AETNA BETTER HEALTH® Coverage Policy/Guideline			
Name:	Zilbrysq (zilucoplan)	Page:	1 of 2
Effective Date:	4/25/2024	Last Review Date:	03/26/2024
Applies to:	☐Illinois ☒Maryland ☐Michigan	☐Florida ☒Florida Kids ☒ Virginia	☒New Jersey ☒Pennsylvania Kids ☒Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Zilbrysq under the patient's prescription drug benefit.

Description:

FDA-Approved Indication
Zilbrysq is indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Zilbrysq

Policy/Guideline:

Documentation
Submission of the following information is necessary to initiate the prior authorization review:

A. For initial requests chart notes, medical records, or claims history documenting:
   1. Positive anti-acetylcholine receptor (AChR) antibody test
   2. Clinical classification of myasthenia gravis score
   3. MG activities of daily living score
   4. Previous medications tried, including response to therapy. If therapy is not advisable, documentation of clinical reasons to avoid therapy.
B. For continuation requests: Chart notes or medical record documentation supporting positive clinical response

Criteria for Initial Approval

Generalized myasthenia gravis (gMG)
Authorization may be granted for the treatment of generalized myasthenia gravis (gMG) when ALL the following criteria are met:

1. Anti-acetylcholine receptor (AChR) antibody positive
2. Myasthenia Gravis Foundation of America (MGFA) clinical classification II to IV
3. MG activities of daily living (MG-ADL) total score ≥6
4. Meets ONE of the following:
   a. Member has had an inadequate response or intolerable adverse event to at least two immunosuppressive therapies over the course of at least 12 months

(e.g., azathioprine, corticosteroids, cyclosporine, methotrexate, mycophenolate, tacrolimus)

b. Member has had an inadequate response or intolerable adverse event to at least one immunosuppressive therapy and intravenous immunoglobulin (IVIG) over the course of at least 12 months
c. Member has a documented clinical reason to avoid therapy with immunosuppressive agents and IVIG

Criteria for Continuation of Therapy

Authorization may be granted for continued treatment in members requesting reauthorization when there is no evidence of unacceptable toxicity or disease progression while on the current regimen and member demonstrates a positive response to therapy (e.g., improvement in MG-ADL score, MG Manual Muscle Test (MMT), MG Composite).

Approval Duration and Quantity Restrictions:

Initial Approval: 6 months
Renewal Approval: 12 Months

Quantity Level Limit:

Medication	Standard Limit	FDA-recommended dosing
Zilbrysq (zilucoplan) 16.6 mg/0.416 mL single-dose prefilled syringes.	28 single-dose prefilled syringes per 28 days	The recommended dosage is given once daily as a subcutaneous injection and is dependent on actual body weight: ○ Less than 56 kg: 16.6 mg ○ 56 kg to less than 77 kg: 23 mg ○ 77 kg and above: 32.4 mg

References:

1. Zilbrysq [package insert]. Smyrna, GA: UCB, Inc.; October 2023.
2. Sanders D, Wolfe G, Benatar M et al. International consensus guidance for management of myasthenia gravis. *Neurology*. 2021; 96 (3) 114-122.
3. Howard JF, 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.
4. Barnett C, Herbelin L, Dimachkie MM, Barohn RJ. Measuring Clinical Treatment Response in Myasthenia Gravis. Neurol Clin. 2018 May;36(2):339-353.