UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2323-3
Program	Prior Authorization/Medical Necessity
Medication	Zilbrysq® (zilucoplan)
P&T Approval Date	1/2024, 1/2025, 9/2025
Effective Date	12/1/2025

1. Background

Zilbrysq (zilucoplan) is a complement inhibitor indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are antiacetylcholine receptor (AChR) antibody positive.

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Zilbrysq** will be approved based on **all** of the following criteria:

   a. Submission of medical records (e.g., chart notes, laboratory values, etc.) confirming **all** of the following:

      (1) Diagnosis of generalized myasthenia gravis (gMG)

      -AND-

      (2) Positive serologic test for anti-AChR antibodies

      -AND-

      (3) Patient has a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of class II, III, or IV at initiation of therapy

      -AND-

      (4) Patient has a Myasthenia Gravis Activities of Daily Living scale (MG-ADL) total score ≥ 6 at initiation of therapy

      -AND-

   b. **One** of the following:

      (1) History of failure of at least two immunosuppressive agents over the course of at least 12 months (e.g., azathioprine, corticosteroids, cyclosporine, methotrexate, mycophenolate, etc.)
      (2) Patient has a history of failure of at least one immunosuppressive therapy and has required four or more courses of plasmapheresis/ plasma exchanges and/or intravenous immune globulin over the course of at least 12 months without symptom control

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-AND-

c. **One** of the following:

(1) Patient has a history of failure to **one** FcRn blocker [e.g., Imaavy (nipocalimab), Vyvgart (efgartigimod alfa), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase)]
(2) Patient has an intolerance or contraindication to **all** FcRn blockers [i.e., Imaavy (nipocalimab), Rystiggo (rozanolixizumab), Vyvgart (efgartigimod alfa), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase)]

-AND-

d. Patient is not receiving **Zilbrysq** in combination with another complement inhibitor [e.g., Soliris (eculizumab), Ultomiris (ravulizumab-cwvz)] or an FcRn blocker [e.g., Imaavy (nipocalimab), Vyvgart (efgartigimod alfa), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase)]

-AND-

e. Prescribed by, or in consultation with, a neurologist

Authorization will be issued for 12 months.

B. Reauthorization

1. **Zilbrysq** will be approved based on **all** of the following criteria:

a. Submission of medical records (e.g., chart notes, laboratory tests) demonstrating **all** of the following:

(1) Improvement and/or maintenance of at least a 2-point improvement (reduction in score) in the MG-ADL score from pre-treatment baseline
(2) Reduction in signs and symptoms of myasthenia gravis
(3) Maintenance, reduction, or discontinuation of dose(s) of baseline immunosuppressive therapy (IST) prior to starting **Zilbrysq**
Note: Add on, dose escalation of IST, or additional rescue therapy from baseline to treat myasthenia gravis or exacerbation of symptoms while on **Zilbrysq** therapy will be considered as treatment failure

-AND-

b. Patient is not receiving **Zilbrysq** in combination with another complement inhibitor [e.g., Soliris (eculizumab), Ultomiris (ravulizumab)] or an FcRn blocker [e.g., Imaavy (nipocalimab), Vyvgart (efgartigimod alfa), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase)]

-AND-

c. Prescribed by, or in consultation with, a neurologist

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Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4. References:

1. Zilbrysq [package insert], Smyrna, GA: UCB, Inc.; April 2024.
2. Howard JF Jr, Bresch S, Genge A, et al. 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. doi:10.1016/S1474-4422(23)00080-7
3. Narayanaswami P, Sanders DB, Wolfe G, et al. International Consensus Guidance for Management of Myasthenia Gravis: 2020 Update. Neurology. 2021;96(3):114-122. doi:10.1212/WNL.0000000000011124
4. Barnett C, Herbelin L, Dimachkie MM, Barohn RJ. Measuring Clinical Treatment Response in Myasthenia Gravis. Neurol Clin. 2018;36(2):339-353. doi:10.1016/j.ncl.2018.01.006

Program	Prior Authorization/Medical Necessity - Zilbrysq® (zilucoplan)
Change Control	
1/2024	New program.
1/2025	Annual review. Updated listing of examples of complement inhibitors and neonatal Fc receptor blockers without change to clinical intent. Updated references.
9/2025	Addition of criteria requiring a trial and failure, intolerance, or contraindication to an FcRn blocker. Updated list of FcRn blocker examples.

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