09-J4000-18

Original Effective Date: 03/15/22

Reviewed: 04/08/26

Revised: 05/15/26

Subject: Efgartigimod alfa-fcab (Vyvgart, Vyvgart Hytrulo) injection

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Generalized myasthenia gravis is an autoimmune neuromuscular disorder characterized by muscle weakness and fatigue. IgG antibodies occur in up to 85% of patients which are most frequently directed at the acetylcholine receptor. Treatment includes the use of cholinesterase inhibitors to prevent the breakdown of acetylcholine at the neuromuscular junction, immunosuppressive therapies, and thymectomy. Myasthenic crisis may occur which is a medical emergency due to respiratory failure and treatment includes plasmapheresis, IVIG, and corticosteroids.

Efgartigimod alfa-fcab (Vyvgart) is FDA-approved for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive. It is a human immunoglobulin G1 (IgG1) derived Fc fragment that binds to the neonatal Fc receptor (FcRn) and reduces IgG. The amount of AChR autoantibodies is also reduced.

Efgartigimod was compared to placebo in 167 patients with AChR antibody positive generalized myasthenia gravis a 26-week study. The patients were included if they had a Myasthenia Gravis Foundation of America (MGFA) clinical classification of class II – IV and a Myasthenia Gravis Activities of Daily Living (MG-ADL) total score of greater than or equal to 5. The patients also had to be on a stable dose of medication that included acetylcholinesterase (AChE) inhibitors, steroids, or non-steroidal immunosuppressive therapies alone or in combination. There were over 80% of patients who received AChE inhibitors, over 70% receiving steroids, and approximately 60% received non-steroidal immunosuppressive therapies. Patients had IgG levels of at least 6 g/L, a median time since diagnosis of MG of 9 years, a median MG-ADL total score of 9, and the median Quantitative Myasthenia Gravis (QMG) total score of 16. The MG-ADL was used to evaluate the efficacy of treatment. The MG-ADL quantifies the impact of gMG on 8 signs or symptoms with a score ranging from 0 to 24, with a higher score indicating less ability to perform a function. A 2-point or greater reduction in the total MG-ADL score from baseline over 4 weeks was considered a responder. The primary endpoint was the percentage of MG-ADL responders during the first treatment cycle. A statistically significant improvement in the percentage of MG-ADL responders was demonstrated with the use of efgartigimod as compared to placebo (67.7% vs 29.7%, $p<0.0001$). The QMG was used to assess the impact on muscle weakness (range 0-39 with higher score indicating severe weakness). A responder was defined as a 3 point or greater reduction in the total QMG score as compared from baseline for at least 4 consecutive weeks. The percentage of QMG responders was significantly higher in the patients treated with efgartigimod vs

the placebo group (63.1% vs 14.1%, p<0.0001). The most common adverse reactions in patients with treated with efgartigimod included respiratory tract infections, headache, and urinary tract infection.

A healthcare provider administered subcutaneous administered form of efgartigimod is formulated in combination with hyaluronidase (Vyvgart Hytulo). It is FDA-approved for the treatment of gMG in adult patients who are AChR antibody positive. It has also been FDA-approved for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP).

POSITION STATEMENT:

Site of Care: If intravenous or subcutaneous efgartigimod (Vyvgart, Vyvgart Hytrulo vial) is administered in a hospital-affiliated outpatient setting, additional requirements may apply depending on the member's benefit. Refer to 09-J3000-46: Site of Care Policy for Select Specialty Medications.

Comparative Effectiveness

The FDA has deemed Vyvgart Hytrulo prefilled syringe in this coverage policy to be appropriate for self-administration or administration by a caregiver (i.e., not a healthcare professional). Therefore, coverage (i.e., administration) in a provider-administered setting such as an outpatient hospital, ambulatory surgical suite, physician office, or emergency facility is not considered medically necessary.

