Medical Policy Bulletin

Title:
Efgartigimod-alfa-fcab (Vyvgart™) and efgartgimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo)
Policy #:
MA08.142e

The Company makes decisions on coverage based on the Centers for Medicare and Medicaid Services (CMS) regulations and guidance, benefit plan documents and contracts, and the member's medical history and condition. If CMS does not have a position addressing a service, the Company makes decisions based on Company Policy Bulletins. Benefits may vary based on contract, and individual member benefits must be verified. The Company determines medical necessity only if the benefit exists and no contract exclusions are applicable. Although the Medicare Advantage Policy Bulletin is consistent with Medicare's regulations and guidance, the Company's payment methodology may differ from Medicare.

When services can be administered in various settings, the Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition. This decision is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of this service.

This Policy Bulletin document describes the status of CMS coverage, medical terminology, and/or benefit plan documents and contracts at the time the document was developed. This Policy Bulletin will be reviewed regularly and be updated as Medicare changes their regulations and guidance, scientific and medical literature becomes available, and/or the benefit plan documents and/or contracts are changed.

Policy

Coverage is subject to the terms, conditions, and limitations of the member's Evidence of Coverage.

In the absence of coverage criteria from applicable Medicare statutes, regulations, NCDs, LCDs, CMS manuals, or other Medicare coverage documents, this policy uses internal coverage criteria developed by the Company in consideration of peer-reviewed medical literature, clinical practice guidelines, and/or regulatory status.

The Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition.

MEDICALLY NECESSARY

EFGARTIGIMOD ALFA-FCAB (VYVGART) AND EFGARTIGIMOD ALFA AND HYALURONIDASE-QVFC (VYVGART HYTRULO)

Generalized myasthenia gravis (gMG)

Efgartigimod alfa-fcab (Vyvgart) and efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo) are considered medically necessary and, therefore, covered for the treatment of adult individuals with generalized myasthenia gravis (gMG) when all of the following criteria are met including dosing and frequency:

- The individual is anti-acetylcholine receptor (AChR) antibody-positive.
- The individual meets Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV.
- The individual has a Myasthenia Gravis–Specific Activities of Daily Living scale (MG-ADL) total score of five or greater.
- The individual is on a stable dose of gMG therapy either in combination or alone of any of the following medications:
    - Acetylcholinesterase (AChE) inhibitors

    - Steroids
    - Nonsteroidal immunosuppressive therapies (NSISTs)
- Dosing and frequency for:
    - Efgartigimod alfa-fcab (Vyvgart)*
        - The recommended dosage is 10 mg/kg administered as an intravenous infusion over 1 hour once weekly for 4 weeks.
        - In individuals weighing 120 kg or more, 1200 mg per infusion.
    - Efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo)* once weekly injections for 4 weeks:
        - Prefilled syringe: 1000 mg efgartigimod alfa and 10,000 units hyaluronidase
        - Vial: 1008 mg efgartigimod alfa and 11,200 units hyaluronidase

*Per package insert: subsequent treatment cycles based on clinical evaluation; safety of initiating subsequent cycles sooner than 50 days from the start of the previous treatment cycle has not been established.

EFGARTIGIMOD ALFA AND HYALURONIDASE-QVFC (VYVGART HYTRULO)

Chronic inflammatory demyelinating polyneuropathy (CIDP)

Efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo) is considered medically necessary and, therefore, covered for the treatment of adult individuals with chronic inflammatory demyelinating polyneuropathy (CIDP) when all of the following criteria are met:

- The individual is 18 years of age or older
- The individual has a diagnosis of CIDP when all of the following criteria are met:
    - The individual has progressive or relapsing motor or sensory impairment caused by neuropathy in more than one limb for at least 2 months
    - The individual has at least one of the following electrodiagnostic findings of demyelination:
        - Motor distal latency prolongation in two nerves
        - Reduction of motor conduction velocity in two nerves
        - Prolongation of F-wave latency in two nerves
        - Absence of F waves in at least one nerve
        - Motor conduction block in at least one nerve
        - Abnormal temporal dispersion in at least two nerves
        - Distal compound muscle action potential (CMAP) duration increase in at least one nerve
- The individual is being treated by or under the supervision of a neurologist
- The individual has had previous treatment with, or has contraindication or intolerance to, an intravenous immune globulin (IVIG) or subcutaneous immune globulin (SCIG) product
- Dosing and frequency for efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo) once weekly injections for 4 weeks:
    - Prefilled syringe: 1000 mg efgartigimod alfa and 10,000 units hyaluronidase
    - Vial: 1008 mg efgartigimod alfa and 11,200 units hyaluronidase

NOTE: Evio has been selected by the Company to administer clinical outcomes monitoring for individuals receiving certain high-cost drug therapies. Vyvgart and Vyvgart Hytrulo are included in the portfolio of high-cost drug/biologic therapies for which Evio will be tracking clinical outcomes. If an individual meets all medical policy criteria, the requesting professional provider and/or individual being treated must agree to providing clinical outcomes data and information via Evio's secure web portal as requested.

