MEDICAL MUTUAL®

Drug Policy

Policy:	**CDP-0712**	**Initial Effective Date: 07/05/2023**
Code(s):	**HCPCS J9334**	**Annual Review Date: 11/20/2025**
SUBJECT:	**Vyvgart Hytrulo ® (efgartigimod alfa-fcab and hyaluronidase-qvfc) (Subcutaneous)**	**Last Revised Date: 11/20/2025**

Subject to: ☒Site of Care
☐Medication Sourcing

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

I. Length of Authorization [1]

- CIDP: Initial coverage will be provided for 6 months and may be renewed annually thereafter.
- gMG: Initial coverage will be provided for 90 days. Coverage may be renewed annually thereafter.

II. Dosing Limits

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

- CIDP: 504 billable units weekly
- gMG: 504 billable units weekly for four doses per 50 days

III. Initial Approval Criteria [1]

Submission of supporting clinical documentation (including but not limited to medical records, chart notes, lab results, and confirmatory diagnostics) related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission as part of the evaluation of this request. Please provide documentation related to diagnosis, step therapy, and clinical markers (i.e., genetic, and mutational testing) supporting initiation when applicable. Please provide documentation via direct upload through the PA web portal or by fax. Failure to submit the medical records may result in the denial of the request due to inability to establish medical necessity in accordance with policy guidelines.

Coverage is provided in the following conditions:

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

Universal Criteria [1]

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- 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 does not have a deficiency of immunoglobulin G (IgG) necessitating supplementation with IgG; **AND**

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) [1,9,10]

- Patient's disease course is progressive or relapsing and remitting for >2 months; **AND**
- Patient has decreased or absent deep tendon reflexes in upper or lower limbs; **AND**
- Electrodiagnostic testing indicating demyelination:
  - Partial motor conduction block in at least 2 motor nerves or in 1 nerve plus one other demyelination criterion listed here in at least 1 other nerve; **OR**
  - Distal CMAP duration increase in at least 1 nerve plus one other demyelination criterion listed here in at least 1 other nerve; **OR**
  - Abnormal temporal dispersion conduction must be present in at least 2 motor nerves; **OR**
  - Reduced motor conduction velocity in at least 2 motor nerves; **OR**
  - Prolonged distal motor latency in at least 2 motor nerves; **OR**
  - Absent F wave in at least 2 motor nerves plus one other demyelination criterion listed here in at least 1 other nerve; **OR**
  - Prolonged F wave latency in at least 2 motor nerves; **AND**
- Baseline in strength/weakness has been documented using an objective clinical measuring tool (e.g., INCAT, Medical Research Council (MRC) muscle strength, 6-MWT, Rankin, Modified Rankin, etc.; **AND**
- Patient has tried and failed on at least 3-month trial of immunoglobulin (IG) or plasma exchange therapy; **AND**
- Will not be used as maintenance therapy in combination with immunoglobulin or intravenous efgartigimod

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.); **AND**
- Patient has a baseline MG-Activities of Daily Living (MG-ADL) total score of at least 5; **AND**

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- Patient had an inadequate response after a minimum one-year trial of concurrent use with an oral corticosteroid plus another immunosuppressive therapy (e.g., azathioprine, cyclosporine, mycophenolate, etc.); **OR**
- Patient required at least one acute or chronic treatment with plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG) in addition to immunosuppressant therapy; **AND**

- Patient will avoid or use with caution medications known to worsen or exacerbate symptoms of myasthenia gravis (MG) (e.g., certain antibiotics, beta-blockers, botulinum toxins, hydroxychloroquine, etc.); **AND**
- Will not be used in combination with other immunomodulatory biologic therapies or with intravenous efgartigimod

† 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.

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IV. Renewal Criteria [1]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the 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 (e.g., anaphylaxis, rash, angioedema, and dyspnea, etc.), severe infusion-related reactions, etc.; **AND**

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) [1,9,10]

- Patient has demonstrated a clinical response to therapy based on an objective clinical measuring tool (e.g., INCAT, Medical Research Council (MRC) muscle strength, 6-MWT, Rankin, Modified Rankin, etc.)

Generalized Myasthenia Gravis (gMG) [1]

- 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
Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)	Administer 1,008 mg / 11,200 units (1,008 mg efgartigimod alfa and 11,200 units hyaluronidase) subcutaneously over approximately 30 to 90 seconds once weekly.
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.

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	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.
Note: *Vyvgart Hytrulo is to be administered by a healthcare professional only.*	

VI. Billing Code/Availability Information

HCPCS Code:

- J9334 – Injection, efgartigimod alfa, 2 mg and hyaluronidase-qvfc; 1 billable unit = 2 mg

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

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11. Allen J, Basta I, Eggers C, et al. Efficacy, Safety, and Tolerability of Efgartigimod in Patients with Chronic Inflammatory Demyelinating Polyneuropathy: Results from the ADHERE Trial (PL5.002). Neurology. April 9, 2024 issue; 102 (17_supplement_1). https://doi.org/10.1212/WNL-.0000000000206324.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
G70.00	Myasthenia gravis without (acute) exacerbation
G70.01	Myasthenia gravis with (acute) exacerbation
G61.81	Chronic inflammatory demyelinating polyneuritis
G61.89	Other inflammatory polyneuropathies
G62.89	Other specified polyneuropathies

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

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

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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,	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
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

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