

Utilization Management and Clinical Medical Policy

Policy Name: Efgartigimod alfa-fcaband (Vyvgart) and Efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo)	Policy Number: MP-RX-FP-177-25	Scope: ☒ MMM MA ☒ MMM MultiHealth	Origination Date: 9/16/2025 Last Review Date: 08/19/2026	Effective Date: 08/19/2026 Frequently Revision: Annual
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Service Category:

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| ☐ Anesthesia | ☐ Medicine Services and Procedures |
| ☐ Surgery | ☐ Evaluation and Management Services |
| ☐ Radiology Procedures | ☐ DME/Prosthetics or Supplies |
| ☐ Pathology and Laboratory Procedures | ☒ Other: Part B Drugs |

Service Description:

This document addresses the use of Efgartigimod alfa-fcaband (Vyvgart®) and Efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo®), a drug approved by the Food and Drug Administration (FDA) for the treatment of generalized myasthenia gravis in adult patients. Vyvgart Hytrulo is additionally approved for the treatment of adults with Chronic Inflammatory Demyelinating Polyneuropathy (CIDP).

Background Information:

Myasthenia Gravis (MG)

Generalized myasthenia gravis (gMG) is an autoimmune neuromuscular disorder characterized by fluctuating motor weakness causing dyspnea, dysphagia, diplopia, dysarthria, and ptosis. Generalized myasthenia gravis is commonly mediated by IgG autoantibodies directed against the neuromuscular junction. Treatment strategies include symptomatic therapy (with anticholinesterase agents such as pyridostigmine), chronic immunotherapy with steroids or other immunosuppressive drugs (such as azathioprine, cyclosporine, or methotrexate), rapid immunotherapy (with plasmapheresis or IV immune globulin), and/or surgical treatment. Vyvgart (efgartigimod alfa-fcab), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc), and Rystiggo (rozanolixizumab-noli) reduce autoantibodies by binding to the neonatal Fc receptor (FcRn), but differ in product administration, frequency, and population. As of the May 2026 labeling update, Vyvgart and Vyvgart Hytrulo are approved for adult patients with generalized myasthenia gravis regardless of anti-acetylcholine receptor (AChR) antibody status. Rystiggo is approved for adult patients with generalized myasthenia gravis who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive. Myasthenia Gravis Foundation of America (MGFA) international consensus guidelines, published prior to approval of FcRn inhibitors, recommend immunosuppressive drugs and/or corticosteroids for individuals who have not met treatment goals after an adequate trial of pyridostigmine.

Chronic Inflammatory Demyelinating Polyneuropathy (or polyradiculoneuropathy) (CIDP)

CIDP is an acquired, immune-mediated neuropathy which currently lacks consensus on one gold standard for confirming diagnosis via electrophysiologic findings and for determining therapeutic improvement. The clinical trial for Vyvgart Hytrulo required individuals to have a diagnosis of definite or probable CIDP as defined in the European Federation of Neurological Societies/Peripheral Nerve Society (EFNS/PNS) 2010 criteria for progressing or relapsing forms of CIDP. The guidelines were updated in 2021 and include many of the same diagnostic features. Overall, a diagnosis of CIDP includes clinical features and electrodiagnostic testing with or without other supportive criteria. The clinical diagnosis of CIDP may be made based on features of either typical or atypical CIDP with an exclusion of other causes of neuropathy. Electrodiagnostic testing reveals characteristic findings, including prolongation of motor distal latency, reduction of motor conduction velocity, prolongation of

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F-wave latency, absence of F-waves, motor conduction block, abnormal temporal dispersion, and distal compound muscle action potential (CMAP) duration increase in one or more nerves. Though not widely used in clinical practice, various clinical assessment tools have been developed, including Inflammatory Neuropathy Cause and Treatment (INCAT) scale, Inflammatory Rasch-built Overall Disability Scale (I-RODS), Medical Research Council (MRC) scale for muscle strength, and tools assessing grip strength. In clinical practice, objective measures of function are often used to assess response to therapy.

