

UnitedHealthcare Pharmacy Clinical Pharmacy Programs

Program Number	2025 P 1428-2
Program	Prior Authorization/Notification
Medication	Zilbrysq [®] (zilucoplan)
P&T Approval Date	1/2024, 1/2025
Effective Date	4/1/2025

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.¹

2. Coverage Criteria^a:

A. Initial Authorization

- 1. **Zilbrysq** will be approved based on <u>all</u> of the following criteria:
 - a. Diagnosis of generalized myasthenia gravis (gMG)

-AND-

b. Positive serologic test for anti-AChR antibodies

-AND-

c. Patient is not receiving Zilbrysq in combination with another complement inhibitor [e.g., Soliris (eculizumab), Ultomiris (ravulizumab-cwvz)] or a neonatal Fc receptor blocker [e.g., Rystiggo (rozanolixizumab-noli), Vyvgart (efgartigimod alfa-fcab), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)]

Authorization will be issued for 12 months.

B. Reauthorization

- 1. **Zilbrysq** will be approved based on **both** of the following criteria:
 - a. Documentation of positive clinical response to Zilbrysq therapy

-AND-

b. Patient is not receiving Zilbrysq in combination with another complement inhibitor [e.g., Soliris (eculizumab), Ultomiris (ravulizumab-cwvz)] or a neonatal Fc receptor blocker [e.g., Rystiggo (rozanolixizumab-noli), Vyvgart (efgartigimod alfa-fcab), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)]

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 also be in place.

4. References:

1. Zilbrysq [package insert], Smyrna, GA: UCB, Inc.; April 2024.

Program	Prior Authorization/Notification - 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 reference.