

**ZILBRYSQ
(zilucoplan)**

Pre - PA Allowance

None

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Generalized myasthenia gravis (gMG)

AND ALL of the following:

- a. Positive serologic test for anti-AChR antibodies
- b. Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV
- c. Documented baseline MG-Activities of Daily Living (MG-ADL) total score \geq 6
(http://c.peerview.com/inReview/programs/150204324/downloads/PVI_practiceaids_RMU.pdf)
- d. Patient has had an inadequate treatment response, intolerance, or contraindication to an acetylcholinesterase inhibitor and at least **ONE** immunosuppressive therapy either in combination or as monotherapy, such as:
 - i. azathioprine
 - ii. cyclosporine
 - iii. mycophenolate mofetil
 - iv. tacrolimus
 - v. methotrexate
 - vi. cyclophosphamide
- e. **NO** dual therapy with another Prior Authorization (PA) C5 complement inhibitor for gMG (see Appendix 1)
- f. Vaccination against Neisseria meningitidis at least 2 weeks prior to initiation [unless Zilbrysq (zilucoplan) treatment cannot be delayed]
- g. Prescriber is enrolled in Zilbrysq REMS program

Prior - Approval Limits

Duration 6 months

**ZILBRYSQ
(zilucoplan)**

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Generalized myasthenia gravis (gMG)

AND ALL of the following:

- a. Decrease of MG-ADL total score from baseline of ≥ 2 points
(http://c.peerview.com/inReview/programs/150204324/downloads/PVI_practiceaids_RMU.pdf)
- b. **NO** dual therapy with another Prior Authorization (PA) C5 complement inhibitor for gMG (see Appendix 1)
- c. Absence of unacceptable toxicity from the drug
- d. Prescriber is enrolled in Zilbrysq REMS program

Prior - Approval *Renewal* Limits

Duration 12 months

Appendix 1 - List of PA C5 complement inhibitors for gMG

Generic Name	Brand Name
eculizumab	Soliris
ravulizumab-cwvz	Ultomiris
zilucoplan	Zilbrysq