Approved Indications

- A. Generalized myasthenia gravis (gMG) in adult patients (Vyvgart and Vyvgart Hytrulo)
- B. Chronic inflammatory demyelinating polyneuropathy (CDIP) in adults patients (Vyvgart Hytrulo only)

Other Uses

- A. None.

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Medical Necessity Guidelines:

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo) single – dose vial

Note: Vyvgart Hytrulo prefilled syringe is not covered under this medical policy.

Clinical criteria for Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) for **generalized myasthenia gravis**:

A. Criteria For Initial Approval (*Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.*)

Initial requests for Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) for *generalized myasthenia gravis* may be approved if the following criteria are met:

- i. Individual is 18 years of age or older; **AND**
- ii. Individual has a diagnosis of generalized myasthenia gravis (gGM); **AND**
- iii. Individual has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV disease; **AND**
- iv. Documentation is provided that individual has a Myasthenia Gravis Activities of Daily Living (MG-ADL) score of at least 5 or higher; **AND**
- v. Documentation is provided that individual meets *both* of the following (A and B):
 - A. Individual meets *one* of the following:
 1. Individual has had a trial and inadequate response or intolerance to an acetylcholinesterase inhibitor; **OR**
 2. Individual is on a stable dose of an acetylcholinesterase inhibitor; **OR**
 3. Individual has a contraindication to acetylcholinesterase inhibitors; **AND**
 - B. Individual meets *one* of the following:
 1. Individual has had a trial and inadequate response or intolerance to one or more immunosuppressive agents (including but not limited to systemic corticosteroids or non-steroidal immunosuppressants); **OR**
 2. Individual is on a stable dose of one or more immunosuppressive agents (including but not limited to systemic corticosteroids or non-steroidal immunosuppressants); **OR**
 3. Individual has a contraindication to systemic corticosteroids and non-steroidal immunosuppressants.

B. Criteria For Continuation of Therapy

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MMM considers continuation of Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) for **generalized myasthenia gravis** therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) when there is no evidence of unacceptable toxicity or disease progression while on the current regimen, and the recommended duration of therapy has not been exceeded. The following information should be submitted for reauthorization:

- i. Reduction in signs or symptoms that impact daily function; **AND**
- ii. Documentation is provided to show at least a 2-point reduction in MG-ADL total score from pretreatment baseline; **AND**
- iii. Individual requires continued treatment to maintain response or to regain clinically meaningful response.

C. Authorization Duration

- i. Initial Approval Duration: 26 weeks
- ii. Reauthorization Approval Duration: 12 months

Clinical criteria for Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) for **chronic inflammatory demyelinating polyneuropathy**:

A. Criteria For Initial Approval *(Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

Initial requests for Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) for *chronic inflammatory demyelinating polyneuropathy* may be approved if the following criteria are met:

- i. Individual is 18 years of age or older; **AND**
- ii. Individual has a diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP); **AND**
- iii. Diagnosis has been verified by all of the following:
 - A. Clinical presentation aligned with one of the following (EAN/PNS 2021):
 1. Typical CIDP; defined as progressive or relapsing symmetric proximal and distal muscle weakness of upper and lower limbs, sensory involvement of at least two limbs, developing over at least 8 weeks, and absent or reduced tendon reflexes in all limbs; **OR**
 2. CIDP variant; defined as one of the following phenotypes that otherwise aligns with CIDP: distal, asymmetric/multifocal, focal, pure motor, or pure sensory; **AND**
 - B. Characteristic electrodiagnostic findings (prolongation of motor distal latency, reduction of motor conduction velocity, prolongation of F-wave latency, absence of F-waves, motor conduction block, abnormal temporal dispersion, and distal compound muscle action potential (CMAP) duration increase) in at least two motor nerves, with

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sensory conduction abnormalities in at least two nerves, consistent with EAN/PNS 2021 criteria; **AND**