EXPERIMENTAL/INVESTIGATIONAL

All other uses for efgartigimod alfa-fcab (Vyvgart) and efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo), are considered experimental/investigational and, therefore, not covered unless the indication is supported as an accepted off-label use, as defined in the Company medical policy on off-label coverage for prescription drugs and biologics.

REQUIRED DOCUMENTATION

An individual's medical record must reflect the medical necessity for the care provided. These medical records may include but are not limited to: records from the professional provider's office, hospital, nursing home, home health agencies, therapies, and test reports.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation is to be available to the Company upon request. Failure to produce the requested information may result in a denial for the service.

When coverage of efgartigimod alfa-fcab (Vyvgart) or efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo) is requested outside of the Dosing and Frequency Requirements listed in this policy, the prescribing professional provider must supply documentation (i.e., published peer-reviewed literature) to the Company that supports this request.

BILLING REQUIREMENTS

For drugs that have more than one method of administration, the appropriate modifier must be appended to indicate the route of administration. To report the intravenous route of administration, append the following modifier: **JA** Administered Intravenously

Inclusion of a code in this policy does not imply reimbursement. Eligibility, benefits, limitations, exclusions, utilization management/referral requirements, provider contracts, and Company policies apply.

Guidelines

There is no Medicare coverage determination addressing efgartigimod-alfa and hyaluronidase-qvfc (Vyvgart Hytrulo); therefore, the Company policy is applicable.

DRUG INFORMATION

In accordance with US Food and Drug Administration (FDA) prescribing information, efgartigimod alfa-fcab (Vyvgart) is administered as an intravenous infusion, 10 mg/kg over 1 hour once weekly for 4 weeks. In individuals weighing 120 kg or more, the recommended dose of efgartigimod alfa-fcab (Vyvgart) is 1200 mg per infusion. Efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo) is administered subcutaneously, 1008 mg/11,200 units (1008 mg efgartigimod-alfa and 11,200 units hyaluronidase) over approximately 30 to 90 seconds in cycles of once weekly injections for 4 weeks.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, efgartigimod alfa-fcab (Vyvgart) and efgartigimod-alfa and hyaluronidase-qvfc (Vyvgart Hytrulo) are covered under the medical benefits of the Company's products when the medical necessity criteria listed in this medical policy are met.

MYASTHENIA GRAVIS FOUNDATION OF AMERICA (MGFA) CLINICAL CLASSIFICATION

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.

A. IIa. Predominantly affecting limb, axial muscles, or both. May also have lesser involvement of oropharyngeal muscles.
B. 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.

A. IIIa. Predominantly affecting limb, axial muscles, or both. May also have lesser involvement of oropharyngeal muscles.
B. 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.

A. IVa. Predominantly affecting limb, axial muscles, or both. May also have lesser involvement of oropharyngeal muscles.

B. 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 individual in class IVb.

MG Activities of Daily Living (MG-ADL) Profile

Grade	**Score**			
Activities of Daily Living (ADL)	0	1	2	3
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

US FOOD AND DRUG ADMINISTRATION (FDA) STATUS

Efgartigimod alfa-fcab (Vyvgart) was approved by the FDA on December 17, 2021, for the treatment of generalized myasthenia gravis (gMG) in adult individuals who are anti-acetylcholine receptor (AChR) antibody positive.

Efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo) was approved by the FDA on June 20, 2023, for the treatment of gMG in adult individuals who are anti-acetylcholine receptor (AChR) antibody positive.

PEDIATRIC USE

The safety and effectiveness of efgartigimod alfa-fcab (Vyvgart) or efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo) for gMG have not been established in the pediatric population.

Description

GENERALIZED MYASTHENIA GRAVIS

Generalized myasthenia gravis (gMG) is a chronic autoimmune neuromuscular disease that causes weakness in the skeletal muscles. The muscle weakness usually worsens after periods of activity and improves after periods of rest. Muscles that control movements of the eye and eyelid, facial expression, chewing, talking, and swallowing are often involved, but those that control breathing and neck and limb movements may also be involved. This weakness is a result of an antibody-mediated, T-cell dependent, immunological attack directed at proteins in the postsynaptic membrane of the neuromuscular junction. MG has an annual incidence of about 7 to 23 cases per million. It most often begins before the age of 40 in women and after age 60 in men.

CHRONIC INFLAMMATORY DEMYELINATING POLYNEUROPATHY (CIDP)

CIDP is an autoimmune condition that affects the myelin sheath around the peripheral nerves. This causes worsening symptoms, like muscle weakness and abnormal sensations, over at least 8 weeks. CIDP is treatable, but it can come back (relapse), which may require ongoing treatment.

