CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Rystiggo (rozanolixizumab-noli)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Rystiggo is a neonatal Fc receptor blocker indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or antimuscle-specific tyrosine kinase (MuSK) antibody positive. Approval was based on the Phase 3 MycarinG study. It is the second FcRn antagonist to be approved; the first was Vyvgart, however, Vyvgart is not approved for the MuSK population.
Myasthenia gravis is an autoimmune disorder affecting the neuromuscular junction, characterized by muscle weakness and fatigue. The cause is an antibody-mediated immunologic attack directed at proteins in the postsynaptic membrane of the neuromuscular junction, most commonly the acetylcholine receptor (90%). Autoantibodies attack the AChR, blocking or destroying the receptors and damaging the neuromuscular junction, which impairs neuromuscular transmission and prevents muscles from contracting, as acetylcholine is unable to activate its receptor. Ocular motility, swallowing, speech, mobility, and respiratory function can all be affected.
Pyridostigmine, an acetylcholinesterase inhibitor, is the initial drug of choice prescribed for MG. It eases symptoms by slowing the breakdown of acetylcholine. If control is inadequate, immunosuppressive treatment is added, such as prednisone and/or azathioprine. Other drugs are used in cases of severe or refractory MG or myasthenic crisis, which is an emergency.

Rystiggo (rozanolixizumab-noli) will be considered for coverage when the following criteria are met:

Myasthenia Gravis

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Member has a documented diagnosis of MGFA class II-IV myasthenia gravis (see appendix); AND
4. Lab result in chart notes shows the member is seropositive for AChR or MuSK antibodies; AND
5. Member has tried and failed at least 1 conventional therapy:
   A. pyridostigmine
   B. corticosteroid for at least 3 months
   C. non-steroid immunosuppressant (e.g., azathioprine) for at least 6 months.
6. **Dosage allowed/Quantity limit:**
   Subcutaneous infusion once weekly for 6 weeks as 1 cycle of treatment; subsequent treatment cycles are based on clinical evaluation and must be at least 63 days apart.

Body Weight of Patient	Dose	Volume to be Infused
Less than 50 kg	420 mg	3 mL
50 kg to less than 100 kg	560 mg	4 mL
100 kg and above	840 mg	6 mL

QL: 18 vials per 42 days

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must document clinically meaningful improvement in symptom severity and daily functioning compared to pre-treatment baseline (e.g., improved MG-ADL or QMG scores); AND
2. Treatment cycles are being prescribed at least 63 days apart.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Rystiggo (rozanolixizumab-noli) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
07/05/2023	New policy for Rystiggo created.

Appendix:

MG Foundation of America (MGFA) Clinical Classification	
Class I	any ocular weakness; all other muscle strength is normal
Class II	mild weakness affecting other than ocular muscles; may also have ocular weakness at any level
Class III	moderate weakness affecting other than ocular muscles; may also have ocular weakness at any level
Class IV	severe weakness affecting other than ocular muscles; may also have ocular weakness at any level
Class V	defined by intubation, with or without mechanical ventilation

References:

1. Rystiggo [prescribing information]. UCB Inc.; 2023.
2. Narayanaswami P, Sanders DB, Wolfe G, et al. International Consensus Guidance for Management of Myasthenia Gravis: 2020 Update. Neurology. 2021;96(3):114-122. doi:10.1212/WNL.0000000000011124
3. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis: Executive summary. Neurology. 2016;87(4):419-425. doi:10.1212/WNL.0000000000002790
4. Alhaidar MK, Abumurad S, Soliven B, Rezania K. Current Treatment of Myasthenia Gravis. *J Clin Med*. 2022;11(6):1597. Published 2022 Mar 14. doi:10.3390/jcm11061597
5. 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. doi:10.1016/S1474-4422(23)00077-7

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