

Vyvgart[®] Hytrulo (efgartigimod alfa-fcab and hyaluronidase-qvfc) (Subcutaneous)

Document Number: MH-0712

Last Review Date: 09/05/2023

Date of Origin: 07/05/2023

Dates Reviewed: 07/2023, 09/2023

I. Length of Authorization ¹

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 Hytrulo 1,008 mg/11,200 units (efgartigimod alfa/hyaluronidase) single-dose vial: 1 vial per week for four doses per 50 days

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

- 1,008 mg/11,200 units 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, ravulizumab, pegcetacoplan, satralizumab, inebilizumab, etc.) or with intravenous efgartigimod; **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**
- Will 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 1,3-5,8

- 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**
 - 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.); **OR**
 - 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 6-month trial of concurrent use 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: 5,6

- **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**

VYVGART® HYTRULO (efgartigimod alfa-fcab and hyaluronidase-qvfc)

Prior Auth Criteria

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

©2023, Magellan Rx Management

MagellanRx
MANAGEMENTSM

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: infection, severe hypersensitivity reactions (e.g., rash, angioedema, and dyspnea, etc.), etc.; **AND**
- Patient has had an improvement (i.e., reduction) of at least 1-point from baseline in the Myasthenia Gravis-Specific Activities of Daily Living scale (MG-ADL) total score **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 1-point from baseline in the Quantitative Myasthenia Gravis (QMG) total score, if available)

V. Dosage/Administration ¹

Indication	Dose
Generalized Myasthenia Gravis (gMG)	Administer 1,008 mg / 11,200 units (1,008 mg efgartigimod alfa and 11,200 units hyaluronidase) subcutaneously over approximately 30 to 90 seconds in cycles of once weekly injections for 4 weeks. Vyvgart Hytrulo is to be administered by a healthcare professional only. 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

NDC:

- 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: 73475-3102-xx

VII. References

1. Vyvgart Hytrulo [package insert]. Boston, MA; Argenx US, Inc., June 2023. Accessed August 2023.
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.00000000000011124.
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 June 28, 2023.
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

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
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)
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