverage with your patient, including any utilization requirements, such as prior authorization (PA) or a step edit, and out-of-pocket costs
 - Reference the "Prior Authorization/Predetermination Checklist" for more information if a PA is required ([see page 19 ▶](#))

2 Determine site of administration

- ☐ Decide if patient will receive RYSTIGGO in office or at a hospital or infusion clinic
- ☐ Schedule the patient for administration at the infusion location selected (eg, in your office or at an ASOC)
 - Visit [RYSTIGGO.com/infusion-finder](https://www.rystiggo.com/infusion-finder) for help locating an infusion center (eg, physician office infusion suite, independent infusion center, or hospital outpatient department) if referring to an ASOC ([see page 6 ▶](#))

*ASOCs that can utilize the buy and bill fulfillment pathway include physician office infusion suites, independent infusion centers, and hospital outpatient departments.

HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification.

Please refer to page 20 for Important Safety Information.

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

Steps 3 to 6 are to be completed by the site of administration. If you've referred your patient to an ASOC, reference the ASOC checklist for more information ([see page 6 ▶](#))

3 Order RYSTIGGO

- ☐ Purchase RYSTIGGO through a **specialty distributor** ([see page 9 ▶](#))

4 Administer RYSTIGGO

- ☐ Collect the patient's co-pay or coinsurance according to your practice's billing protocols at time of visit
- ☐ Administer RYSTIGGO. RYSTIGGO should only be prepared and infused by an HCP¹
- ☐ Schedule your patient's next appointment. RYSTIGGO should be administered as a subcutaneous infusion once weekly for 6 weeks¹

5 Submit claim

- ☐ Confirm the health plan's timeframe for submitting claims after services are provided
- ☐ Fill out a CMS-1500 form for billing prescribed medications administered in a physician office infusion suite ([see page 16 ▶](#)) **OR** a CMS-1450 (UB-04) form for billing prescribed medications administered in a hospital outpatient department, independent infusion center, or via a home infusion ([see page 17 ▶](#))
 - Be sure to bill all relevant insurance(s) (primary, secondary, supplemental, and tertiary) for **both administration and medication** as appropriate for each plan
 - Please note: RYSTIGGO acquisition and administration are billed under the **medical benefit**
- ☐ Ensure you have the appropriate medication and billing codes to submit your claim
 - Reference the "Coding and Billing Guide for the Use of RYSTIGGO" for more information ([see page 19 ▶](#))

6 Manage reimbursement

- ☐ Process payment claims for **both administration and medication**
- ☐ Review the remittance advice to ensure appropriate payment once received
- ☐ File an appeal, if the claim is rejected or denied

ASOC=alternate site of care; CMS=Centers for Medicare & Medicaid Services; HCP=healthcare professional.

You can refer patients to an ASOC* where RYSTIGGO will be purchased and administered. Use this checklist to help navigate the process to refer your patient to an ASOC and support them throughout treatment.

1 Verify benefits and determine site of administration

- ☐ Contact your patient's health plan to confirm your patient's benefits
- ☐ Collect information that may be required by your patient's health plan before approving RYSTIGGO (eg, copy of your patient's insurance cards, appropriate HCPCS code [J-code], ICD-10-CM diagnosis code(s), documented prescription/medication order, use of prior medications)
- ☐ Review coverage with your patient, including any utilization requirements, such as a PA or a step edit, and out-of-pocket costs
 - Reference the "Prior Authorization/Predetermination Checklist" for more information if a PA is required ([see page 19](#) ▶)

2 Locate an ASOC

- ☐ Visit [RYSTIGGO.com/infusion-finder](https://www.rystiggo.com/infusion-finder) for help finding ASOCs near your patient's preferred treatment location

3 Establish communication with the ASOC

- ☐ Call the ASOC to confirm the site can administer RYSTIGGO and the process for referring patients to their site for administration
- ☐ Use the preferred referral process from the ASOC
- ☐ Collect required information (eg, treatment site information, patient insurance and medical information, referring physician information and signature, and provider order of RYSTIGGO documented in chart)
- ☐ Send required information to the ASOC

4 Maintain follow-up communication with the ASOC

- ☐ Ensure your patient has received their RYSTIGGO and has scheduled their next appointment. RYSTIGGO should be administered as a subcutaneous infusion once weekly for 6 weeks¹
 - **Please note:** The ASOC will bill your patient's health plan for administration and medication, as applicable

*ASOCs include physician office infusion suites, independent infusion centers, hospital outpatient departments, and home infusion.
HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; PA=prior authorization.

