Rystiggo (rozanolixizumab-noli)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Rystiggo (rozanolixizumab-noli) policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

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.

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

A. For initial requests: Chart notes, medical records, or claims history documenting:
    a. Positive anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody test
    b. Myasthenia Gravis Foundation of America (MGFA) clinical classification
    c. MG activities of daily living score (MG-ADL)
    d. Use of an acetylcholinesterase (AChE) inhibitor, steroid, non-steroidal immunosuppressive therapy (NSIST), and/or intravenous immunoglobulin (IVIG) where applicable
    e. Prior chronic treatment with plasmapheresis or plasma exchange (if applicable)

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B. For continuation requests: Chart notes or medical record documentation supporting positive clinical response

Criteria for Initial Approval

Generalized myasthenia gravis (gMG)

Authorization of 6 months may be granted for treatment of generalized myasthenia gravis (gMG) when all of the following criteria are met:

A. Member is anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive
B. Member has Myasthenia Gravis Foundation of America (MGFA) clinical classification II to IV
C. Member has a MG activities of daily living (MG-ADL) total score of 5 or more
D. Member had an inadequate response with two or more conventional therapies (e.g., pyridostigmine, corticosteroids, immunosuppressant such as azathioprine, cyclosporine, mycophenolate, etc.) OR member required chronic treatment with plasmapheresis, plasma exchange (PE) or intravenous immunoglobulin (IVIG) in addition to immunosuppressant therapy
E. Member is on a stable dose of at least one of the following:
    a. Acetylcholinesterase inhibitors (e.g., pyridostigmine)
    b. Steroids (at least 1 month of treatment)
    c. Nonsteroidal immunosuppressive therapy (NSIST) (at least 6 months of treatment) (e.g., azathioprine, mycophenolate mofetil)

Continuation of Therapy

Generalized myasthenia gravis (gMG)

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when there is no evidence of unacceptable toxicity or disease progression while on the current regimen and member demonstrates a positive response to therapy (e.g., improvement in MG-ADL score, changes compared to baseline in Quantitative Myasthenia Gravis [QMG] total score).

Rystiggo (rozanolixizumab-noli) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J9333 – injection, rozanolixizumab-noli, 1 mg (effective 1/1/24)

REFERENCES

- Rystiggo [package insert]. Smyrna, GA: UCB, Inc.; June 2024.
- Sanders D, Wolfe G, Benatar M et al. International consensus guidance for management of myasthenia gravis. *Neurology*. 2021; 96 (3) 114-122.
- Bril V, Drużdż A, Grosskreutz J, et al. Safety and efficacy of rozanolixizumab in patients with generalised myasthenia gravis (MycarinG): a randomised, double-blind, placebo-controlled, adaptive phase 3 study. Lancet Neurol. 2023;22(5):383-394.

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POLICY HISTORY

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