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

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

1. **Generalized Myasthenia Gravis.** Approve for 6 months if the patient meets the following criteria (A, B, C, **and** D)
   A. Patient is ≥ 18 years of age; **AND**
   B. Patient has confirmed anti-acetylcholine receptor antibody positive generalized myasthenia gravis; **AND**
   C. Treatment cycles are no more frequent than every 50 days from the start of the previous treatment cycle; **AND**
   D. Patient meets both of the following (i and ii):
      i. Myasthenia Gravis Foundation of America classification of II to IV; **AND**
      ii. Myasthenia Gravis Activities of Daily Living (MG-ADL) score of ≥ 5; **AND**
   E. Patient meets one of the following (i or ii):
      i. Patient received or is currently receiving pyridostigmine; **OR**
      ii. Patient has had inadequate efficacy, a contraindication, or significant intolerance to pyridostigmine; **AND**
   F. 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).
   G. 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:

1. Member has responded positively to the treatment as determined by the prescribing physician; **AND**
2. 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	Annual Review: Under Initial Criteria for Myasthenia Gravis: Removed the following "Patient meets one of the following (i or ii): i. Patient received or is currently receiving two different immunosuppressant therapies for ≥ 1 year; OR ii. Patient had inadequate efficacy, a contraindication, or significant intolerance to two different immunosuppressant therapies; AND Note: Examples of immunosuppressant therapies tried include azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus, and cyclophosphamide." Added the following: "Patient is ≥ 18 years of age; 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): i Myasthenia Gravis Foundation of America classification of II to IV; AND ii Myasthenia Gravis Activities of Daily Living (MG-ADL) score of ≥ 5; AND" "The medication is being prescribed by or in consultation with a neurologist."
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.