POLICY Document for ENSPRYNG (satralizumab-mwge)

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

ENSPRYNG (satralizumab-mwge)

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
Enspryng is indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) 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: Immunoassay used to confirm anti-aquaporin-4 (AQP4) antibody is present.
B. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

III. CRITERIA FOR INITIAL APPROVAL

Neuromyelitis optica spectrum disorder (NMOSD)
Authorization of 12 months may be granted for treatment of neuromyelitis optica spectrum disorder (NMOSD) when all of the following criteria are met:

A. Anti-aquaporin-4 (AQPR) antibody positive.
B. Member exhibits one of the following core clinical characteristics of NMOSD:
    1. Optic neuritis
    2. Acute myelitis
    3. Area postrema syndrome (episode of otherwise unexplained hiccups or nausea and vomiting)
    4. Acute brainstem syndrome
    5. Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic

magnetic resonance imaging (MRI) lesions
6. Symptomatic cerebral syndrome with NMOSD-typical brain lesions

C. The member will not receive the requested drug concomitantly with other biologics for the treatment of NMOSD.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when all of the following criteria are met:

A. The member demonstrates a positive response to therapy (e.g., reduction in number of relapses).
B. The member will not receive the requested drug concomitantly with other biologics for the treatment of NMOSD.

REFERENCES:

SECTION 1

1. Empaveli [package insert]. Waltham, MA: Apellis Pharmaceuticals, Inc; February 2024.
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. Enspryng [package insert]. South San Francisco, CA: Genentech, Inc.; March 2022.
2. Wingerchuk DM, Banwell B, Bennett JL, et al. International consensus diagnostic criteria for neuromyelitis optica spectrum disorders. Neurology. 2015; 85:177-189.