

Rozanolixizumab-noli

(Rystiggo®) J9333 (1 mg)

Covered with prior authorization

Initial Requests

Requests for Rystiggo (Rozanolixizumab-noli) may be approved if the following criteria are met:

- Individual is 18 years of age or older; **AND**
- Individual has a diagnosis of generalized myasthenia gravis (gMG) confirmed by positive Anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibodies; **AND**
- Individual has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IVa disease; **AND**
- Individual has a Myasthenia Gravis Activities of Daily Living (MG-ADL) score of at least 3 or higher; **AND**
- Individual is currently on a stable dose, or has had a trial and inadequate response, intolerance or contraindication to an acetylcholinesterase inhibitor; **AND**
- Individual is currently on a stable dose, or has had a trial and inadequate response, intolerance or contraindication to one or more immunosuppressive agents (including but not limited to systemic corticosteroids or nonsteroidal immunosuppressants).

Continuation of therapy requests may be approved if the following criteria are met:

- Individual has experienced a prior clinical response to rozanolixizumab-noli treatment as defined by the following:
 - Reduction in signs or symptoms that impact daily function; **AND**
 - Documentation is provided of at least a 2-point reduction in MG-ADL total score from pre-treatment baseline; **AND**
- Individual requires continued treatment to maintain response or to regain clinically meaningful response.

Exclusion criteria:

- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.
- Individuals with significant known risk factors unless the record provides an assessment of clinical benefit that outweighs the risk.
- Individual is using in combination with maintenance immunoglobulin treatment, eculizumab, efgartigimod-alfa, nipocalimab, ravulizumab, rituximab, or zilucoplan.

Initial Approval Duration: 26 weeks

Continuation Approval Duration: 1 year

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:

RYSTIGGO (rozanolixizumab-noli) is a neonatal Fc receptor blocker indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or antimuscle-specific tyrosine kinase (MuSK) antibody positive

References:

1. Bril V, Druzdź A, Grosskreutz J, et al. Safety and efficacy of rozanolixizumab in patients with generalised myasthenia gravis (MycarinG): A randomised, double-blind, placebo-controlled, adaptive phase 3 study. *Lancet Neurol.* 2023;22(5):383-394.
2. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2026; Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: February 6, 2026.

Criteria History/ Revision Information:

Date	Summary of Changes
April 2024	Criteria for use summary developed by Ascension Medical Specialty Prior Authorization Team
May 2024	Criteria for use summary approved by the Ascension Medication Specialty Prior Authorization Expert Review Panel.
July 2024	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.
February 2026	Criteria for use summary developed by Ascension Medical Specialty Prior Authorization Team
March 2026	Criteria for use summary approved by the Ascension Medication Specialty Prior Authorization Expert Review Panel.
May 2026	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call [833-980-2352](tel:833-980-2352) to speak to a member of the Ascension Rx prior authorization team.