

**rozanolixizumab-noli (Rystiggo)****Medical Benefit Drug Policy****Place of Service**

Home Infusion Administration  
Infusion Center Administration  
Office Administration  
Outpatient Facility Administration

**Drug Details****USP Category:** ANTIMYASTHENIC AGENTS**Mechanism of Action:** Neonatal Fc receptor blocker**HCPCS:**

J9333:Injection, rozanolixizumab-noli, 1 mg

**How Supplied:**

280 mg/2 mL (140 mg/mL) single-dose vial

**Condition(s) listed in policy** *(see coverage criteria for details)*

- Generalized Myasthenia Gravis

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

**Special Instructions and Pertinent Information**

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

**Coverage Criteria****The following condition(s) require Prior Authorization/Preservice.****Generalized Myasthenia Gravis****Meets medical necessity if all the following are met:****Initial authorization:**

1. Prescribed by or in consultation with a neurologist
2. One of the following:
  - a. Patient has a positive serological test or Anti-AChR, and patient had an inadequate response, intolerable side effect, or contraindication to preferred product (e.g. Vyvgart or Vyvgart Hytrulo)
  - b. Patient has a positive serological test for Anti-MUSK

3. If anti-AChR-positive, patient is on at least one treatment for gMG (e.g., acetylcholinesterase inhibitors, corticosteroids, or non-steroidal immunosuppressive therapies)
4. Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV
5. Myasthenia Gravis - Activities of Daily Living (MG-ADL) total score  $\geq 3$

Reauthorization:

1. Patient's continued response to therapy as shown by ONE of the following (a or b):
  - a. Improvement of at least 2 points (reduction in score) in MG-ADL total score
  - b. Reduction in signs and symptoms of myasthenia gravis

**Covered Doses:**

Less than 50 kg: 420 mg given subcutaneously once weekly for 6 weeks

50 kg to less than 100 kg: 560 mg given subcutaneously once weekly for 6 weeks

100 kg and above: 840 mg given subcutaneously once weekly for 6 weeks

**Coverage Period:**

Initial: 1 treatment course (Consist of 6 weeks) given as often as every 63 days from the previous treatment course for 6 months

Reauthorization: Yearly

**ICD-10:**

G70.00, G70.01

**References**

1. AHFS. Available by subscription at <http://www.lexi.com>
2. DrugDex. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
3. Rystiggo (rozanolixizumab-noli). Prescribing information. UCB, Inc.; Smyrna, GA. 6/2023.

**Review History**

Date of Last Annual Review: 4Q2024

Changes from previous policy version:

- Generalized Myasthenia Gravis: Clarified that MG-ADL score required is 3 or more

*Blue Shield of California Medication Policy to Determine Medical Necessity  
Reviewed by P&T Committee*