## rozanolixizumab-noli (Rystiggo)

## Commercial 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 Health and Safety Code section 1367.21 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.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct)** may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

**CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION**

*MCG Care Guidelines, 19th edition, 2015*

ADMINISTRATION OF THIS DRUG IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted)*

1. Patient is initiating their first 2 doses of Rystiggo or is being re-initiated on Rystiggo after at least 6 months off therapy. *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

**OR**

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. Patient has experienced a previous severe adverse event on Rystiggo based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on Rystiggo based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
4. Patient is clinically unstable based on documentation submitted.
5. Patient is physically or cognitively unstable based on documentation submitted.

**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 ≥ 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*