



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 per 1 mg

How Supplied:

NDC: 50474-980-79: 280 mg/2 mL (140 mg/mL) single-dose vial

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

- Generalized myasthenia gravis

The following condition(s) require Prior Authorization/Preservice:

Generalized myasthenia gravis

1. Prescribed by or in consultation with a neurologist, AND
2. Positive serological test for anti-AChR or anti-MuSK antibodies, AND
3. If anti-AChR-positive, patient is on at least one treatment for gMG (e.g., acetylcholinesterase inhibitors, corticosteroids, or non-steroidal immunosuppressive therapies), AND
4. Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV, AND
5. Myasthenia Gravis - Activities of Daily Living (MG-ADL) total score > 3

Covered Doses:

Less than 50 kg: 420 mg given as a subcutaneous infusion once weekly for 6 weeks

50 kg to less than 100 kg: 560 mg given as a subcutaneous infusion once weekly for 6 weeks

100 kg and above: 840 mg given as a subcutaneous infusion once weekly for 6 weeks

Coverage Period:

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

Reauthorization: Yearly, based upon patient's continued response to therapy as shown by one of the following:

1. Improvement of at least 2 points (reduction in score) in MG-ADL total score, OR

2. Reduction in signs and symptoms of myasthenia gravis

Additional Information

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]. Smyrna, GA: UCB, Inc.; 6/2023.

Review History

Date of Last Annual Review: 4Q2023

Date of last revision: 2/28/2024

Changes from previous policy version:

- Generalized myasthenia gravis: Clarified reauthorization requirement to include clinical response (i.e., MG-ADL total score, signs and symptoms). *Rationale: Published literature supports MG-ADL score to assess clinical treatment response in myasthenia gravis.*

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