RYSTIGGO can be obtained through a network specialty pharmacy. Use this checklist to help navigate the specialty pharmacy fulfillment pathway.

Please note: The prescribing physician's office is responsible for all steps **only** if they are the site of care where RYSTIGGO is administered. Steps 4 to 6 are completed if an alternate site of care (ASOC) is selected and the ASOC chooses to acquire RYSTIGGO through a specialty pharmacy.*

1 Verify benefits

- ☐ Contact your patient's health plan to confirm your patient's benefits
- ☐ Collect information that may be required by your patient's health plan before approving RYSTIGGO (eg, copy of your patient's insurance cards, appropriate HCPCS code [J-code], ICD-10-CM diagnosis code(s), documented prescription/medication order, use of prior medications)
- ☐ Review coverage with your patient, including any utilization requirements, such as a PA or a step edit, and out-of-pocket costs
 - Reference the "Prior Authorization/Predetermination Checklist" for more information if a PA is required ([see page 19](#) ▶)

2 Determine site of administration

- ☐ Determine if patient will receive RYSTIGGO in office, at a hospital or infusion clinic, or at home
- ☐ Schedule the patient for administration at the infusion location selected, in your office, or at an alternate site of care (ASOC)
 - Visit [RYSTIGGO.com/infusion-finder](https://www.rystiggo.com/infusion-finder) for help locating an infusion center (eg, physician office infusion suite, independent infusion center, or hospital outpatient department) if referring to an ASOC ([see page 6](#) ▶)
 - Visit [ucbONWARD.com](https://www.ucbONWARD.com) for information about the specialty pharmacies with home infusion capabilities in UCB's limited distribution network or contact one directly ([see page 9](#) ▶)

3 Send prescription

- ☐ Send the prescription for RYSTIGGO to a **specialty pharmacy** ([see page 9](#) ▶)

*ASOCs that can utilize the specialty pharmacy fulfillment pathway include physician office infusion suites, independent infusion centers, hospital outpatient departments, and home infusion.

HCP=healthcare professional; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; PA=prior authorization.

Steps 4 to 6 are to be completed by the site of administration. If you've referred your patient to an ASOC, reference the ASOC checklist for more information ([see page 6 ►](#))

4 Administer RYSTIGGO

- ☐ Collect the patient's co-pay or coinsurance according to your practice's billing protocols at time of visit
- ☐ Administer RYSTIGGO. RYSTIGGO should only be prepared and infused by an HCP¹
- ☐ Schedule your patient's next appointment. RYSTIGGO should be administered as a subcutaneous infusion once weekly for 6 weeks¹

5 Submit claim

- ☐ Confirm the health plan's timeframe for submitting claims after services are provided
- ☐ Fill out a CMS-1500 form when billing for administration in a physician office infusion suite ([see page 16 ►](#)) **OR** a CMS-1450 (UB-04) form when billing for administration in a hospital outpatient department, independent infusion center, or via a home infusion ([see page 17 ►](#))
 - Be sure to bill all relevant insurance(s) (primary, secondary, supplemental, and tertiary) for **administration only** as appropriate for each plan
 - Please note: RYSTIGGO **administration only** is billed under the **medical benefit** when RYSTIGGO is acquired through a Specialty Pharmacy
- ☐ Ensure you have the appropriate medication and billing codes to submit your claim
 - Reference the "Coding and Billing Guide for the Use of RYSTIGGO" for more information ([see page 19 ►](#))

6 Manage reimbursement

- ☐ Process payment claims for **administration only**
- ☐ Review the remittance advice to ensure appropriate payment once received
- ☐ File an appeal, if the claim is rejected or denied

ASOC=alternate site of care; CMS=Centers for Medicare & Medicaid Services; HCP=healthcare professional.

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How to Acquire RYSTIGGO for Your Patients

RYSTIGGO can be obtained directly from a specialty distributor or through a specialty pharmacy and should be administered by an HCP. Please contact the following authorized specialty distributors or specialty pharmacies.

Specialty distributors

RYSTIGGO can be acquired via buy and bill through the following network of authorized specialty distributors.

