Medical Policy

Vyvgart™ (efgartigimod alfa-fcab)	
MEDICAL POLICY NUMBER	MED_Clin_Ops-106
CURRENT VERSION EFFECTIVE DATE	01/01/2024
APPLICABLE PRODUCT AND MARKET	Individual Family Plan: ALL Small Group: ALL Medicare Advantage: ALL

Brand New Day/Central Health Medicare Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/ Central Health Medicare Plan policy may contact the Health Plan. Brand New Day/Central Health Medicare Plan policies and practices are compliant with federal and state requirements, including mental health parity laws.

If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at http://www.cms.gov *for additional information.*

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PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity for Vyvgart™ (efgartigimod alfa-fcab) therapy.

POLICY

Prior Authorization and Medical Review is required.

Coverage for Vyvgart will be provided for six months and may be renewed.

- Max Units (per dose and over time): 1200 mg weekly for four doses per 50 days

Medical Policy

Initial

A. Patient is 18 years of age or older; **AND**
B. Vyvgart will not be used in combination with other immunomodulatory biologic therapies (i.e., rituximab, eculizumab, etc.); **AND**
C. Patient will avoid or use with caution medications known to worsen or exacerbate symptoms of Myasthenia Gravis (e.g., certain antibiotics, beta-blockers, botulinum toxins, hydroxychloroquine, etc.); **AND**
D. Vyvgart must not be administered with live-attenuated or live vaccines during treatment; **AND**
E. Patient does not have an active infection, including clinically important localized infections; **AND**
F. Patient has a baseline immunoglobulin G (IgG) level of at least 6 g/L (600 mg/dL); **AND**

Generalized Myasthenia Gravis (gMG)

A. Patient has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II to IV disease*; **AND**
B. Patient has a positive serologic test for anti-acetylcholine receptor (AChR) antibodies; **AND**
C. Patient has had a thymectomy (Note: Applicable only to patients with thymomas OR non-thymomatous patients who are 50 years of age or younger); **AND**
D. Physician has assessed objective signs of neurological weakness and fatiguability on a baseline neurological examination (e.g., including, but not limited to, the Quantitative Myasthenia Gravis (QMG) score, etc.); **AND**
E. Patient has a baseline MG-Activities of Daily Living (MG-ADL) total score of at least 5; **AND**
F. Patient had an inadequate response after a minimum one-year trial with two (2) or more immunosuppressive therapies (e.g., corticosteroids plus an immunosuppressant such as azathioprine, cyclosporine, mycophenolate, etc.); **OR**
    a. Patient required chronic treatment with plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG) in addition to immunosuppressant

* Myasthenia Gravis Foundation of America (MGFA) Disease Clinical Classification
Class I: Any ocular muscle weakness; may have weakness of eye closure. All other muscle strength is normal.
Class II: Mild weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity.
- IIa. Predominantly affecting limb, axial muscles, or both. May also have lesser involvement of oropharyngeal muscles.
- IIb. Predominantly affecting oropharyngeal, respiratory muscles, or both. May also have lesser or equal involvement of limb, axial muscles, or both.

Class III: Moderate weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity.
- IIIa. Predominantly affecting limb, axial muscles, or both. May also have lesser involvement of oropharyngeal muscles.
- IIIb. Predominantly affecting oropharyngeal, respiratory muscles, or both. May also have lesser or equal involvement of limb, axial muscles, or both.

Class IV: Severe weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity.

- IVa. Predominantly affecting limb, axial muscles, or both. May also have lesser involvement of oropharyngeal muscles.
- IVb. Predominantly affecting oropharyngeal, respiratory muscles, or both. May also have lesser or equal involvement of limb, axial muscles, or both.

Class V: Defined as intubation, with or without mechanical ventilation, except when employed during routine postoperative management. The use of a feeding tube without intubation places the patient in class IVb.

Renewal

A. Patient continues to meet initial criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc.; **AND**
B. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: infection, severe hypersensitivity reactions, etc.; **AND**
C. Patient has had an improvement (i.e., reduction) of at least 2-points from baseline in the Myasthenia Gravis-Specific Activities of Daily Living scale (MG-ADL) total score sustained for at least 4-weeks**; **AND**
D. Improvement in muscle strength testing with fatigue maneuvers as evidenced on neurologic examination when compared to baseline; **AND**
E. Patient requires continuous treatment, after an initial beneficial response, due to new or worsening disease activity (Note: a minimum of 50 days must have elapsed from the start of the previous treatment cycle)

*(** May substitute an improvement of at least 3-points from baseline in the Quantitative Myasthenia Gravis (QMG) total score sustained for at least 4-weeks, if available)*

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value

DEFINITIONS

A. VYVGART™ (efgartigimod alfa-fcab) injection, for intravenous use. Initial U.S. Approval: 2021
    a. VYVGART (efgartigimod alfa-fcab) injection is a preservative free, sterile, colorless to slightly yellow, clear to slightly opalescent solution supplied as 400 mg/20 mL (20 mg/mL) in one single-dose vial per carton.

CODING

Applicable NDC Codes	
73475-3041-xx	Vyvgart 400 mg/20 mL single-dose vial

Applicable Procedure Code	
J3590	Unclassified biologics

Applicable ICD-10 Codes	
G70.0	Myasthenia gravis
G70.00	Myasthenia gravis without (acute) exacerbation
G70.01	Myasthenia gravis with (acute) exacerbation

EVIDENCE BASED REFERENCES

1. Vyvgart [package insert]. Boston, MA; Argenx, Inc., December 2021. Accessed December 2021.

POLICY HISTORY

Original Effective Date	5/24/2022
Revised Date	March 1, 2023 - Adopted by MA UM Committee (no policy revisions made) January 1, 2024 - Updated to Brand New Day/Central Health Medicare Plan/Central Health Medicare Plan
P&T Committee Endorsement	5/24/2022