C. Other causes of neuropathy (including but not limited to drug or toxin induced neuropathy, Lyme disease, IgM neuropathy, hereditary neuropathy, prominent sphincter disturbance, multifocal motor neuropathy, and diabetic neuropathy) have been ruled out (EAN/PNS 2021); **AND**

- iv. Documentation is provided that individual demonstrates objective functional impairment from CIDP (including but not limited to requiring support to walk or upper limb symptoms affecting or preventing ability to perform certain functions [such as zips and buttons, washing or brushing hair, using a knife and fork together, or handling small coins]); **AND**
- v. Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) is prescribed by or in consultation with a neurologist; **AND**
- vi. Documentation is provided that individual has had a trial and inadequate response or intolerance to one of the following (EAN/PNS 2021):
 - A. Immunoglobulins (intravenous or subcutaneous); **OR**
 - B. Plasma Exchange; **OR**
 - C. Corticosteroids (daily oral or pulsed high-dose)

B. Criteria For Continuation of Therapy

MMM considers continuation of Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) for *chronic inflammatory demyelinating polyneuropathy* therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) when there is no evidence of unacceptable toxicity or disease progression while on the current regimen. The following information should be submitted for reauthorization:

- i. Documentation is provided that there is clinically significant improvement in neurological symptoms on physical examination (for example, an objective change in function that is clinically meaningful, such as the individual can now work or perform tasks that they previously could not) or stabilization of neurological function compared with pretreatment baseline.

C. Authorization Duration

- i. Initial Approval Duration: 6 months
- ii. Reauthorization Approval Duration: 12 months

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

Requests for Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) may not be approved for the following:

- i. Individual is using in combination with maintenance immunoglobulin treatment, eculizumab, nupoccalimab, ravulizumab, rituximab, zilucoplan, or rozanolixizumab-noli; **OR**

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- ii. When the above criteria are not met and for all other indications.

Efgartigimod alfa-fcab (Vyvgart)

- A. Criteria For Initial Approval** (*Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.*)

Initial requests for Vyvgart (efgartigimod alfa-fcab) for *generalized myasthenia gravis* may be approved if the following criteria are met:

- i. Individual is 18 years of age or older; **AND**
- ii. Individual has a diagnosis of generalized myasthenia gravis (gMG); **AND**
- iii. Individual has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV disease; **AND**
- iv. Documentation is provided that individual has a Myasthenia Gravis Activities of Daily Living (MG-ADL) score of at least 5 or higher; **AND**
- v. Documentation is provided that individual meets both of the following (A and B):
 - A. Individual meets one of the following:
 1. Individual has had a trial and inadequate response or intolerance to an acetylcholinesterase inhibitor; **OR**
 2. Individual is on a stable dose of an acetylcholinesterase inhibitor; **OR**
 3. Individual has a contraindication to acetylcholinesterase inhibitors; **AND**
 - B. Individual meets one of the following:
 1. Individual has had a trial and inadequate response or intolerance to one or more
 2. Immunosuppressive agents (including but not limited to systemic corticosteroids or non-steroidal immunosuppressants); **OR**
 3. Individual has had a trial and inadequate response or intolerance to one or more immunosuppressive agents (including but not limited to systemic corticosteroids or non-steroidal immunosuppressants); **OR**

B. Criteria For Continuation of Therapy

MMM considers continuation of Vyvgart (efgartigimod alfa-fcab) therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) when there is no evidence of unacceptable toxicity or disease progression while on the current regimen. The following information should be submitted for reauthorization:

- i. Reduction in signs or symptoms that impact daily function; **AND**
- ii. Documentation is provided to show at least a 2-point reduction in MG-ADL total score from pretreatment baseline.
- iii. Individual requires continued treatment to maintain response or to regain clinically meaningful response.

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C. Authorization Duration

- i. Initial Approval Duration: 26 weeks
- ii. Reauthorization Approval Duration: 12 months

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

Requests for Vyvgart (efgartigimod alfa-fcab) may not be approved for the following:

- i. Individual is using in combination with maintenance immunoglobulin treatment, eculizumab, nipocalimab, ravulizumab, rituximab, zilucoplan, or rozanolixizumab-noli; **OR**
- ii. When the above criteria are not met and for all other indications.