	P: Phone / F: Fax	Website	Order Entry Number for Vials by NDC Code			
			50474-980-79	50474-981-83	50474-982-84	50474-983-86
ASD Healthcare (ABSG)	P: 800-746-6273 / F: 800-547-9413	www.asdhealthcare.com	10281436	10291247	10291317	10291318
Besse Medical	P: 800-543-2111 / F: 800-543-8695	www.besse.com	10281486	10291314	10291452	10291453
Oncology Supply	P: 800-633-7555 / F: 800-248-8205	www.oncologysupply.com	10281459	10291208	10291319	10291460
BioCareSD [®]	P: 800-304-3064 / F: 602-850-6221	store.biocaresd.com	50474-0980-79	1000771	1000772	1000773
CuraScript SD [®]	P: 877-599-7748 / F: 800-862-6208	www.curascriptsds.com	477273	10005074	10005075	10005076
CardinalHealth [™] SPD	P: 877-453-3972 / F: 877-274-9897	specialtyonline.cardinalhealth.com	5860515	5937800	5937818	5937826
CardinalHealth Metro Medical [™]	P: 877-768-2002 / F: 800-926-3161	www.metromedicalorder.com	980790	981830	982840	983860
McKesson Specialty Health [*]	P: 855-477-9800 / F: 800-800-5673	mscs.mckesson.com	5015791	5018161	5018162	5018163
McKesson Plasma and Biologics	P: 877-625-2566 / F: 888-752-7626	connect.mckesson.com	2836328	2974277	2974285	2974293

*For multi-specialty customers.

Specialty pharmacies

The specialty pharmacies listed below have been selected to dispense RYSTIGGO.

	P: Phone / F: Fax	Website
CVS Specialty [®]	P: 800-378-0695 / F: 800-323-2445	www.cvsspecialty.com
KabaFusion	P: 877-577-4844 / F: 877-445-8821	www.kabafusion.com
PANTHERx Rare	P: 833-418-7760 / F: 412-567-6135	www.pantherxrare.com



The team at ONWARD[™] can help enrolled patients explore the possibility of home infusion administration for RYSTIGGO if interested and eligible.

HCP=healthcare professional.

Please refer to page 20 for Important Safety Information.

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

The RYSTIGGO Infusion Finder is designed to help patients and their doctors identify sites of care with the ability to administer RYSTIGGO. To register your office as an alternate site of care (ASOC), visit RYSTIGGO.com/infusion-sign-up and complete these 3 simple steps.*

STEP 1
Contact Information

This information will be used to contact you about your listing and will not be listed in the RYSTIGGO Infusion Finder website. *Indicates required field.

*Contact First Name

*Contact Last Name

*Contact Email Address

*What is your role at your practice?
(Please choose one)
☐ Office Manager
☐ Physician
☐ Physician Assistant
☐ Nurse Practitioner
☐ Registered Nurse
☐ Other

STEP 2
Listing Information

This information will appear when a user searches for a practice near them using the RYSTIGGO Infusion Finder website. *Indicates required field.

*Practice Name

Practice Email Address

Practice Website

*Address 1

Address 2

*City

STEP 3
Release to Publish Practice Information on RYSTIGGO Infusion Finder website.

Your registration will be complete after you read and acknowledge the Release below and click Submit.

The Practice understands that UCB, Inc., its affiliates, and/or designees would like to use contact information for the Practice on UCB's website, at www.rystiggo.com/infusion-finder. Specifically, UCB will publish the following information for the Practice: (i) Practice name; (ii) Practice address; (iii) Practice telephone number; and (iv) Practice website (together, the "Practice Information"). The Practice understands that UCB would like to share the Practice Information as part of an online database of providers that offers RYSTIGGO[®] to patients with a prescription from a physician, to allow these patients to search for nearby RYSTIGGO providers and contact information ("infusion finder").

1 Fill out your office's contact information

- Double check the contact email. You will receive confirmation of inclusion in the RYSTIGGO Infusion Finder via email to the address listed in this section
- The information provided in this section will be used to contact you about your listing. It will not be listed in the RYSTIGGO Infusion Finder website

2 Provide your office's listing information

- This information will appear when a user searches for a practice near them using the RYSTIGGO Infusion Finder website

3 Read and acknowledge agreement to the Release to Publish Practice Information

- Registration is complete after you read and acknowledge the Release and click "Submit"



Scan the QR code or visit
RYSTIGGO.com/infusion-sign-up
to register*

*Inclusion in the Infusion Finder is subject to approval. No fees or other remuneration have been or will be exchanged for inclusion in the Infusion Finder. The inclusion of any location in the Infusion Finder is not an endorsement, referral, or recommendation from UCB of that practice, nor does it represent an endorsement of any UCB product by the practice. See Full Disclaimer on RYSTIGGO.com/infusion-sign-up.

