AETNA BETTER HEALTH® Coverage Policy/Guideline			
Name:	Rystiggo (rozanolixizumab)	Page:	1 of 2
Effective Date:	12/26/2023	Last Review Date:	08/11/2023
Applies to:	☒Illinois ☒Maryland ☐Michigan	☐Florida ☒Florida Kids ☒ Virginia	☐New Jersey ☒Pennsylvania Kids ☒Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Rystiggo under the patient's prescription drug benefit.

Description:

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.

Applicable Drug List:

Rystiggo

Policy/Guideline:

Criteria for Initial Approval:

I. 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. Clinical classification of myasthenia gravis score
3. MG activities of daily living score
4. Use of an acetylcholinesterase (AChE) inhibitor, steroid, or non-steroidal immunosuppressive therapy (NSIST)

II. Generalized myasthenia gravis (gMG)

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

1. Anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive
2. Myasthenia Gravis Foundation of America (MGFA) clinical classification II to IVa
3. MG activities of daily living (MG-ADL) total score of 3 or more with at least 3 points from non-ocular symptoms

4. 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)

Criteria for Continuation of Therapy

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

A. For continuation requests chart notes, medical records, or claims history documenting:

1. Chart notes or medical record documentation supporting positive clinical response.

II. Authorization may be granted for continuation of treatment in members requesting reauthorization when the following criteria are met:

1. The member has no evidence of unacceptable toxicity or disease progression while on the current regimen
2. The 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).

Approval Duration and Quantity Restrictions:

Initial and Renewal Approval: 6 months

Quantity Level Limit: Reference Formulary for drug specific quantity level limits

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.