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

1. Prescribed by or in consultation with a neurologist
2. Patient is on at least one treatment for gMG (e.g. acetylcholinesterase inhibitors, corticosteroids, or non-steroid immunosuppressive therapies)
3. Patient had an inadequate response, intolerable side effect, or contraindication to one preferred product (e.g. Vyvgart, Vyvgart Hytrulo, BKEMV or Epysqli)
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

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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:

G70.0, G70.00, G70.01

References

1. Rystiggo (rozanolixizumab-noli) [Prescribing Information]. Smyrna, GA: UCB, Inc.; December 2025.

Review History

Date of Last Annual Review: 1Q2026
Changes from previous policy version:

- Replace Coverage for Generalized Myasthenia Gravis (gMG):
  - Remove requirement of anti-AChR and anti-MuSK serotypes for gMG
  - Clarify prerequisite therapy requirement to include first-line treatments for gMG. *Rationale: Rystiggo pivotal trial*

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