

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 starting new therapy with this drug (allowed for 2 doses). Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.
2. Patient is being re-initiated on this drug after being off therapy for at least 6 months (allowed for 2 doses). Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.
3. Additional clinical monitoring is required during administration as evidenced by one of the following:
 - a. Patient has experienced a previous severe adverse event on this drug based on documentation submitted.
 - b. Patient continues to experience moderate to severe adverse events on this drug based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
 - c. Patient is clinically unstable based on documentation submitted.
 - d. 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

1. Prescribed by or in consultation with a neurologist
2. Meets one of the following:
 - a. Patient has a positive serological test for Anti-AChR, and BOTH of the following:
 - i. Patient is on at least one treatment for gMG (e.g. acetylcholinesterase inhibitors, corticosteroids, or non-steroid immunosuppressive therapies)
 - ii. Patient had an inadequate response, intolerable side effect, or contraindication to one preferred product (e.g. Vyvgart, Vyvgart Hytrulo, or Epysqli)
 - b. Patient has a positive serological test for Anti-MuSK
3. Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV
4. 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

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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

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) [prescribing information]. Smyrna, GA: UCB Inc; December 2025.

Review History

Date of Last Annual Review: 1Q2026

Changes from previous policy version:

- Clarify prerequisite therapy requirement to include biosimilar Epysqli for AChR positive generalized myasthenia gravis. Rationale: More cost-effective therapeutic alternatives available

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