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



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

Dosing

The recommended dosage of RYSTIGGO is based on body weight

RYSTIGGO is supplied in **single-dose vials**. Each vial is for one-time use only. **Discard any remaining solution.**

Body weight of patient	Dose	Dosage volume	Vials per cycle
<50 kg	420 mg	3 mL	6 vials
50 kg to <100 kg	560 mg	4 mL	6 vials
≥100 kg	840 mg	6 mL	6 vials

Recommended dose is given as a weekly subcutaneous infusion in a 6-week treatment cycle*[†]



In RYSTIGGO clinical studies:

- **8 weeks** of observation followed the 6-week treatment period
 - The safety of initiating subsequent treatment cycles sooner than 9 weeks (63 days) from the start of the previous treatment cycle has not been established
- **4 treatment cycles** were initiated per year, on average (range: 1-7 cycles)

*RYSTIGGO is intended for subcutaneous administration using an infusion pump at a constant flow rate of up to 20 mL/hr.

[†]If a scheduled infusion is missed, RYSTIGGO may be administered up to 4 days after the scheduled time point. Thereafter, resume the original dosing schedule until the treatment cycle is completed.

[‡]The recommended minimal time for initiating subsequent treatment cycles is 63 days from the start of the previous treatment cycle.

gMG=generalized myasthenia gravis; NDC=National Drug Code.

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.

Please refer to page 20 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).

RYSTIGGO is a once-weekly subcutaneous infusion administered in approximately 15 minutes once preparation is complete



Administration

- Time of administration may vary by patient. Duration of infusion may be longer based on flow rate and patient weight
- RYSTIGGO is intended to be infused in the lower right or lower left part of the abdomen, below the navel
- Rotate infusion sites for subsequent administrations
- Infuse RYSTIGGO within 4 hours of puncturing the vial. RYSTIGGO should be administered immediately after priming the infusion set

Observation

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.

Administration considerations

Concomitant use of RYSTIGGO with medications that bind to the human neonatal Fc receptor (eg, immunoglobulin products, monoclonal antibodies, or antibody derivatives containing the human Fc domain of the immunoglobulin G subclass) may lower systemic exposures and reduce effectiveness of such medications.

Recommended equipment for administering RYSTIGGO



Infusion pump with occlusion alarm limits at maximum setting

Device shown was used in RYSTIGGO clinical trials and is one of several that can be used for administration.



≤61-cm administration tubing



Infusion set with a ≥26-gauge or larger needle

Visit RYSTIGGOhcp.com/dosing to view the RYSTIGGO dosing and administration video for step-by-step instructions on the proper dosing and subcutaneous infusion of RYSTIGGO.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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.

Please refer to page 20 for additional Important Safety Information.

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

RYSTIGGO can be administered by an HCP in 4 different locations:



Physician office infusion suite

These physician offices have capabilities to both prescribe and infuse RYSTIGGO.

Physician's office can obtain RYSTIGGO directly from a specialty distributor or through a specialty pharmacy in UCB's limited distribution network.



Independent infusion center

These centers are independent from physician offices and hospitals. Infusion nurses staff these centers; physicians may or may not be on site.

Independent infusion center can obtain RYSTIGGO directly from a specialty distributor or through a specialty pharmacy in UCB's limited distribution network.



Hospital outpatient department

These facilities exist within hospitals for patients who do not need to be admitted to receive infusions.

Hospital outpatient department can obtain RYSTIGGO directly from a specialty distributor or through a specialty pharmacy in UCB's limited distribution network.



Home infusion

Some patients may be eligible for RYSTIGGO to be administered at home by a trained nurse. Eligibility is based on patient's insurance plan. Not all patients are eligible.

RYSTIGGO will be available through a defined network of specialty pharmacies with home infusion capabilities: CVS Specialty[®], KabaFusion, and PANTHERx Rare.

To learn more about how to acquire RYSTIGGO, [see page 9](#) ▶

Alternate site of care (ASOC)



RYSTIGGO can be administered at an ASOC.* The RYSTIGGO Infusion Finder is designed to help patients and their doctors identify sites of care with the ability to administer RYSTIGGO. Visit [RYSTIGGO.com/infusion-finder](https://www.rystiggo.com/infusion-finder) to find a location for your patient.[†]

Want to register your practice as an ASOC with the RYSTIGGO Infusion Finder?
[See page 10](#) ▶ to learn more.

*ASOCs include physician office infusion suites, independent infusion centers, hospital outpatient departments, and home infusion.

