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, 05/08/2024, 07/17/2024, 10/28/2025, 04/07/2026		

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

Scope: Medicaid, Commercial, Medicare

Policy Statement:

Vyvgart (efgartigimod alfa-fcab) and Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvtc) vials* 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.

*Vyvgart Hytrulo prefilled syringes can be administered by patients and/or caregivers, therefore available under the pharmacy benefit. Refer to Vyvgart Hytrulo PFS policy on pharmacy benefit for Medicaid members.

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.

Summary of Evidence:
Vyvgart (efgartigimod) and Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvtc) are indicated for the treatment of generalized myasthenia gravis (gMG) in adults who test positive for the anti-acetylcholine receptor (AChR) antibody. The medication causes a reduction in overall levels of IgG, including the abnormal AChR antibodies that are present in myasthenia gravis. The safety and efficacy of Vyvgart were evaluated in a 26-week clinical study of 167 members with myasthenia gravis who were randomized to receive either Vyvgart or placebo. The study showed that more members with myasthenia gravis with antibodies responded to treatment during the first cycle of Vyvgart (67.7%) compared to those who received placebo (29.7%) on a measure that assesses the impact of myasthenia gravis on daily function. More members receiving Vyvgart also demonstrated response on a measure of

muscle weakness compared to placebo. In ADAPTsc, 110 members were randomized in a 1:1 ratio to receive Vyvgart Hytrulo or Vyvgart for one treatment cycle (one treatment cycle consisted of four doses at once-weekly intervals). The primary endpoint of noninferiority was met, and Vyvgart Hytrulo demonstrated a mean total IgG reduction of 66.4% from baseline at Day 29, compared to 62.2% with Vyvgart (P <0.0001). Vyvgart Hytrulo was evaluated in members with chronic inflammatory demyelinating polyneuropathy (CIDP) using the adjusted Inflammatory Neuropathy Cause and Treatment (aINCAT) disability scale, ranging from 0 to 10 points with a higher number representing more disability. Members who received Vyvgart Hytrulo experienced a longer time to clinical deterioration (i.e., increase of ≥1 point in aINCAT score) compared to members who received placebo, which was statistically significant, as demonstrated by a hazard ratio of 0.394 [95% CI (0.253, 0.614), p<0.0001]. The most common side effects associated with the use of Vyvgart include respiratory tract infections, headache, and urinary tract infections. Injection site reactions were also common (≥15%) with Vyvgart Hytrulo treatment. As Vyvgart causes a reduction in IgG levels, the risk of infections may increase. Hypersensitivity reactions such as eyelid swelling, shortness of breath, and rash have occurred.

Initial Criteria:

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

- Member is at least 18 years of age; **AND**
- Prescribed by, or in consultation with, a neurologist; **AND**
- Only one formulation of efgartigimod will be used (intravenous or subcutaneous); **AND**
- Will not be used in combination with other immunomodulatory biologic therapies (e.g., Imaavy (nipocalimab), Rystiggo (rozanolixizumab), Zilbrysq (zilucoplan), Soliris/Epysqli/Bkemv (eculizumab), Ultomiris (ravulizumab), Uplizna (inebilizumab), etc.); **AND**
- The member does NOT have any FDA labeled contraindications to the requested agent; **AND**
- The requested quantity (dose) is within FDA labeled dosing for the requested indication

Generalized Myasthenia Gravis (gMG) † Φ [1,2,4-6, 9]

- Submission of medical records (e.g., chart notes, laboratory values, etc.) to support the diagnosis of generalized myasthenia gravis (gMG); **AND**
- Member has a positive serologic test for anti-acetylcholine receptor (AChR) antibodies; **AND**
- Member has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II to IVb 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 or the MG-Activities of Daily Living (MG-ADL) score, etc.); **AND**
- Member has a baseline MG-Activities of Daily Living (MG-ADL) total score of greater than or equal to 5; **AND**
- The member meets one of the following:
    - The member has tried and had an inadequate response to at least ONE conventional agent used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide); **OR**
    - The member has an intolerance or hypersensitivity to ONE conventional agent used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide); **OR**
    - The member has an FDA labeled contraindication to ALL conventional agents used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide); **OR**
    - The member required chronic intravenous immunoglobulin (IVIG); **OR**
    - The member required chronic plasmapheresis/plasma exchange; **AND**
- The member's current medications have been assessed and any medications known to exacerbate myasthenia gravis (e.g., beta blockers, procainamide, quinidine, magnesium, anti-programmed death receptor-1 monoclonal antibodies, hydroxychloroquine, aminoglycosides) have been discontinued OR discontinuation of the offending agent is NOT clinically appropriate; **AND**
- For Medicaid members requesting Vyvgart IV at a weekly dose requiring 3 vials (>800mg to 1200mg), documentation that member is unable to tolerate Vyvgart Hytrulo and medical rationale has been provided

