

DRUG POLICY

Zilbrysq® (zilucoplan)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

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

POLICY

Required Documentation

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

1. For initial requests: chart notes, medical records, or claims history documenting
 - A. Positive anti-acetylcholine receptor (AChR) antibody test
 - B. Clinical classification of myasthenia gravis score
 - C. MG activities of daily living score
 - D. Previous use of intravenous immunoglobulin (if applicable), immunosuppressive therapies, prior chronic treatment with plasmapheresis or plasma exchange (if applicable)
2. For continuation requests: chart notes, medical record documentation supporting positive clinical response

Criteria for Initial Approval

Generalized myasthenia gravis (gMG)

Authorization of 6 months may be granted for treatment of generalized myasthenia gravis (gMG) when all of 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. Member has failed treatment over at least one year with at least two immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate, tacrolimus, methotrexate, cyclophosphamide, rituximab), OR member has failed at least one immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG)
5. Member has a documented inadequate response to Rystiggo, Vyvgart, Vyvgart Hytrulo, eculizumab, or Ultomiris
6. Member will not use concomitantly with eculizumab, Ultomiris, Rystiggo, Vyvgart, Vyvgart Hytrulo, Intravenous Immune Globulin, and Rituximab for the same indication

Continuation of Therapy

Generalized myasthenia gravis (gMG)

Authorization of 12 months 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, changes compared to baseline in Quantitative Myasthenia Gravis [QMG] total score).

Other

Zilbrysq (zilucoplan) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Non-Formulary Exception Criteria

Non-Formulary Exception criteria applies to formularies which do not include the requested product(s) on the formulary drug list. Meeting the criteria above may satisfy some, or all, portions of the Non-Formulary Exception Criteria. A medication that is non-formulary may be covered when the Criteria for Approval AND the following criteria are met:

1. The requested drug must be used for an FDA-approved indication, or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines). Diagnostic testing/lab results required when applicable.
2. The prescribed dose/quantity must fall within the FDA-approved labeling or dosing guidelines found in the compendia of current literature.
3. All covered formulary alternative drugs on any tier will be ineffective, have been ineffective, would not be as effective as the non-formulary drug, or would have adverse effects. Documentation is required and must include chart note(s) or other documentation indicating prior treatment failure, severity of the adverse event (if any), and dosage and duration of the prior treatment, or contraindication to formulary alternatives.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits Apply

Medication	Standard Limit	FDA Recommended Dosing
Zilbrysq (zilucoplan) 16.6 mg/0.416 mL Prefilled Syringe	1 syringe per day	Administer dose subcutaneously according to actual body weight once daily: • <56 kg: 16.6 mg subcutaneously once daily
Zilbrysq (zilucoplan)	1 syringe per day	

23 mg/0.574 mL Prefilled Syringe		• ≥56 to <77 kg: 23 mg subcutaneously once daily • ≥77 kg: 32.4 mg subcutaneously once daily
Zilbrysq (zilucoplan) 32.4 mg/0.81 mL Prefilled Syringe	1 syringe per day	

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

REFERENCES

Zilbrysq [package insert]. Smyrna, GA: UCB, Inc.; October 2023.

Sanders D, Wolfe G, Benatar M et al. International consensus guidance for management of myasthenia gravis. *Neurology*. 2021; 96 (3) 114-122.

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.

Barnett C, Herbelin L, Dimachkie MM, Barohn RJ. Measuring Clinical Treatment Response in Myasthenia Gravis. *Neurol Clin*. 2018 May;36(2):339-353.

POLICY HISTORY

Policy #: 05.05.37

Original Effective Date: June 2, 2024

Reviewed: October 2025

Revised: October 2025

Current Effective Date: January 1, 2026