[†]The inclusion of any location in the Infusion Finder is not an endorsement, referral, or recommendation from UCB of that practice, nor does it represent an endorsement of any UCB product by the practice. See Full Disclaimer on [RYSTIGGO.com/infusion-sign-up](https://www.rystiggo.com/infusion-sign-up).

HCP=healthcare professional.

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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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^{8,9,‡}

Revenue code ⁵	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).

⁹Additional 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 August 2024.

Please refer to page 20 for Important Safety Information.

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CMS-1500 sample claim form: physician office

A sample of a completed CMS-1500 form is provided below as a general example 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.

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 14 and 15 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.

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL										15. OTHER DATE QUAL MM DD YY										16. DATE OF BIRTH MM DD YY																																																																					
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE																														17a. NAME 17b. NPI										18. F. NAME 18. G. NAME 18. H. NAME 18. I. NAME 18. J. NAME 18. K. NAME 18. L. NAME																																																	
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)																														20. C. NAME 20. D. NAME 20. E. NAME 20. F. NAME 20. G. NAME 20. H. NAME 20. I. NAME 20. J. NAME 20. K. NAME 20. L. NAME										21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) A. G70.XX B. C. D. E. F. G. H. I. J. K. L. ICD Ind. 0																																																	
24. A. DATE(S) OF SERVICE From To MM DD YY MM DD YY										B. PLACE OF SERVICE EMG										C. D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS MODIFIER										E. DIAGNOSIS POINTER										F. \$ CHARGES										G. DAYS OR UNITS										H. ICD-10 Family Plan										I. ID. QUAL.										J. RENDERING PROVIDER ID. #									
1 N450474098284 ML4 MM DD YY MM DD YY																				J9333 JZ										A										560										NPI																																							
2 MM DD YY MM DD YY																				96XXX										A										1										NPI																																							
3 MM DD YY MM DD YY																																																																																									
ASSIGNMENT? NO										28. TOTAL CHARGE \$										29. AMOUNT PAID \$										30. Rsvd for NUCC Use																																																											

Sample Claim Forms: CMS-1450/UB-04

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

A sample of a completed CMS-1450/UB-04 form is provided below as a general example 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.

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 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 14 and 15 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 providers 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 provider's sole responsibility to determine and submit appropriate codes. Healthcare providers 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.

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.

Please refer to page 20 for Important Safety Information.

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

ONWARD means personalized support for patients with gMG*

ONWARD is an individualized support experience built to help patients with gMG through every step of their RYSTIGGO treatment.



Your RYSTIGGO patients can access important resources, including:



A dedicated, medically trained
Care Coordinator to provide
personalized support†



Help in reviewing insurance
coverage and potential financial
assistance options



Tools and resources to start and
stay on treatment, as prescribed



Help tracking symptoms and
ongoing treatment support

**ONWARD is here to help support gMG patients during
every step of their RYSTIGGO treatment.**

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 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.

†ONWARD does not provide medical advice and does not replace the care of the healthcare professional. Care Coordinators will refer patients to their healthcare provider for any treatment-related questions.

gMG=generalized myasthenia gravis.

Helpful websites



ucbONWARD.com

- ✓ Provides benefits investigation
- ✓ Offers PA appeal/claim support
- ✓ Explore the possibility of home infusion administration



RYSTIGGO.com/infusion-finder

- ✓ Find an ASOC (eg, physician office infusion suite, hospital outpatient department, or independent infusion center) based on your patient's preferred treatment location

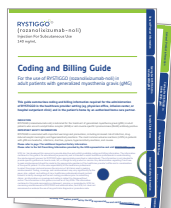


RYSTIGGO.com/infusion-sign-up

- ✓ Register to become an alternate site of care (ASOC)

Additional resources to help your patients access RYSTIGGO

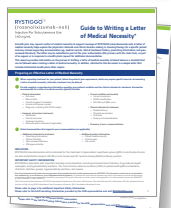
Visit RYSTIGGOhcp.com to access these helpful resources



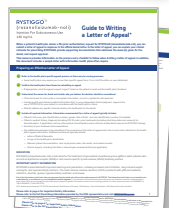
Coding and Billing Guide for the Use of RYSTIGGO



Prior Authorization/ Predetermination Checklist



Guide to Writing a Letter of Medical Necessity



Guide to Writing a Letter of Appeal



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

PA=prior authorization.

Please refer to page 20 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

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

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.rystiggohcp.com).

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

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

References: 1. RYSTIGGO [prescribing information]. Smyrna, GA: UCB, Inc. 2. Centers for Medicare & Medicaid Services. ICD-10-CM tabular list of diseases 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 27, 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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