POLICY Document for
RYSTIGGO (rozanolixizumab-noli)

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, and overall, clinically appropriate use. This document provides specific information to both sections of the overall policy.

Section 1: Preferred Product
- Policy information specific to preferred medications

Section 2: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 1: Preferred Product

CAREFIRST: EXCEPTIONS CRITERIA
COMPLEMENT INHIBITORS

PREFERRED PRODUCTS: ULTOMIRIS, VYVGART, VYVGART HYTRULO

Client Requested: The intent of the criteria is to ensure that patients follow selection elements as established by CareFirst.

POLICY
This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the Complement inhibitor products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment with a targeted product.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Complement Inhibitor Products

	Product(s)
Preferred*	• **Ultomiris** (ravulizumab-cwvz) • **Vyvgart** (efgartigimod alfa) • **Vyvgart** Hytrulo (efgartigimod alfa and hyaluronidase)
Targeted	• **Empaveli** (pegcetacoplan) • **Enspryng** (atralizumab-mwge)

	• **Piasky** (crovalimab) • **Rystiggo** (rozanolixizumab) • **Soliris** (eculizumab) • **Uplizna** (inebilizumab-cdon)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

II. EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.

For Myasthenia Gravis, coverage for the targeted product is provided when member has a documented inadequate response, contraindication, or intolerable adverse event to all the preferred products.

For all other indications, coverage for the targeted product is provided when member has a documented inadequate response, contraindication, or intolerable adverse event to Ultomiris.

Section 2: Clinical Criteria

SPECIALTY GUIDELINE MANAGEMENT

RYSTIGGO (rozanolixizumab-noli)

POLICY

I. INDICATIONS

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

FDA-Approved Indication
Rystiggo is indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.

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

II. 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) or anti-muscle-specific tyrosine kinase (MuSK) antibody test
   2. Myasthenia Gravis Foundation of America (MGFA) clinical classification
   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.

III. EXCLUSIONS

The requested medication will not be used in combination with another neonatal Fc receptor blocker (e.g., Vyvgart, Vyvgart Hytrulo) or complement inhibitor (e.g., Soliris, Ultomiris, Zilbrysq).

IV. 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:

A. Anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive
B. Myasthenia Gravis Foundation of America (MGFA) clinical classification II to IV
C. MG activities of daily living (MG-ADL) total score of greater than or equal to 5
D. Meets one of the following:
    1. 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)
    2. 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
    3. Member has a documented clinical reason to avoid therapy with immunosuppressive agents and IVIG

V. CONTINUATION OF THERAPY

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, MG Manual Muscle Test (MMT), MG Composite).

REFERENCES:

SECTION 1

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2. Enspryng [package insert]. San Francisco, CA: Genentech, Inc.; March 2022.
3. Piasky [package insert]. South San Francisco, CA: Genetech Inc; June 2024.
4. Rystiggo [package insert]. Smyrna, GA: UCB, Inc; June 2023.
5. Soliris [package insert]. Boston, MA: Alexion Pharmaceuticals Inc; September 2024.
6. Ultomiris [package insert]. Boston, MA: Alexion Pharmaceuticals Inc; September 2024.
7. Uplinza [package insert]. Deerfield, IL: Horizon Therapeutics; July 2021.
8. Vyvgart [package insert]. Boston, MA: argenx US, Inc; August 2024
9. Vyvgart Hytrulo [package insert]. Boston, MA: argenx US, Inc; August 2024

SECTION 2

1. Rystiggo [package insert]. Smyrna, GA: UCB, Inc.; June 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. Bril V, Drużdż A, Grosskreutz J, et al. Safety and efficacy of rozanolixizumab in patients with generalised myasthenia gravis (MycarinG): a randomised, double-blind, placebo-controlled, adaptive phase 3 study. Lancet Neurol. 2023;22(5):383-394.
4. Barnett C, Herbelin L, Dimachkie MM, Barohn RJ. Measuring Clinical Treatment Response in Myasthenia Gravis. Neurol Clin. 2018 May;36(2):339-353.