Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 260.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Vyvgart (efgartigimod alfa-fcab) and Vyvgart Hytrulo (Efgartigimod Alfa and Hyaluronidase Injection)

Applicable line of business:

Commercial	X	Medicaid	X
Medicare	X	ACA	X
CHIP	X		

I. Policy:
Vyvgart (efgartigimod alfa-fcab) and Vyvgart Hytrulo (Efgartigimod Alfa and Hyaluronidase Injection)

II. Purpose/Objective:
To provide a policy of coverage regarding Vyvgart (efgartigimod alfa-fcab) and Vyvgart Hytrulo (Efgartigimod Alfa and Hyaluronidase Injection).

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Vyvgart (efgartigimod alfa-fcab) is a human IgG1 antibody fragment that binds to the neonatal Fc receptor (FcRn), resulting in the reduction of circulating IgG antibodies, including acetylcholine receptor (AChR) autoantibodies, that cause neuromuscular junction (NMJ) damage and dysfunction.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Vyvgart (efgartigimod alfa-fcab) and Vyvgart Hytrulo (Efgartigimod Alfa and Hyaluronidase Injection) will be considered medically necessary for the commercial, exchange, CHIP, and Medicaid lines of business when all of the following criteria are met:

Generalized Myasthenia Gravis (gMG)
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that the medication is prescribed by or in consultation with a neurologist **AND**
- Medical record documentation of a diagnosis of generalized myasthenia gravis (gMG) that is anti-acetylcholine receptor (AChR) antibody positive **AND**
- Medical record documentation of Myasthenia Gravis Foundation of America Clinical Classification (MGFA) Class II to IV **AND***
- Medical record documentation of a baseline Myasthenia Gravis-Activities of Daily Living (MG-ADL) score of 5 or more **AND****
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids **AND**
- Medical record documentation of therapeutic failure on intolerance to, or contraindication to at least two (2) non-steroidal immunosuppressive therapies OR has failed at least one (1) immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) **AND**
- Medical record documentation of failure on intolerance to, or contraindication to intravenous immunoglobulin (IVIG)

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that the medication is prescribed by or in consultation with a neurologist **AND**
- Documented evidence of focal or symmetric neurologic deficits that are slowly progressive or relapsing over 2 months or longer **AND**
- Physician provided documentation of EMG abnormalities consistent with the diagnosis of Chronic Inflammatory Demyelinating Polyneuropathy with the presence of at least ONE of the following:
    - Motor distal latency prolongation $\geq$ 50% above upper limit of normal (ULN) in two nerves (excluding median neuropathy at the wrist from carpal tunnel syndrome) **OR**
    - Reduction of motor conduction velocity $\geq$ 30% below lower limit of normal (LLN) in two nerves **OR**
    - Prolongation of F-wave latency $\geq$ 20% above ULN in two nerves (> 50% if amplitude of distal negative peak compound muscle action potential (CMAP) <80% of LLN values) **OR**
    - Absence of F-waves in two nerves if these nerves have distal negative peak CMAP amplitudes $\geq$ 20% of LLN + $\geq$ 1 other demyelinating parameter in $\geq$ 1 other nerve **OR**
    - Partial motor conduction block: $\geq$ 30% amplitude reduction of the proximal negative peak CMAP relative to distal, if distal negative peak CMAP $\geq$ 20% of LLN, in two nerves, or in one nerve + $\geq$1 other demyelinating parameter in $\geq$ 1 other nerve **OR**
    - Abnormal temporal dispersion (>30% duration increase between the proximal and distal negative peak CMAP) in $\geq$ 2 nerves **OR**
    - Distal CMAP duration (interval between onset of the first negative peak and return to baseline of the last negative peak) increase in $\geq$ 1 nerve (median $\geq$ 6.6 ms, ulnar $\geq$ 6.7 ms, peroneal $\geq$ 7.6 ms, tibial $\geq$ 8.8 ms) + $\geq$ 1 other demyelinating parameter in $\geq$ 1 other nerve

