Medical Policy:

Rystiggo (rozanolixizumab-noli) subcutaneous injection

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.390	February 19, 2025	July 28, 2023

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

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.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

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

I. INITIAL CRITERIA

1. **Myasthenia Gravis**
    A. Patient is ≥ 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 ≥ 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

II. 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/2mL

50474-0981-83	Rystiggo 420mg/3mL
50474-0982-84	Rystiggo 560mg/4mL
50474-0983-86	Rystiggo 840mg/6mL

ICD-10 Diagnoses

Code	Description
G70.00	Myasthenia gravis without (acute) exacerbation
G70.01	Myasthenia gravis with (acute) exacerbation
G70.2	Congenital and developmental myasthenia

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	2/19/2025	Annual Review: No Criteria changes. Added G70.02.
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.