

## Medical Policy: Rystiggo (rozanolixizumab-noli) subcutaneous injection

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.390	January 8, 2024	July 28, 2023

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EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

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## Definitions

Rystiggo 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.

## Length of Authorization

Coverage will be provided for 6 months initially and may be renewed. Continuation approval duration is 1 year.

## Dosing Limits [Medical Benefit]

- (Less than 50 kg) 420 mg (3 mL) as a subQ infusion up to 20 mL/hour using an infusion pump once weekly for 6 weeks; administer subsequent treatment cycles 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
- (50 kg to less than 100 kg) 560 mg (4 mL) as a subQ infusion up to 20 mL/hour using an infusion pump once weekly for 6 weeks; administer subsequent treatment cycles 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

- (100 kg or greater) 840 mg (6 mL) as a subQ infusion up to 20 mL/hour using an infusion pump once weekly for 6 weeks; administer subsequent treatment cycles 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
- Max Units (per dose and over time) [HCPCS Unit]:
  - 840 mg weekly for 6 doses per 63 days

## Guideline

### INITIAL CRITERIA

#### 1. **Myasthenia Gravis**

- A. Patient is  $\geq 18$  years of age; **AND**
- B. Patient has confirmed anti-acetylcholine receptor antibody positive generalized myasthenia gravis **OR** anti-muscle-specific tyrosine kinase (MuSK) antibody positive myasthenia gravis; **AND**
- C. Treatment cycles are no more frequent than 63 days from the start of the previous treatment cycle; **AND**
- D. Patient meets both of the following (i and ii):
  - i. Myasthenia Gravis Foundation of America classification of II to IV; **AND**
  - ii. Myasthenia Gravis Activities of Daily Living (MG-ADL) score of  $\geq 3$  for non-ocular symptoms; **AND**
- E. Patient meets **ONE** of the following (i or ii):
  - i. Patient received or is currently receiving pyridostigmine; **OR**
  - ii. Patient has had inadequate efficacy, contraindication, or significant intolerance to pyridostigmine; **AND**
- F. Patient has evidence of unresolved symptoms of generalized myasthenia gravis,  
*Note: Examples of unresolved symptoms include: difficulty swallowing, difficulty breathing or a functional disability resulting in the discontinuation of physical activity (e.g, double vision, talking, impairment of mobility); **AND***
- G. The medication is prescribed by, or in consultation with, a neurologist

### RENEWAL CRITERIA

#### 1. **Myasthenia Gravis**

- A. Patient is continuing to derive benefit from Rystiggo, according to the prescriber  
*Note: Examples of derived benefit include reductions in exacerbations of myasthenia gravis; improvements in speech, swallowing, mobility, and respiratory function*

### Limitations/Exclusions:

1. Concomitant Use with Another Neonatal Fc Receptor Blocker, a Complement Inhibitor, or a Rituximab Product.

*Note: Examples of neonatal Fc receptor blockers are Vyvgart (efgartigimod alfa-fcab intravenous infusion) and Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc subcutaneous injection).*

*Note: Examples of complement inhibitors are Soliris (eculizumab intravenous infusion), Ultomiris (ravulizumab-cwvz intravenous infusion or subcutaneous injection), and Zilbrysq (zilucoplan subcutaneous injection).*

## Applicable Procedure Codes

Code	Description
J9333	Injection, rozanolixizumab-noli, 1 mg

## Applicable NDCs

Code	Description
50474-0980-79	Rystiggo 140mg/mL 2mL

## ICD-10 Diagnoses

Code	Description
G70	Myasthenia gravis and other myoneural disorders
G70.0	Myasthenia gravis
G70.00	Myasthenia gravis without (acute) exacerbation
G70.01	Myasthenia gravis with (acute) exacerbation

## Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	1/8/2024	Annual Review: Updated dosing limits. Initial Criteria: Myasthenia Gravis Updated Myasthenia Gravis Activities of Daily Living (MG-ADL) score of from > 5 to “3 for non-ocular symptoms;” Removed references to corticosteroids in current or prior therapy. Added Renewal criteria and limitations and exclusions; updated J code to J9333
EmblemHealth & ConnectiCare	07/28/2023	New Policy

## References

1. Product Information: RYSTIGGO® subcutaneous injection, rozanolixizumab-noli subcutaneous injection. UCB Inc (per FDA), Smyrna, GA, 2023.