AND

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to one (1) intravenous or subcutaneous immune globulin (IVIG/SCIG) therapy, one (1) corticosteroid therapy, OR plasma exchange (PLEX) **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to one (1) non-steroidal immunosuppressive therapy (can include but is not limited to azathioprine, cyclophosphamide, cyclosporine, methotrexate, mycophenolate) **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to rituximab

AUTHORIZATION DURATION:

Generalized Myasthenia Gravis (gMG)

Initial approval will be for 6 months. Subsequent approvals will be for 6 months and will require:

- Medical record documentation of continued disease improvement or lack of disease progression **AND**
- Medical record documentation that the member is responding positively to therapy as evidenced by a 2-point reduction from baseline in Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score**

The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Vyvgart (efgartigimod alfa-fcab) and and Vyvgart Hytrulo (Efgartigimod Alfa and Hyaluronidase Injection) will be considered medically necessary for the Medicare line of business when all of the following criteria are met:

Generalized Myasthenia Gravis (gMG)

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that the medication is prescribed by or in consultation with a neurologist **AND**
- Medical record documentation of a diagnosis of generalized myasthenia gravis (gMG) that is anti-acetylcholine receptor (AChR) antibody positive **AND**
- Medical record documentation of Myasthenia Gravis Foundation of America Clinical Classification (MGFA) Class II to IV **AND***
- Medical record documentation of a baseline Myasthenia Gravis-Activities of Daily Living (MG-ADL) score of 5 or more**

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that the medication is prescribed by or in consultation with a neurologist **AND**
- Documented evidence of focal or symmetric neurologic deficits that are slowly progressive or relapsing over 2 months or longer **AND**
- Physician provided documentation of EMG abnormalities consistent with the diagnosis of Chronic Inflammatory Demyelinating Polyneuropathy with the presence of at least ONE of the following:
    - Motor distal latency prolongation $\geq$ 50% above upper limit of normal (ULN) in two nerves (excluding median neuropathy at the wrist from carpal tunnel syndrome) **OR**
    - Reduction of motor conduction velocity $\geq$ 30% below lower limit of normal (LLN) in two nerves **OR**
    - Prolongation of F-wave latency $\geq$ 20% above ULN in two nerves (> 50% if amplitude of distal negative peak compound muscle action potential (CMAP) <80% of LLN values) **OR**
    - Absence of F-waves in two nerves if these nerves have distal negative peak CMAP amplitudes $\geq$ 20% of LLN + $\geq$ 1 other demyelinating parameter in $\geq$ 1 other nerve **OR**
    - Partial motor conduction block: $\geq$ 30% amplitude reduction of the proximal negative peak CMAP relative to distal, if distal negative peak CMAP $\geq$ 20% of LLN, in two nerves, or in one nerve + $\geq$1 other demyelinating parameter in $\geq$ 1 other nerve **OR**
    - Abnormal temporal dispersion (>30% duration increase between the proximal and distal negative peak CMAP) in $\geq$ 2 nerves **OR**
    - Distal CMAP duration (interval between onset of the first negative peak and return to baseline of the last negative peak) increase in $\geq$ 1 nerve (median $\geq$ 6.6 ms, ulnar $\geq$ 6.7 ms, peroneal $\geq$ 7.6 ms, tibial $\geq$ 8.8 ms) + $\geq$ 1 other demyelinating parameter in $\geq$ 1 other nerve

AND

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to one (1) intravenous or subcutaneous immune globulin (IVIG/SCIG) therapy, one (1) corticosteroid therapy, OR plasma exchange (PLEX) **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to one (1) non-steroidal immunosuppressive therapy (can include but is not limited to azathioprine, cyclophosphamide, cyclosporine, methotrexate, mycophenolate) **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to rituximab

AUTHORIZATION DURATION:

Generalized Myasthenia Gravis (gMG)

Initial approval will be for 6 months. Subsequent approvals will be for 6 months and will require:

- Medical record documentation of continued disease improvement or lack of disease progression **AND**
- Medical record documentation that the member is responding positively to therapy as evidenced by a 2-point reduction from baseline in Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score**

