POLICY Document for VYVGART (efgartigimod alfa)

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

CAREFIRST: VYVGART

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

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

Initial criteria:

- Age 18 years of age and older
  AND
- The patient must have myasthenia gravis
  AND
- Positive serologic test for anti-AChR antibodies
  AND
- Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV
  AND
- Documented baseline MG-Activities of Daily Living (MG-ADL) total score ≥ 5 with at least 50% of the score due to non-ocular symptoms (https://solirisgmg.com/Content/solirisgmg_com/assets/pdf/MG_ADL_Assessment.pdf)
  AND
- Patient has had an inadequate treatment response, intolerance, or contraindication to an
- acetylcholinesterase inhibitor and at least ONE immunosuppressive therapy either in combination or as monotherapy, such as:
  - azathioprine
  - cyclosporine
  - mycophenolate mofetil
  - tacrolimus
  - methotrexate
  - cyclophosphamide

  AND
- Prescriber agrees that the patient will be monitored during administration and for one hour after for clinical signs and symptoms of hypersensitivity reactions
  AND
- Absence of active infection (e.g., urinary tract infection or respiratory tract infection)
  AND
- NOT given concurrently with live vaccines
  AND
- IgG levels of at least 6g/L

Continuation criteria:

- Age 18 years of age and older
  AND
- The patient must have myasthenia gravis
  AND
- Decrease of (MG-ADL) total score from pre-treatment baseline of at least 2 points in MG- ADL total score (https://solirisgmg.com/Content/solirisgmg_com/assets/pdf/MG_ADL_Assessment.pdf)
  AND
- At least 49 days have passed since the start of the previous treatment cycle
  AND
- Prescriber agrees that the patient will be monitored during administration and for one hour after for clinical signs and symptoms of hypersensitivity reactions
  AND
- Absence of active infection (e.g., urinary tract infection or respiratory tract infection)
  AND
- NOT given concurrently with live vaccines
  AND
- Dosing Limits: 12 vials per 28 days

Efgartigimod alfa-fcab may be considered investigational in patients less than 18 years of age and for all other indications.

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