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) [2,10,11]

- Request is for Vyvgart Hytrulo; **AND**
- The member's disease course is progressive or relapsing and remitting for at least 2 months; **AND**
- The member has progressive or relapsing motor sensory impairment of more than one limb; A**ND**
- Diagnosis confirmed by electrodiagnostic testing indicating demyelination with at least one of the following:
    - Prolonged distal motor latency in at least 2 motor nerves; **OR**
    - Reduced motor conduction velocity in at least 2 motor nerves; **OR**
    - Prolonged F-wave 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**
  - Partial motor conduction block in at least 2 motor nerves or in 1 nerve plus one other demyelination criterion listed here; **OR**
  - Abnormal temporal dispersion conduction in at least 2 motor nerves; **OR**
  - Distal CMAP duration increase in at least 1 nerve plus one other demyelination criterion listed here in at least 1 other nerve; **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**
- The member has tried and had an inadequate response to at least a 3-month trial of or intolerance to one standard of care therapy (i.e., corticosteroids, immunoglobulins, plasma exchange therapy) or an FDA-labeled contraindication to ALL standard of care of therapies aforementioned; **AND**
- Will not be used as maintenance therapy in combination with immunoglobulin

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

§ Myasthenia Gravis Foundation of America (MGFA) Disease Classifications[6,7]:

- 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 member in class IVb.

Continuation of Therapy Criteria[1,2]:

- The member was previously approved for the requested agent through the plan's Medical Drug Review process (Note: members not previously

approved for the requested agent will require initial evaluation review); **AND**

- The requested agent continues to be prescribed by, or in consultation with, a neurologist; **AND**
- Only one formulation of efgartigimod will be used (intravenous or subcutaneous); **AND**
- The member will not be using the requested agent in combination with other immunomodulatory biologic therapies (e.g., Imaavy (nipocalimab), Rystiggo (rozanolixizumab), Zilbrysq (zilucoplan), Soliris/Epysqli/Bkemv (eculizumab), Ultomiris (ravulizumab), Uplizna (inebilizumab), etc.); **AND**
- The member does NOT have any FDA labeled contraindications to the requested agent; **AND**
- The requested quantity (dose) is within FDA labeled dosing for the requested indication; **AND**

Generalized Myasthenia Gravis (gMG)

- Documentation that the member 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**
- Member requires continuous treatment, after an initial beneficial response, due to new or worsening disease activity (Note: Subsequent treatment cycles administered NO sooner than 28 days from the last administration 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)*

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

- Member 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.)

Coverage Durations:

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

Dosage/Administration:

Generalized Myasthenia Gravis (gMG)

Drug	Dose for 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 members weighing ≥120 kg, the recommended dose is 1200mg) • Administer subsequent treatment cycles based on clinical evaluation. • *Note: In clinical trials, subsequent treatment cycles were administered NO sooner than 28 days from the last administration of the previous treatment cycle.*	600 billable units weekly for four doses per 56 days
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. • *Note: In clinical trials, subsequent treatment cycles were administered NO sooner than 28 days from the last administration of the previous treatment cycle.*	504 billable units weekly for four doses per 56 days

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

Drug	Dose for CIDP	Maximum dose (1 billable unit = 2 mg)
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 as once weekly injections by a healthcare professional only.	504 billable units weekly

*This policy does not apply to Vyvgart Hytrulo single-dose 5 mL prefilled syringes containing 1,000 mg efgartigimod alfa and 10,000 units hyaluronidase that can be administered by patients and/or caregivers.

Dosing varies for prefilled syringe compared with vial. Refer to Vyvgart Hytrulo PFS policy on pharmacy benefit for Medicaid.

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

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

*This policy does not apply to Vyvgart Hytrulo 1,000 mg efgartigimod alfa and 10,000 units hyaluronidase per 5 mL (200 mg/2,000 units per mL) in a single-dose prefilled syringe: 73475-1221-xx

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12. 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.

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
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 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

Policy Rationale:
Vyvgart and Vyvgart Hytrulo were reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Vyvgart and Vyvgart Hytrulo according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For Medicare members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.