# Commercial PA Criteria

***Effective: February 8, 2024***

***Prior Authorization:*** Zilbrysq (zilucoplan)

***Products Affected:*** Zilbrysq (zilucoplan) subcutaneous injection

***Medication Description:*** ZILBRYSQ is indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive. Zilucoplan binds to the complement protein C5 and inhibits its cleavage to C5a and C5b, preventing the generation of the terminal complement complex, C5b-9. The precise mechanism by which zilucoplan exerts its therapeutic effect in generalized myasthenic gravis is unknown but is presumed to involve reduction of C5b-9 deposition at the neuromuscular junction**.**

***Covered Uses:***

1. Generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive

***Exclusion Criteria:***

1. Unresolved Neisseria meningitidis infection
2. Concomitant Use with Another Complement Inhibitor, a Neonatal Fc Receptor Blocker, or a Rituximab Product. There is no evidence to support concomitant use of Zilbrysq with another complement inhibitor, a neonatal Fc receptor blocker, or a rituximab product.
   *Note: Examples of complement inhibitors are Soliris (eculizumab intravenous infusion) and Ultomiris (ravulizumab-cwvz intravenous infusion or subcutaneous injection).*
   *Note: Examples of Neonatal Fc receptor blockers are Rystiggo [rozanolixizumab-noli subcutaneous infusion) Vyvgart (efgartigimod alfa-fcab intravenous infusion), and Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc subcutaneous injection).*

***Required Medical Information:***

1. Diagnosis
2. Previous Therapies Tried and Failed

***Prescriber Restriction:*** The medication is being prescribed by, or in consultation with, a neurologist.

***Age Restriction***: 18 years of age or older

***Coverage Duration:***

Initial: 3 months
Continuation: 12 months

***Other Criteria:***

**Initial Approval Criteria**

**1. Generalized Myasthenia Gravis.**

A. Patient has confirmed anti-acetylcholine receptor antibody-positive generalized myasthenia gravis; **AND**



Confidential Information

This document is confidential and proprietary to ConnectiCare. Unauthorized use and distribution are prohibited.

B. Patient meets both of the following (i and ii):
   i. Myasthenia Gravis Foundation of America classification of II to IV; **AND**
   ii. Myasthenia Gravis Activities of Daily Living (MG-ADL) score of ≥ 6; **AND**

C. Patient meets one of the following (i or ii):
   i. Patient received or is currently receiving pyridostigmine; **OR**
   ii. Patient has had inadequate efficacy, a contraindication, or significant intolerance to pyridostigmine; **AND**

D. Patient meets one of the following (i or ii):
   i. Patient received or is currently receiving two different immunosuppressant therapies for ≥ 1 year; **OR**
   ii. Patient had inadequate efficacy, a contraindication, or significant intolerance to two different immunosuppressant therapies; **AND**
   *Note: Examples of immunosuppressant therapies tried include azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus, and cyclophosphamide.*

E. Patient has evidence of unresolved symptoms of generalized myasthenia gravis; **AND**
   *Note: Evidence of unresolved symptoms of generalized myasthenia gravis includes difficulty swallowing, difficulty breathing, and a functional disability resulting in the discontinuation of physical activity (e.g., double vision, talking, impairment of mobility).*

**Renewal Criteria**

**1. Generalized Myasthenia Gravis.**

A. Patient is continuing to derive benefit from Zilbrysq, according to the prescriber

*Note: Examples of derived benefit include reductions in exacerbations of myasthenia gravis; improvements in speech, swallowing, mobility, and respiratory function*

***References:***

1. Product Information: ZILBRYSQ® subcutaneous injection, zilucoplan subcutaneous injection. UCB Inc (per FDA), Smyrna, GA, 2023.

***Policy Revision history***

| Rev # | Type of Change | Summary of Change | Sections Affected | Date |
|---|---|---|---|---|
| 1 | New Policy | New Policy | All | 02/08/2024 |



Confidential Information

This document is confidential and proprietary to ConnectiCare. Unauthorized use and distribution are prohibited.