

Policy Name:	Rystiggo (rozanolixizumab)	Policy#:	3194P
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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 and Health Alliance Northwest 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

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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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