



# Pharmacy Drug Policy & Procedure

<b>Policy Name:</b>	<b>Rystiggo (rozanolixizumab)</b>	<b>Policy#:</b>	<b>3194P</b>
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## Purpose of the Policy

The purpose of this policy is to define coverage criteria for Rystiggo (rozanolixizumab)

## Statement of the Policy

Health Alliance Medical Plans will approve the use of Rystiggo (rozanolixizumab) under the medical benefit if the following criteria are met.

## Criteria

### 1. Coverage Criteria

- 1.1 Diagnosis of generalized myasthenia gravis with positive blood genetic test for anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibodies
- 1.2 Documentation to support a Myasthenia Gravis Foundation of America Clinical Classification of II, III, or IV at the start of therapy
- 1.3 Documentation to support a Myasthenia Gravis-Activities of Daily Living Score (MG-ADL) score greater than or equal to 3
- 1.4 Documentation to support a quantitative myasthenia gravis (QMG) score greater than or equal to 11
- 1.5 Age 18 years or older
- 1.6 Prescribed by or in consultation with a neurologist (nervous system doctor) or physician that specializes in treatment of generalized myasthenia gravis
- 1.7 Trial and failure, intolerance or contraindication to standard of care therapies (such as pyridostigmine, mycophenolate, etc)
- 1.8 For patients with anti-acetylcholine receptor (AChR) antibodies; previous trial and failure, intolerance or contraindication to at least one treatment cycle of Vyvgart
- 1.9 Review of chart notes documenting diagnosis and confirming that the patient has met all of the above requirements for treatment with Rystiggo by both a pharmacist and medical director

### 2. Exclusion Criteria

- 2.1 Rystiggo will not be covered in addition to Vyvgart, Soliris or Ultomiris

### 3. Approval Period

- 3.1 Initial: one 6 week cycle over 12 months
- 3.2 Reauthorization: one 6 week cycle over 12 months with documentation to support improvement in MG-ADL score
  - Maximum 5 treatment cycles per year

## CPT Codes

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## HCPCS Codes

J9333

Injection, rozanolixizumab-noli, 1 mg

## References

1. Rystiggo (rozanolixizumab) [prescribing information]. Smyrna, GA: UCB Inc; July 2023.
2. Bril V, Drużdż 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 May;22(5):383-394.
3. Verschuuren J. New therapies for autoimmune myasthenia gravis. *Lancet Neurol.* 2023 May;22(5):368-369.
4. Narayanaswami P, Sanders DB, Wolfe G, et al. International Consensus Guidance for Management of Myasthenia Gravis: 2020 Update. *Neurology.* 2021 Jan 19;96(3):114-122.
5. Sacca F, Barnett C, Vu T, et al. Efgartigimod improved health-related quality of life in generalized myasthenia gravis: results from a randomized, double-blind, placebo-controlled, phase 3 study (ADAPT). *J Neurol.* 2023 Apr;270(4):2096-2105.

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