Initiation of intravenous or subcutaneous efgartigimod (Vyvgart, Vyvgart Hytrulo vial or prefilled syringe) **meets the definition of medical necessity** when **ALL** of the indication- specific criteria are met:

1. Generalized Myasthenia Gravis (gMG)
    a. Member meets **ALL** of the following - documentation must be provided:
        i. Anti-acetylcholine receptor (AchR) antibody positive disease – lab documentation must be submitted
        ii. Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II – IV
        iii. Myasthenia Gravis Activities of Daily Living (MG-ADL) total score greater than or equal to 5
        iv. **ONE** of the following[a]:
            1. Member had an inadequate response to at least **ONE** of the following immunosuppressants:
                a. azathioprine
                b. cyclosporine
                c. mycophenolate mofetil
                d. tacrolimus
                e. methotrexate
                f. cyclophosphamide
                g. rituximab
            2. Member required chronic immune globulin therapy or chronic plasmapheresis/plasma exchange
    b. Efgartigimod is not used concurrently with eculizumab or biosimilars, inebilizumab, nipocalimab, ravulizumab, rituximab, rozanolixizumab, zilucoplan, or immune globulin therapy
    c. Intravenous efgartigimod not permitted to be used concomitantly with subcutaneous efgartigimod

d. Treatment is prescribed by or in consultation with a neurologist

e. There is no evidence of an active infection

f. If Vyvgart (intravenously administered product) is requested, the member has tried and had an inadequate response or contraindication to Vyvgart Hytrulo (subcutaneous administered vial or prefilled syringe) OR there is a clinical reason to support the use of Vyvgart IV– documentation must be submitted

g. The dose does not exceed the following:

i. Vyvgart: 10 mg/kg[b] weekly for 4 weeks (4 doses per 4 week cycle)

ii. Vyvgart Hytrulo vial: 1008 mg/11200 units weekly for 4 weeks (4 doses per 4 week cycle)

iii. Vyvgart Hytrulo prefilled syringe: 1000 mg/10000 units weekly for 4 weeks (4 doses per 4 week cycle)

2. Chronic inflammatory demyelinating polyneuropathy (CIDP)

i. Member's clinical course is relapsing and remitting or progressive for more than 2 months

ii. Member's disease has been confirmed by **BOTH** of the following physiologic findings

a. Hypo- or areflexia

b. Motor or sensory impairment of more than one limb

iii. ONE of the following – documentation must be submitted:

a. Member continues to have signs of active disease and was previously approved by Florida Blue for maintenance treatment of CIDP with immune globulin therapy

b. **ONE** of the following is confirmed by electrophysiologic findings:

i. Motor distal latency prolongation of greater than or equal to 50% of the upper limit of normal in at least 2 nerves

ii. Reduction of motor conduction velocity of greater than or equal to 30% below the lower limit of normal in at least 2 nerves

iii. Prolongation of F-wave latency of greater than or equal to 20% above the upper limit of normal in at least two nerves

iv. Motor conduction block in two nerves (greater than or equal to 30% reduction of the proximal relative to distal negative peak compound muscle action potential (CMAP) amplitude, excluding the tibial nerve, and distal negative peak CMAP amplitude of greater than or equal to 20 % of lower limit of normal)

v. Abnormal temporal dispersion or greater than 30% duration increase between the proximal and distal negative peak CMAP in at least 2 nerves (at least 100% in tibial nerve)

c. **TWO** of the following has been confirmed by electrophysiologic findings:

i. Absence of F-wave latency in at least 2 motor nerves

ii. Motor conduction block in one nerve (greater than or equal to 30% reduction of the proximal relative to distal negative peak CMAP amplitude, excluding the tibial nerve, and distal negative peak CMAP amplitude of greater than or equal to 20% of lower limit of normal)

iii. Distal CMAP duration prolongation in at least 1 nerve

iv. Motor distal latency prolongation of greater than or equal to 50% of the upper limit of normal in at least 1 nerve

v. Reduction of motor conduction velocity of greater than or equal to 30% below the lower limit of normal in at least 1 nerve

vi. Prolongation of F-wave latency of greater than or equal to 20% above the upper limit of normal in at least one nerve

vii. Abnormal temporal dispersion or greater than 30% duration increase between the proximal and distal negative peak CMAP in at least one nerve (at least 100% in tibial nerve)

iv. Member had an inadequate response or contraindication to a three month trial of immune globulin therapy or plasma exchange– documentation must be submitted

