

## Medical Policy:

### Vyvgart (efgartigimod alfa-fcab) intravenous infusion and Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase- human recombinant injection, solution

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.349	August 8, 2023	February 10, 2022

#### Medical Guideline Disclaimer Property of EmblemHealth. All rights reserved.

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

## Definitions

Vyvgart, a neonatal Fc receptor blocker, is indicated for the treatment of generalized myasthenia gravis (MG) in adult patients who are anti-acetylcholine receptor antibody positive.

## Length of Authorization

Coverage will be provided for 6 months initially and may be renewed. Continuation approval duration is 1 year.

## Dosing Limits [Medical Benefit]

### Vyvgart:

- **Patient < 120 kg:** The recommended dosage is 10 mg/kg administered by intravenous infusion once weekly for 4 weeks, then no more frequently than once every 50 days.
- **Patient ≥ 120 kg:** The recommended dose is 1200 mg administered by intravenous infusion once weekly for 4 weeks, then no more frequently than once every 50 days.

## Vyvgart Hytrulo:

- The recommended dosage of Vyvgart Hytrulo is 1,008 mg / 11,200 units (1,008 mg efgartigimod alfa and 11,200 units hyaluronidase) administered subcutaneously over approximately 30 to 90 seconds in cycles of once weekly injections for 4 weeks.

## Guideline

### I. INITIAL APPROVAL CRITERIA

- Generalized Myasthenia Gravis.** Approve for 6 months if the patient meets the following criteria (A, B, C, and D)
  - Patient is  $\geq 18$  years of age; **AND**
  - Patient has confirmed anti-acetylcholine receptor antibody positive generalized myasthenia gravis; **AND**
  - Treatment cycles are no more frequent than every 50 days from the start of the previous treatment cycle; **AND**
  - Patient meets both of the following (i and ii):
    - Myasthenia Gravis Foundation of America classification of II to IV; **AND**
    - Myasthenia Gravis Activities of Daily Living (MG-ADL) score of  $\geq 5$ ; **AND**
  - Patient meets one of the following (i or ii):
    - Patient received or is currently receiving pyridostigmine; **OR**
    - Patient has had inadequate efficacy, a contraindication, or significant intolerance to pyridostigmine; **AND**
  - Patient has evidence of unresolved symptoms of generalized myasthenia gravis, such as difficulty swallowing, difficulty breathing, or a functional disability resulting in the discontinuation of physical activity (e.g., double vision, talking, impairment of mobility).
  - The medication is being prescribed by or in consultation with a neurologist.

### II. RENEWAL CRITERIA

Approve for 1 year if the patient meets the following:

- Member has responded positively to the treatment as determined by the prescribing physician; **AND**
- Member has not experienced unacceptable toxicity from the drug.

### Limitations/Exclusions:

None

## Applicable Procedure Codes

Code	Description
J9332	Injection, efgartigimod alfa-fcab, 2mg
J9334	Injection, efgartigimod alfa, 2 mg and hyaluronidase-qvfc
J3590	unclassified biologics

## Applicable NDCs

Code	Description
73475-3041-05	Vyvgart 400MG/20ML Solution
73475-3102-xx	Vyvgart Hytrulo 1,008 mg efgartigimod alfa and 11,200 units hyaluronidase per 5.6 mL (180 mg/2,000 units per mL) single-dose vial

## ICD-10 Diagnoses

Code	Description
G70	Myasthenia gravis and other myoneural disorders
G70.0	Myasthenia gravis
G70.00	Myasthenia gravis without (acute) exacerbation
G70.01	Myasthenia gravis with (acute) exacerbation

## Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	8/8/2023	Addition of Vyvgart Hytrulo (and J code 1/5/2024)
EmblemHealth & ConnectiCare	5/2/2023	<p>Annual Review:</p> <p>Under Initial Criteria for Myasthenia Gravis:</p> <p>Removed the following “Patient meets one of the following (i or ii):</p> <ul style="list-style-type: none"> <li>i. Patient received or is currently receiving two different immunosuppressant therapies for <math>\geq 1</math> year; OR</li> <li>ii. Patient had inadequate efficacy, a contraindication, or significant intolerance to two different immunosuppressant therapies; AND</li> </ul> <p>Note: Examples of immunosuppressant therapies tried include azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus, and cyclophosphamide.”</p> <p>Added the following: “Patient is <math>\geq 18</math> years of age; AND “Treatment cycles are no more frequent than every 50 days from the start of the previous treatment cycle; AND</p> <p>Patient meets both of the following (i and ii):</p> <ul style="list-style-type: none"> <li>i Myasthenia Gravis Foundation of America classification of II to IV; AND</li> <li>ii Myasthenia Gravis Activities of Daily Living (MG-ADL) score of <math>\geq 5</math>; AND” “The medication is being prescribed by or in consultation with a neurologist.”</li> </ul>
EmblemHealth & ConnectiCare	1/18/2023	Transfer to New Template, removed unclassified codes (J3590 and C9399) and added J9332
EmblemHealth & ConnectiCare	2/10/2022	New Policy

## References

1. Vyvgart® intravenous infusion [prescribing information]. Boston, MA: Argenx; December 2021.

2. Product Information: VYVGART® HYTRULO subcutaneous injection, efgartigimod alfa hyaluronidase-qvfc subcutaneous injection. Halozyme Therapeutics, Inc (per FDA), San Diego, CA, 2023.