Mass General Brigham
Health Plan

Rystiggo (rozanolixizumab-noli)
Effective 12/01/2023

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693 **Non-Specialty Medications** All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview
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.

Coverage Guidelines
Authorization may be granted for members new to Mass General Brigham Health Plan who are currently receiving treatment with the requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members meeting ALL the following criteria:

1. Member has a diagnosis of generalized myasthenia gravis (MG) with ONE of the following:
    a. Positive anti-acetylcholine receptor (AChR) antibody test
    b. Positive anti-muscle-specific tyrosine kinase (MuSK) antibody test
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. 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
Authorization may be granted for members for continued treatment when there is no evidence of unacceptable toxicity or disease progression 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).

Limitations

1. Initial approvals and reauthorizations will be granted for 6 months

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.

Review History

10/11/2023 - Reviewed at Sept P&T, Effective 12/1/2023