v. The member's baseline strength has been evaluated using at least **ONE** objective measuring tool: Inflammatory Neuropathy Cause and Treatment disability score (INCAT), Medical Research Council (MRC) muscle strength, 6-minute walk test (6-MWT), Rankin, Modified Rankin, adjusted Inflammatory Neuropathy Cause and Treatment disability score (aINCAT), inflammatory Rasch-built Overall Disability Scale (I-RODS), or grip strength – documentation must be submitted

vi. Efgartigimod hyaluronidase is not used concurrently with eculizumab or biosimilars, inebilizumab, nipocalimab, ravulizumab, rituximab, rozanolixizumab, zilucoplan, or maintenance immune globulin therapy

vii. Intravenous efgartigimod not permitted to be used concomitantly with subcutaneous efgartigimod

viii. Treatment is prescribed by or in consultation with a neurologist

ix. There is no evidence of an active infection

x. The dose does not exceed the following (only requests for Vyvgart Hytrulo will be covered for CIDP):

a. Vyvgart Hytrulo vial: 1008 mg/11200 units once weekly injection

b. Vyvgart Hytrulo prefilled syringe: 1000 mg/10000 units once weekly

Approval duration: 6 months

Continuation of intravenous or subcutaneous efgartigimod (including transitioning between products) **meets the definition of medical necessity** when **ALL** of the following criteria are met:

1. An authorization or reauthorization for efgartigimod has been previously approved by Florida Blue or another health plan in the past 2 years for the treatment of generalized myasthenia gravis **OR** chronic inflammatory demyelinating polyneuropathy, **OR** the member has previously met **ALL** indication-specific criteria.
2. For continuation of therapy for Generalized Myasthenia Gravis (gMG), member's diagnosis has been confirmed by the following – lab documentation must be provided:
    a. Anti-acetylcholine receptor (AchR) antibody positive disease
3. Member has a history of beneficial response to therapy for **ONE** of the following:
    a. gMG – examples of beneficial response include decrease in MG-ADL total score to show improvement, decrease in the Quantitative myasthenia gravis total score to show improvement – documentation must be provided
    b. CIDP - member demonstrates a beneficial response to therapy using ONE objective measuring tool: Inflammatory Neuropathy Cause and Treatment disability score (INCAT), Medical Research Council (MRC) muscle strength, 6-MWT, Rankin, Modified Rankin,

aINCAT score, I-RODS, or grip strength improvement **AND** there are no signs of neurological worsening after starting treatment with efgartigimod – documentation must be provided

4. There is no evidence of an active infection
5. Efgartigimod is not used concurrently with eculizumab or biosimilars, inebilizumab, nipocalimab, ravulizumab, rituximab, rozanolixizumab, zilucoplan, or immune globulin therapy
6. Intravenous efgartigimod not permitted to be used concomitantly with subcutaneous efgartigimod
7. If Vyvgart (intravenously administered product) is requested, the member has tried and had an inadequate response or contraindication to Vyvgart Hytrulo (subcutaneous administered vial or prefilled syringe) OR there is a clinical reason to support the use of Vyvgart IV– documentation must be submitted
8. The dose does not exceed the following:
    a. gMG
        1. Vyvgart: 10 mg/kg[b] weekly for 4 weeks (4 doses per 4 week cycle)
        2. Vyvgart Hytrulo vial: 1008 mg/11200 units weekly for 4 weeks (4 doses per 4 week cycle)
        3. Vyvgart Hytrulo prefilled syringe: 1000 mg/10000 units weekly for 4 weeks (4 doses per 4 week cycle)
    b. CIDP (only requests for Vyvgart Hytrulo will be covered for CIDP):
        1. Vyvgart Hytrulo vial: 1008 mg/11200 units once weekly injection
        2. Vyvgart Hytrulo prefilled syringe: 1000 mg/10000 units once weekly

Approval duration: 1 year

[a] Not required if the member is switching to efgartigimod and member and was previously approved by Florida Blue for the use of eculizumab or biosimilars, nipocalimab, ravulizumab, rozanolixizumab, or zilucoplan for the treatment of myasthenia gravis.

