Policy Title:	Vyvgart (efgartigimod alfa-fcab) (Intravenous)		
		Department:	PHA
Effective Date:	03/01/2022		
Review Date:	02/17/2022, 8/4/2022, 4/27/2023		

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

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

Policy Statement:

Vyvgart (efgartigimod alfa-fcab) is 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) 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, 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

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

- 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 of one year trial with either:
    - History of failure of two or more immunosuppressive agents over the course of at least 12 months [e.g., 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;

† 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 initial criteria; 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 *; 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

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable. ***

Dosage/Administration:

Indication	**Dose**	**Maximum dose (1 billable unit = *2* mg)**
Generalized Myasthenia Gravis (gMG)	• 1200 mg weekly for four doses per 50 days • 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.	600 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

References:

1. Vyvgart [package insert]. Boston, MA; Argenx, Inc., December 2021. Accessed May 2022.
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 (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