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

Prior Authorization/ Predetermination Checklist

Your patient's health plan may require a prior authorization (PA) before RYSTIGGO (rozanolixizumab-noli) coverage can be approved. A common reason for coverage denial is incomplete or missing information on the request form. Contact the individual payer for requirements and clinical coverage guidelines for RYSTIGGO, if available. This checklist is provided as an educational resource regarding common PA requirements for RYSTIGGO.

1 Diagnosis Code[1,*]

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

*These diagnosis codes are informational and not intended to be directive or a guarantee of reimbursement. They include potential codes for the FDA-approved indication for RYSTIGGO. Please consult the most recent version of the ICD-10-CM for a full list of myasthenia gravis codes.

2 Clinical Information

Provide relevant supporting documentation, including chart notes and lab tests.

MGFA Clinical Classification†: _____ Date of latest assessment: _____

MGFA Clinical Classification at onset: _____ Date of initial assessment: _____

MG-ADL score: _____ Date of assessment: _____

Comorbidities: _____

Serological and electrophysiologic testing

AChR antibody test: ☐ Positive ☐ Negative ☐ Not known MuSK antibody test: ☐ Positive ☐ Negative ☐ Not known

☐ Repetitive nerve stimulation test (result): _____ Date of assessment: _____

☐ Single fiber electromyography test (result): _____ Date of assessment: _____

†RYSTIGGO was studied in adult patients ranging from MGFA Clinical Classification II to IVa.[2]

3 Medication History[3,4]

Document medication history for treatment of myasthenia gravis, including treatment category, therapy name, duration of treatment, reason for discontinuation, if applicable (eg, inadequate response, intolerance), and associated contraindications, if applicable.

Treatment category	Drug/therapy name(s)	Treatment duration	Reason for discontinuation	Associated contraindications
☐ FcRn receptor antagonists (eg, efgartigimod)				
☐ Monoclonal antibodies (eg, eculizumab, ravulizumab, rituximab)				
☐ Oral corticosteroids (eg, prednisone)				
☐ AChE inhibitors (eg, pyridostigmine)				
☐ Non-steroidal ISTs (eg, azathioprine, cyclosporine)				
☐ Other immunomodulatory therapy (eg, IVIg, PLEX, SCIg)				

AChE=acetylcholinesterase; AChR=acetylcholine receptor; FcRn=neonatal Fc receptor; FDA=Food and Drug Administration; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; IST=immunosuppressive therapy; IVIg=intravenous immunoglobulin; MG-ADL=Myasthenia Gravis Activities of Daily Living; MGFA=Myasthenia Gravis Foundation of America; MuSK=muscle-specific tyrosine kinase; PLEX=plasma exchange; SCIg=subcutaneous immunoglobulin.

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 the next page for additional 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

Prior Authorization/ Predetermination Checklist (cont'd)

4 Prescribed Dose Options[2,*]

- ☐ 420 mg once weekly for 6 weeks (body weight <50 kg)
- ☐ 560 mg once weekly for 6 weeks (body weight ≥50 kg to <100 kg)
- ☐ 840 mg once weekly for 6 weeks (body weight ≥100 kg)

*Provide clinical rationale if prescribed dose is different from body weight recommendations.

5 Reauthorization

If the patient has already been approved for RYSTIGGO under this plan, document the following:

☐ Change in MGFA Clinical Classification: _____ ☐ Change in MG-ADL score: _____

MG-ADL=Myasthenia Gravis Activities of Daily Living; MGFA=Myasthenia Gravis Foundation of America.

ucb RRE Rare Reimbursement Executive

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

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Infections: RYSTIGGO may increase the risk of infection. Delay RYSTIGGO administration in patients with an active infection until the infection is resolved. During treatment with RYSTIGGO, monitor for clinical signs and symptoms of infection. If serious infection occurs, administer appropriate treatment and consider withholding RYSTIGGO until the infection has resolved.

Immunization

Immunization with vaccines during RYSTIGGO treatment has not been studied. The safety of immunization with live or live-attenuated vaccines and the response to immunization with any vaccine are unknown. Because RYSTIGGO causes a reduction in IgG levels, vaccination with live-attenuated or live vaccines is not recommended during treatment with RYSTIGGO. Evaluate the need to administer age-appropriate vaccines according to immunization guidelines before initiation of a new treatment cycle with RYSTIGGO.

Aseptic Meningitis: Serious adverse reactions of aseptic meningitis (also called drug-induced aseptic meningitis) have been reported in patients treated with RYSTIGGO. If symptoms consistent with aseptic meningitis develop, diagnostic workup and treatment should be initiated according to the standard of care.

Hypersensitivity Reactions: Hypersensitivity reactions, including angioedema and rash, were observed in patients treated with RYSTIGGO. Management of hypersensitivity reactions depends on the type and severity of the reaction. Monitor patients during treatment with RYSTIGGO and for 15 minutes after for clinical signs and symptoms of hypersensitivity reactions. If a reaction occurs, institute appropriate measures if needed.

ADVERSE REACTIONS

In a placebo-controlled study, the most common adverse reactions (reported in at least 10% of RYSTIGGO-treated patients) were headache, infections, diarrhea, pyrexia, hypersensitivity reactions, and nausea. Serious infections were reported in 4% of patients treated with RYSTIGGO. Three fatal cases of pneumonia were identified, caused by COVID-19 infection in two patients and an unknown pathogen in one patient. Six cases of infections led to discontinuation of RYSTIGGO.

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

For more information about RYSTIGGO, visit RYSTIGGOhcp.com.

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

References: 1. Centers for Medicare & Medicaid Services. ICD-10-CM tabular list of diseases and injuries. Updated April 1, 2024. Accessed June 28, 2024. https://www.cms.gov/medicare/coding-billing/icd-10-codes/2024-icd-10-cm. **2.** RYSTIGGO [prescribing information]. Smyrna, GA: UCB, Inc. **3.** Farmakidis C, Pasnoor M, Dimachkie MM, Barohn RJ. Treatment of myasthenia gravis. *Neurol Clin*. 2018;36(2):311-337. **4.** Menon D, Bril V. Pharmacotherapy of generalized myasthenia gravis with special emphasis on newer biologicals. *Drugs*. 2022;82(8):865-887.

US-RZ-2400228 | July 2024