[b] For members 120 kg or greater, the dose does not exceed 1200 mg

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

FDA-approved

- **Generalized myasthenia gravis in adults who are anti-acetylcholine receptor (AChR) antibody positive:**
    - Vyvgart: 10 mg/kg administered as an IV infusion over one hour once weekly for 4 weeks. In patients weighing 120 kg or more, the dose is 1200 mg per infusion.
    - Vyvgart Hytrulo vial: 1008 mg / 11,200 units administered subcutaneously over approximately 30 to 90 seconds in cycles of once weekly injections for 4 weeks
    - Vyvgart Hytrulo prefilled syringe: 1000 mg / 10,000 units administered subcutaneously over approximately 20 to 30 seconds in cycles of once weekly injections for 4 weeks
    - Subsequent treatment cycles are based on clinical evaluation.
- **Chronic Inflammatory Demyelinating Polyneuropathy:**

- Vyvgart Hytrulo vial: 1008 mg / 11,200 units administered subcutaneously over approximately 30 to 90 seconds in cycles of once weekly injections
- Vyvgart Hytrulo prefilled syringe: 1000 mg / 10,000 units administered subcutaneously over approximately 20 to 30 seconds in cycles of once weekly injections
- Not all patients respond to treatment. Consider the appropriateness of continuing treatment in patients who experience worsening of neurological symptoms after starting therapy.

Dose Adjustments

- None

Drug Availability

- Vyvgart: 400 mg in 20 mL (20 mg/mL) single-dose vial
- Vyvgart Hytrulo vial: 1008 mg efgartigimod alfa and 11,200 units hyaluronidase per 5.6 mL (180 mg/2000 units per mL) in a single dose vial)
- Vyvgart Hytrulo prefilled syringe: 1000 mg / 10,000 units administered subcutaneously over approximately 20 to 30 seconds in cycles of once weekly injections

PRECAUTIONS:

Boxed Warning

- None

Contraindications

- Contraindicated in patients with serious hypersensitivity to efgartigimod alfa, to hyaluronidase, or to any of the excipients

Precautions/Warnings

- Infection: Delay administration to patients with an active infection. Monitor for signs and symptoms of infection in patients receiving therapy. If serious infection occurs administer appropriate treatment and consider withholding until the infection has resolved.
- Hypersensitivity reaction: Angioedema, dyspnea, rash, and urticaria have occurred. If a hypersensitivity reaction occurs, discontinue the infusion and institute appropriate therapy.
- Infusion-related reaction: if severe reaction occurs discontinue the infusion. If mild to moderate infusion occurs, see prescribing information.
- Avoid combined use of efgartigimod with immunoglobulin products, monoclonal antibodies, or antibody derivatives containing the human Fc domain of the IgG subclass due to lower systemic exposure and reduced effectiveness of medications.

BILLING/CODING INFORMATION:

HCPCS Coding

J9332	Injection, efgartigimod alfa-fcab, 2 mg
J9334	Injection, efgartigimod alfa, 2 mg and hyaluronidase-qvfc

ICD-10 Diagnosis Codes That Support Medical Necessity

G70.00 – G70.01	Myasthenia gravis
G61.81	Chronic inflammatory demyelinating polyneuritis

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Part D: Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

Medicare Advantage: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

Table 1: Myasthenia Gravis Foundation of America (MGFA) Clinical Classification System

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.

Table 2: Myasthenia Gravis Activities of Daily Living (MG-ADL)

Grade	0	1	2	3	Score
Talking	Normal	Intermittent slurring or nasal speech	Constant slurring or nasal, but can be understood	Difficult to understand speech	

Chewing	Normal	Fatigue with solid food	Fatigue with soft food	Gastric tube	
Swallowing	Normal	Rare episode of choking	Frequent choking necessitating changes in diet	Gastric tube	
Breathing	Normal	Shortness of breath with exertion	Shortness of breath at rest	Ventilator dependence	
Impairment of ability to brush teeth or comb hair	None	Extra effort, but no rest periods needed	Rest periods needed	Cannot do one of these functions	
Impairment of ability to arise from a chair	None	Mild, sometimes uses arms	Moderate, always uses arms	Severe, requires assistance	
Double vision	None	Occurs, but not daily	Daily, but not constant	Constant	
Eyelid droop	None	Occurs, but not daily	Daily, but not constant	Constant	
Total Score					