The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

**Note: Class I Myasthenia gravis is indicated by any eye muscle weakness, possible ptosis (drooping or falling of the upper eyelid) and no other evidence of muscle weakness elsewhere, Class II to IV include muscle weakness in areas of the body beyond the eye.*

Note: Corticosteroids: betamethasone, dexamethasone, methylprednisolone, prednisone
Cholinesterase inhibitors: pyridostigmine, neostigmine
Immunosuppressants: azathioprine, mycophenolate, cyclosporine, Rituxan

****MG 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 _____	

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Dynamed. Myasthenia Gravis. EBSCO Information Services. Accessed October 19,2023. Https://www.dynamed.com.ezproxy.sju.edu/condition/myasthenia-gravis
2. Myasthenia Gravis Foundation of America (MGFA) Myasthenia.org. Available at: https://myasthenia.org/Portals/0/MGFA%20Classification.pdf (Accessed: 19 Oct 2023).
3. Vyvgart Hytrulo (Efgartigimod Alfa and hyaluronidase- human recombinant injection) [Prescribing Information]. Boston, MA: ArgenX US, Inc; 2023
4. Vyvgart (Efgartigimod Alfa) [Prescribing Information]. Boston, MA: ArgenX US, Inc; 2023
5. Howard JF Jr, Bril V, Vu T, Karam C, Peric S, Margania T, Murai H, Bilinska M, Shakarishvili R, Smilowski M, Guglietta A, Ulrichts P, Vangeneugden T, Utsugisawa K, Verschuuren J, Mantegazza R; ADAPT Investigator Study Group. Safety, efficacy, and tolerability of efgartigimod in patients with generalized myasthenia gravis (ADAPT): a multicenter, randomized, 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. PMID: 34146511.
6. Evaluating the Pharmacodynamic Noninferiority of Efgartigimod PH20 SC Administered Subcutaneously as Compared to Efgartigimod Administered Intravenously in Patients With Generalized Myasthenia Gravis (ADAPTsc). ClinicalTrials.gov identifier: NCT04735432. Updated Feb 28, 2023. Accessed Oct 19, 2023. https://clinicaltrials.gov/study/NCT04735432?intr=efgartigimod%20PH20%20SC&rank=4&tab=table#administrative-information
7. https://www.vyvgarthcp.com/content/dam/vyvgart/hcp/pdfs/VYVGART-Hytrulo-Acquisition-Guide-Product-Fact-Sheet.pdf
8. Farmakidis C, Pasnoor M, Dimachkie MM, Barohn RJ. Treatment of Myasthenia Gravis. Neurol Clin. 2018 May;36(2):311-337. doi: 10.1016/j.ncl.2018.01.011. PMID: 29655452; PMCID: PMC6690491.
9. Barth D, Nabavi Nouri M, Ng E, Nwe P, Bril V. Comparison of IVIg and PLEX in patients with myasthenia gravis. Neurology. 2011 Jun 7;76(23):2017-23. doi: 10.1212/WNL.0b013e31821e5505. Epub 2011 May 11. PMID: 21562253; PMCID: PMC3109880.
10. Sanders, D. B., Wolfe, G. I., Benatar, M., Evoli, A., Gilhus, N. E., Illa, I., Kuntz, N., Massey, J. M., Melms, A., Murai, H., Nicolle, M., Palace, J., Richman, D. P., Verschuuren, J. & Narayanaswami, P. (2016). International consensus guidance for management of myasthenia gravis. Neurology, 87 (4), 419-425. doi: 10.1212/WNL.0000000000002790.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 5/17/22

Revised: 8/25/22 (formulary alternative removal), 5/11/23 (LOB carve out, Medicaid business segment), 12/28/23 (references added), 1/1/24 (Vyvgart Hytrulo & references from 11/2023), 10/18/24 (CIDP, LOB table, taglines)

Reviewed:

MA UM Committee approval: 12/31/23, 5/22/24, 11/8/24