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Limits or Restrictions:

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Vyvgart (efgartigimod alfa-fcab) Quantity Limit

Drug	Weight	Recommended Dosage
Vyvgart (efgartigimod alfa-fcab) 400 mg/20 mL single-dose vial	Less than 120 kg	10 mg/kg IV once weekly for 4 weeks (4 weeks = 1 cycle) *
	120 kg and above	1200 mg (total of 3 vials) once weekly for 4 weeks (4 weeks = 1 cycle)*
Exceptions		
- May approve for additional treatment cycles (4 weeks = 1 cycle) based on clinical relapse/response, but no sooner than 50 days from the start of the previous treatment cycle. - Administer subsequent treatment cycles based on clinical evaluation.		

Vyvgart Hytrulo (efgartigimod alfa-fcab and hyaluronidase-qvfc) Quantity Limit

Drug	Recommended Dosage	Treatment Duration	Limit
<i>Generalized Myasthenia Gravis (gMG)</i>			
Vyvgart Hytrulo 1,008 mg efgartigimod alfa and 11,200 units hyaluronidase (180mg/2,000 units per mL) in a single dose vial.	1,000 mg efgartigimod alfa and 10,000 units hyaluronidase administered over 20 to 30 seconds.	- Administer in cycles of once weekly injections for 4 weeks. - Administer subsequent treatment cycles based on clinical evaluation.	4 vials per 28 days
<i>Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)</i>			
Vyvgart Hytrulo 1,008 mg efgartigimod alfa and 11,200 units hyaluronidase	1,000 mg efgartigimod alfa and 10,000 units	Administer as once weekly injections.	4 vials per 28 days

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(180mg/2,000 units per mL) in a single dose vial.	hyaluronidase administered over approximately 20 to 30 seconds.		
Exceptions			
- Vyvgart Hytrulo is for subcutaneous use only. - Prefilled syringe can be administered by patients and/or caregivers. - Vial to be administered with a winged infusion set by a healthcare professional only.			

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Codes Information:

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

ICD-10 Diagnostic Codes:

Codes	Description
G61.81	Chronic inflammatory demyelinating polyneuritis
G70.00-G70.01	Myasthenia gravis

HCPCS Codes:

Codes	Description
J9334	Injection, efgartigimod alfa, 2 mg and hyaluronidase-qvfc [Vyvgart Hytrulo]
J9332	Injection, efgartigimod alfa-fcab, 2mg [Vyvgart]

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Reference Information:

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2. argenx BV and Halozyme, Inc. (2026). Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) injection, for subcutaneous use: Prescribing information. Revised May 2026. Accessed June 19, 2026.
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11. Joint Task Force of the EFNS and the PNS (2010) European Federation of Neurological Societies/Peripheral Nerve Society Guidelines on management of paraproteinemic demyelinating neuropathies. Report of a Joint Task Force of the European Federation of Neurological Societies and the Peripheral Nerve Society—First revision. *Journal of the Peripheral Nervous System*, 15, 185-195.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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Policy History:

Type of Review	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Annual Review	Updated Service Description, Background Information, and Approved Indications to remove the anti-acetylcholine receptor (AChR) antibody-positive restriction from the gMG indication and clinical criteria for approval for both products. Updated Vyvgart Hytrulo chronic inflammatory demyelinating polyneuropathy criteria to align with current diagnostic terminology and EAN/PNS 2021 guidance, and revised continuation language to focus on ongoing clinical benefit rather than fixed maximum treatment duration. Added nivalimab to combination exclusion criteria for myasthenia gravis. Updated quantity limits table for Vyvgart by adding treatment duration; and recommended dosage and treatment duration for Vyvgart Hytrulo. Updated reference information. Coding reviewed: no changes. Wording and formatting changes, including incorporation of new policy template.	8/14/2026	8/19/2026
Policy Inception	8/28/25: Elevance Health Policy Adoption	9/5/2025	9/16/2025