Table 3: Quantitative Myasthenia Gravis Score for Disease Severity

Test item	None	Mild	Moderate	Severe	Score
Grade	**0**	**1**	**2**	**3**	
(1) Double vision on lateral gaze, seconds	61	11-60	1-10	Spontaneous	
(2) Ptosis on upward gaze, seconds	61	11-60	1-10	Spontaneous	
(3) Weakness of facial muscles	Normal lid closure	Complete, weak, some resistance	Complete, without resistance	Incomplete	
(4)Swallowing water	Normal	Minimal coughing or throat clearing	Severe coughing/choking or nasal regurgitation	Cannot swallow (test not attempted)	
(5) Speech after counting aloud from 1-50	None at 50	Dysarthria at 30-49	Dysarthria at 10-29	Dysarthria at 9	
(6) Ability to keep right arm outstretched, seconds	240	90-239	10-89	0-9	
(7) Ability to keep left arm outstretched, seconds	240	90-239	10-89	0-9	
(8) Vital capacity as	Greater or equal to 80	65-79	50-64	Less than 50	

percent of predicted					
(9) Right hand grip strength, kgW	Men – 45 or greater Women – 30 or greater	Men – 15-44 Women – 10-29	Men – 5-14 Women – 5-9	Men –0-4 Women – 0-4	
(10) Left hand grip strength, kgW	Men – 45 or greater Women – 30 or greater	Men – 15-44 Women – 10-29	Men – 5-14 Women – 5-9	Men –0-4 Women – 0-4	
(11) Ability to keep head lifted when lying supine, seconds	120	30-119	1-29	0	
(12) Ability to keep the right leg outstretched, seconds	100	31-99	1-30	0	
(13) Ability to keep the left leg outstretched, seconds	100	31-99	1-30	0	
				Total QMG Score:	

RELATED GUIDELINES:

Eculizumab (Soliris), 09-J1000-17

Immune Globulin Therapy, 09-J0000-06

Ravulizumab (Ultomiris), 09-J3000-26

Rituximab Products, 09-J0000-59

Rozanolixizumab-noli (Rystiggo), 09-J4000-55

Zilucoplan (Zilbrysq), 09-J4000-78

OTHER:

None.

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6. Van den Bergh P, van Doorn P, Hadden R, et al. European Academy of Neruology/Peripheral Nerve Society guideline on diagnosis and treatment of chronic inflammatory demyelinating polyradiculoneuropathy: Report of a joint task force – second revision. Eur J Neurol. 2021; 28:3556-3583.
7. Vyvgart (efgartigimod alfa-fcab) injection. Argenx US, Inc. Boston, MA. April 2025.
8. Vyvgart Hytrulo (efgartigimod alfa-fcab and hyaluronidase) injection. Argenx US, Inc. Boston, MA. March 2026.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 04/08/26.

GUIDELINE UPDATE INFORMATION:

03/15/22	New Medical Coverage Guideline.
06/15/22	Updated position statement to include site of care policy.
07/01/22	Revision: Added HCPCS code J9332 and deleted code J3590.
07/15/22	Revision to guideline consisting of updating the position statement.
08/15/23	Review and revision to guideline; consisting of updating the position statement to include Vyvgart Hytrulo.
09/15/23	Revision to guideline; consisting of including Vyvgart Hytrulo in the site of care statement.
10/15/23	Review and revision to guideline; consisting of updating the position statement for Myasthenia Gravis.
01/01/24	Revision: Added HCPCS code J9334 and deleted code J3590.
05/15/24	Revision to guideline consisting of updating the agents not to be used in combination and lab documentation requirements. Update to warnings and references.
08/15/24	Update to position statement to include chronic inflammatory demyelinating polyneuropathy (CIDP) and update to dosing.
10/15/24	Update to position statement to revise chronic inflammatory demyelinating polyneuropathy (CIDP) criteria.
07/01/25	Update to position statement to include Vyvgart Hytrulo prefilled syringe and updated agents not to be used in combination.
10/15/25	Update to position statement to include Vyvgart Hytrulo prefilled syringe preferred over administration of the Vyvgart and Vyvgart Hytrulo provider administered products.
1/01/26	Update to position statement for agents not to be used in combination and inclusion of a clinical reason to bypass the step through Vyvgart Hytrulo. Update to agents are not permitted for use in combination.
05/15/26	Update to position statement and dosing for labeling changes of Vyvgart Hytrulo.