Policy Title:	Vyvgart (efgartigimod alfa-fcab) and Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvtc) (Intravenous and Subcutaneous)		
		Department:	PHA
Effective Date:	03/01/2022		
Review Date:	02/17/2022, 8/4/2022, 4/27/2023, 12/14/2023, 01/10/2024		

Purpose: To support safe, effective, and appropriate use of Vyvgart (efgartigimod alfa-fcab) and Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvtc).

Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

Policy Statement:

Vyvgart (efgartigimod alfa-fcab) and Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvtc) are covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:

Coverage of Vyvgart (efgartigimod alfa-fcab) and Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvtc) will be reviewed prospectively via the prior authorization process based on criteria below.

Initial Criteria:

MMP members who have previously received this medication within the past 365 days are not Subject to Step Therapy Requirements.

- Patient is at least 18 years of age; AND
- Will not be used in combination with other immunomodulatory biologic therapies (i.e., rituximab, eculizumab, ravulizumab, pegcetacoplan, satralizumab, inebilizumab, etc.); AND
- Only one formulation of efgartigimod will be used (intravenous or subcutaneous); 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 [1,2,4-6, ,8]

- Submission of medical records (e.g., chart notes, laboratory values, etc.) to support the diagnosis of generalized myasthenia gravis (gMG); AND
- Prescribed by, or in consultation with, a neurologist; AND
- Patient has a positive serologic test for anti-acetylcholine receptor (AChR) antibodies; AND
- Patient has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II to IV disease§; AND
- Physician has assessed objective signs of neurological weakness and fatigability 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 of concurrent use with two (2) or more immunosuppressive therapies (e.g., corticosteroids plus an immunosuppressant such as azathioprine, methotrexate, cyclosporine, mycophenylate, etc.) OR
- Patient has required chronic treatment with plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG) in addition to immunosuppressant therapy; AND

- For Vyvgart Hytrulo requests, documentation that patient is unable to tolerate the intravenous formulation of Vyvgart and medical rationale has been provided

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

§ Myasthenia Gravis Foundation of America (MGFA) Disease Classifications::

- 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.

Continuation of Therapy Criteria:

- Patient continues to meet universal and other indication-specific relevant criteria identified in initial criteria section; AND
- 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 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
- 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)

(*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)

Coverage Durations:

- Initial coverage: 90 days
- Continuation of therapy coverage: 6 months

Dosage/Administration:

Drug	Dose for Generalized Myasthenia Gravis (gMG)	Maximum dose (1 billable unit = 2 mg)
Vyvgart IV	• 10mg/kg IV over 1 hour once weekly for four doses per 50 days (for patients weighing ≥120 kg, the recommended dose is 1200mg) • Administer subsequent treatment cycles based on clinical evaluation.	600 billable units weekly for four doses per 50 days

	The safety of initiating subsequent cycles sooner than 50 days from the start of the previous treatment cycle has not been established.	
Vyvgart Hytrulo	• Vyvgart Hytrulo is supplied as a single-dose 5.6 ml vial containing 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 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.	504 billable units weekly for four doses per 50 days

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:
Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J9332	Injection, efgartigimod alfa-fcab, 2mg
J9334	Injection, efgartigimod alfa, 2 mg and hyaluronidase-qvfc *[effective 1/1/24]*

NDC:

- Vyvgart 400 mg/20 mL single-dose vial: 73475-3041-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: 73475-3102-xx

References:

1. Vyvgart [package insert]. Boston, MA; Argenx, Inc., December 2021. Accessed December 2023.
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4. 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.
5. Howard JF Jr, Bril V, Vu T, Karam C, ADAPT Investigator Study Group, et al. Safety (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.
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7. 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 5, 2023.
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9. 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)
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