Vyvgart™ (efgartigimod alfa-fcab)
(Intravenous)

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I. Length of Authorization

Initial coverage will be provided for 90 days. Coverage may be renewed every 6 months thereafter.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Vyvgart 400 mg/20 mL single-dose vial: 3 vials per week for four doses per 50 days

B. Max Units (per dose and over time) [HCPCS Unit]:

- 600 billable units (1200 mg) weekly for four doses per 50 days

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria [1,3]

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

Generalized Myasthenia Gravis (gMG) † Φ [1,3,4,5,8]

- Patient has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II to IV disease §; **AND**

- Patient has a positive serologic test for anti-acetylcholine receptor (AChR) antibodies; **AND**
- 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**
- 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**
- Patient has a baseline MG-Activities of Daily Living (MG-ADL) total score of at least 5; **AND**
- 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**
    - Patient required chronic treatment with plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG) in addition to immunosuppressant therapy

† FDA approved indication(s); ‡ Compendia recommended indication(s); Φ Orphan Drug

§ Myasthenia Gravis Foundation of America (MGFA) Disease Clinical Classification [5]:

– **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.

IV. Renewal Criteria [1]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include infection, severe hypersensitivity reactions, etc.; **AND**

- 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 Δ; **AND**
- Improvement in muscle strength testing with fatigue maneuvers as evidenced on neurologic examination when compared to baseline; **AND**
- 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)

  (Δ 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)

V. Dosage/Administration [1]

Indication	Dose
Generalized Myasthenia Gravis (gMG)	Administer 10 mg/kg as an intravenous infusion over one hour once weekly for 4 weeks. In patients weighing 120 kg or more, the recommended dose of VYVGART is 1200 mg (3 vials) per infusion. Administer subsequent treatment cycles based on clinical evaluation. The safety of initiating subsequent cycles sooner than 50 days from the start of the previous treatment cycle has not been established.

VI. Billing Code/Availability Information

HCPCS Code:

- J3590 – Unclassified biologics *(Discontinue use on 07/01/2022)*
- J9332 – Injection, efgartigimod alfa-fcab, 2 mg; 1 billable unit = 2 mg *(Effective 07/01/2022)*
- C9399 – Unclassified drugs or biologicals (HOPPS only) *(Discontinue use on 07/01/2022)*

NDC:

- Vyvgart 400 mg/20 mL single-dose vial: 73475-3041-xx

VII. References

1. Vyvgart [package insert]. Boston, MA; Argenx, Inc., December 2021. Accessed December 2021.
2. Sussman J, Farrugia ME, Maddison P, et al. Myasthenia gravis: Association of British Neurologists' management guidelines. Pract Neurol 2015; 15: 199-206.
3. Narayanaswami P, Sanders D, Wolfe G, Benatar M, et al. International consensus guidance for management of myasthenia gravis, 2020 update. Neurology® 2021;96:114-122. doi:10.1212/WNL.0000000000011124.

4. Howard JF Jr, Bril V, Vu T, Karam C, ADAPT Investigator Study Group, et al. Safety, efficacy, and tolerability of efgartigimod in patients with generalised myasthenia gravis (ADAPT): a multicentre, randomised, placebo-controlled, phase 3 trial. Lancet Neurol. 2021 Jul;20(7):526-536. doi: 10.1016/S1474-4422(21)00159-9. Erratum in: Lancet Neurol. 2021 Aug;20(8):e5.
5. Jayam-Trouth A, Dabi A, Solieman N, Kurukumbi M, Kalyanam J. Myasthenia gravis: a review. *Autoimmune Dis*. 2012;2012:874680. doi:10.1155/2012/874680
6. Institute for Clinical and Economic Review. *Eculizumab and Efgartigimod for the Treatment of Myasthenia Gravis: Effectiveness and Value*. Draft evidence report. July 22, 2021. https://icer.org/wp-content/uploads/2021/03/ICER_Myasthenia-Gravis_Draft-Evidence-Report_072221.pdf. Accessed December 22, 2021.
7. Guidon AC, Muppidi S, Nowak RJ, et al. Telemedicine visits in myasthenia gravis: expert guidance and the Myasthenia Gravis Core Exam (MG-CE). Muscle Nerve 2021; 64:270-276
8. Gronseth GS, Barohn R, Narayanaswami P. Practice advisory: Thymectomy for myasthenia gravis (practice parameter update): Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Neurology. 2020;94(16):705. Epub 2020 Mar 25.

Appendix 1 – Covered Diagnosis Codes

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

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs)may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC