# Pharmacy Drug Policy & Procedure

| Policy Name: | Zilbrysq (zilucoplan) | Policy#: | 3259P |
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## Purpose of the Policy

The purpose of this policy is to define coverage criteria for Zilbrysq (zilucoplan)

## Statement of the Policy

Health Alliance Medical Plans will approve the use of Zilbrysq (zilucoplan) under the specialty pharmacy benefit if the following criteria are met.

## Criteria

**1. Coverage Criteria**

1.1 Diagnosis of generalized myasthenia gravis (gMG) as supported by both of the following:
- Myasthenia Gravis Foundation of America (MGFA) clinical classification of II to IV
- Myasthenia Gravis-Activities of Daily Living Score (MG-ADL) score ≥6

1.2 Documented positive serological test for anti-acetylcholine (AchR) antibodies

1.3 Age 18 years or older

1.4 Prescribed by or in consultation with a neurologist (nervous system doctor) or physician that specializes in treatment of generalized myasthenia gravis

1.5 Documentation of meningococcal vaccine series OR will receive vaccine at least 2 weeks prior to first dose (unless treatment cannot be delayed)

1.6 Lab cultures rule out any unresolved serious *Nesseria meningitidis* infection, if patient was diagnosed with *N. meningitidis* infection recently

1.7 Documented trial and failure, intolerance or contraindication to conventional therapies (i.e. pyridostigmine, immunosuppressant therapies)

1.8 Documented trial and failure, intolerance, or contraindication to Ultomiris, or documented barriers to Ultomiris access that impede treatment (such as unmanageable distance from treatment location or inability to schedule treatments, etc)

1.9 Review of chart notes documenting diagnosis and confirming that the patient has met all of the above requirements for treatment with Zilbrysq by both a pharmacist and medical director

**2. Exclusion Criteria**

2.1 Zilbrysq will not be covered in addition to any other biologics indicated for myasthenia gravis

2.2 Patients with unresolved *Neisseria meningitidis* infection or who are not vaccinated against *Neisseria meningitidis*

**3. Managed Dose Limit**

3.1 Dose limit based on package size to allow one syringe daily

3.2 Dosing more frequently than once per day is not supported

**4. Approval Period**

4.1 Initial: 12 months

4.2 Reauthorization: 12 months with documentation to support improvement in MG-ADL score

| CPT Codes | |
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| **HCPCS Codes** | |
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## References


1. Zilbrysq (zilucoplan) [prescribing information]. Smyrna, GA: UCB Inc; April 2024.
2. Howard JF Jr, Bresch S, Genge A, et al; RAISE Study Team. Safety and efficacy of zilucoplan in patients with generalised myasthenia gravis (RAISE): a randomised, double-blind, placebo-controlled, phase 3 study. Lancet Neurol. 2023;22(5):395-406.
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.



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