Generic Name: zilucoplan

Applicable Drugs: Zilbrysq®

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/14/2025

Date Last Reviewed / Revised: 2/14/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met)

I. Documented diagnosis of one of the following conditions AND must meet ALL criteria listed:
   a. Generalized Myasthenia Gravis (gMG)
      i. MGFA clinical classification class II, III, or IV.
      ii. Documentation of a serologic test confirming the presence of acetylcholine receptor antibodies (AchR-Ab+).
      iii. Baseline Myasthenia Gravis-specific Activities of Daily Living scale (MG-ADL) total score of ≥ 6. See Other Criteria for MG-ADL scale criteria.
      iv. Member has documented treatment failure, intolerance, or contraindication to **both** of the following (1 and 2):
         1. Corticosteroids (at least 3 months of treatment)
         2. Nonsteroidal immunosuppressive therapy (at least one agent for at least 3 months of treatment) (e.g. azathioprine, cyclosporine, methotrexate, mycophenolate, etc.)

II. Patient is 18 years of age or older.

III. Treatment must be prescribed by or in consultation with a neurologist.

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- MGFA class I
- Active infection or sepsis
- Untreated hepatitis B, hepatitis C, or HIV with low CD4 count

- Coadministration with other immunomodulatory biologic therapies (e.g. rituximab, eculizumab, efgartigimod, rozanolixizumab, etc.)
- Pregnancy

OTHER CRITERIA

- Meningococcal vaccination should be completed or updated at least 2 weeks prior to administering the first dose of Zilbrysq®.
- MG-ADL Scoring Template:

Grade	0	1	2	3	Score
Talking	Normal	Intermittent slurring or nasal speech	Constant slurring or nasal, but can be understood	Difficult to understand speech	
Chewing	Normal	Fatigue with solid food	Fatigue with soft food	Gastric tube	
Swallowing	Normal	Rare episode of choking	Frequent choking necessitating changes in diet	Gastric tube	
Breathing	Normal	Shortness of breath with exertion	Shortness of breath at rest	Ventilator dependence	
Impairment of ability to brush teeth or comb hair	None	Extra effort, but no rest periods needed	Rest periods needed	Cannot do one of these functions	
Impairment of ability to arise from a chair	None	Mild, sometimes uses arms	Moderate, always uses arms	Severe, requires assistance	
Double vision	None	Occurs, but not daily	Daily, but not constant	Constant	
Eyelid droop	None	Occurs, but not daily	Daily, but not constant	Constant	
				Total Score:	

Wolfe GI, Herbelin L, Nations SP, Foster B, Bryan WW, Barohn RJ. Neurology 1999;52(7):1487-9

QUANTITY / DAYS SUPPLY RESTRICTIONS

- 28 single-dose prefilled syringes per 28 days

APPROVAL LENGTH

- **Authorization:** 6 months
- **Re-Authorization:** 6 months, with an updated letter of medical necessity or progress notes showing clinically significant improvement or maintenance with treatment and that the patient is adherent to treatment and the medication is tolerated. Clinical improvement or

maintenance may be demonstrated by a ≥ 2-point reduction in MG-ADL score from baseline or by physician attestation that patient is continuing to derive benefit from treatment (as evidenced by reductions in exacerbations, improvements in speech, swallowing, mobility, or respiratory function, etc.)

APPENDIX

N/A

REFERENCES

1. Zilbrysq. Prescribing Information. UCB; April 2024, Accessed August 19, 2024. https://www.ucb-usa.com/zilbrysq-prescribing-information.pdf
2. Howard JF, 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. *The Lancet Neurology*. 2023;22(5):395-406. doi:https://doi.org/10.1016/S1474-4422(23)00080-7
3. Safety, Tolerability, and Efficacy of Zilucoplan in Subjects With Generalized Myasthenia Gravis (RAISE). Clinicaltrials.gov. Published 2024. Accessed August 8, 2024. https://clinicaltrials.gov/study/NCT04115293?intr=Zilucoplan&viewType=Table&limit=10&aggFilters=phase:3