Draft Revised Policy: Do Not Implement

Rozanolixizumab-noli (Rystiggo®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
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.

All other indications are considered experimental/investigational and not medically necessary.

II. 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:
   1. Positive anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody test
   2. Myasthenia Gravis Foundation of America (MGFA) clinical classification ~~of myasthenia gravis score~~
   3. MG activities of daily living score
   4. Previous medications tried, including response to therapy. If therapy is not advisable, documentation of clinical reasons to avoid therapy.
   5. ~~Use of an acetylcholinesterase (AChE) inhibitor, steroid, or non-steroidal immunosuppressive therapy (NSIST)~~

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

III. EXCLUSIONS

The requested medication will not be used in combination with another neonatal Fc receptor blocker (e.g., Vyvgart, Vyvgart Hytrulo) or complement inhibitor (e.g., Soliris, Ultomiris, Zilbrysq).

IV. 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. Anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive
B. Myasthenia Gravis Foundation of America (MGFA) clinical classification II to IV~~a~~
~~C.~~ MG activities of daily living (MG-ADL) total score of greater than or equal to 5 ~~3 or more with at least 3 points from non-ocular symptoms~~
D. Meets ~~On a stable dose of at least~~ one of the following:
    1. Member has had an inadequate response or intolerable adverse event to at least two immunosuppressive therapies over the course of at least 12 months (e.g., azathioprine, corticosteroids, cyclosporine, methotrexate, mycophenolate, tacrolimus)
    2. Member has had an inadequate response or intolerable adverse event to at least one immunosuppressive therapy and intravenous immunoglobulin (IVIG) over the course of at least 12 months
    3. Member has a documented clinical reason to avoid therapy with immunosuppressive agents and IVIG

~~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)~~

V. CONTINUATION OF THERAPY

Authorization of 12 ~~6~~ 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, MG Manual Muscle Test (MMT), MG composite) ~~changes compared to baseline in Quantitative Myasthenia Gravis (QMG) total score~~).

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Rystiggo [package insert]. Smyrna, GA: UCB, Inc.; June 2023.
2. Sanders D, Wolfe G, Benatar M et al. International consensus guidance for management of myasthenia gravis. *Neurology*. 2021; 96 (3) 114-122.

3. 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.
4. Barnett C, Herbelin L, Dimachkie MM, Barohn RJ. Measuring Clinical Treatment Response in Myasthenia Gravis. Neurol Clin. 2018 May;36(2):339-353.

EFFECTIVE DATE

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