PEER-REVIEWED LITERATURE

SUMMARY

The safety, efficacy, and tolerability of efgartigimod alfa-fcab (Vyvgart) was demonstrated in the multicenter, randomized, placebo-controlled Phase 3 ADAPT trial. The ADAPT trial demonstrated that significantly more anti-AChR antibody-positive generalized myasthenia gravis (gMG) individuals responded, based on the Myasthenia Gravis Activities of Daily Living (MG-ADL) scale, following treatment with efgartigimod alfa-fcab (Vyvgart) compared with placebo (68% vs. 30%; *P*<0.0001). Responders were defined as having at least a two-point reduction on the MG-ADL scale sustained for 4 or more consecutive weeks during the first treatment cycle. Additionally, there were significantly more responders on the Quantitative Myasthenia Gravis (QMG) scale following treatment with efgartigimod alfa-fcab (Vyvgart) compared with placebo (63% vs. 14%; *P*<0.0001). Responders were defined as having at least a three-point reduction on the QMG scale sustained for 4 or more consecutive weeks during the first treatment cycle. The most common adverse events in the ADAPT trial were respiratory tract infection (33% vs. 29% placebo), headache (32% vs. 29% placebo), and urinary tract infection (10% vs. 5% placebo).

The ADAPT trial established the effectiveness of efgartigimod alfa-fcab (Vyvgart) intravenous (IV) formulation for the treatment of AChR antibody positive gMG in adult individuals. In the trial ADAPTsc , efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo) demonstrated a comparable pharmacodynamic effect on AChR antibody reduction to the efgartigimod alfa-fcab (Vyvgart) IV formulation, which established the efficacy of efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo) . This study enrolled 110 randomly assigned individuals who received one cycle of once weekly administrations for 4 weeks, of either efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo) subcutaneously (n=55) or efgartigimod alfa-fcab (Vyvgart) intravenously (n=55).

The maximum mean reduction in AChR-Ab level was observed at week 4, with a mean reduction of 62.2% and 59.7% in the efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo) SC and efgartigimod alfa-fcab (Vyvgart) IV arm, respectively. The decrease in total IgG levels followed a similar pattern.

The ost common adverse events were injection site reactions and occurred in 38% of individuals receiving efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo).

The primary endpoint was met, with a comparable mean reduction in total IgG with the subcutaneous versus the IV formulation. Secondary endpoints were met in 69.1% of individuals who responded on the MG-ADL score and 65.5% of individuals who responded on the QMG-score. From this study, individuals could enter an open label to receive efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo) to evaluate the long-term safety and tolerability of subcutaneous formulation.

In a placebo-controlled study in individuals with CIDP (Study 3, stage B), 221 individuals were randomly assigned to receive once-weekly administration of either efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo) 1008 mg/11,200 units subcutaneously (n=111) or placebo (n=110) [see Clinical Studies (14.2)]. The mean duration of treatment with efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo) in stage B was 25 weeks. The overall safety profile observed in individuals with CIDP treated with efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo) was consistent with the known safety profile of efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo) and of efgartigimod alfa-fcab (Vyvgart) administered intravenously.

In Study 3, injection site reactions occurred in 15% of individuals treated with efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo) compared to 6% of individuals who received placebo. The most common of these injection

site reactions were injection site bruising and injection site erythema. All injection site reactions were mild to moderate in severity. Most injection site reactions occurred during the first 3 months of treatment.

OFF-LABEL INDICATIONS

There may be additional indications contained in the policy section of this document due to evaluation of criteria highlighted in the company's off-label policy, and/or review of clinical guidelines issued by leading professional organizations and government entities.

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Coding

Inclusion of a code in this table does not imply reimbursement. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

The codes listed below are updated on a regular basis, in accordance with nationally accepted coding guidelines. Therefore, this policy applies to any and all future applicable coding changes, revisions, or updates.

In order to ensure optimal reimbursement, all health care services, devices, and pharmaceuticals should be reported using the billing codes and modifiers that most accurately represent the services rendered, unless otherwise directed by the Company.

The Coding Table lists any CPT, ICD-10, and HCPCS billing codes related only to the specific policy in which they appear.

CPT Procedure Code Number(s)
N/A

ICD - 10 Procedure Code Number(s)
N/A

ICD - 10 Diagnosis Code Number(s)
Report the most appropriate diagnosis code in support of medically necessary criteria as listed in the policy.

HCPCS Level II Code Number(s)
J9332 Injection, efgartigimod alfa-fcab, 2mg

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

Revenue Code Number(s)
N/A

Policy History

Revisions From MA08.142e:

03/20/2026	This version of the policy will become effective 03/20/2026.
	
	The following was added to this policy:
	
	• Dosing and frequency for:
	  ○ Efgartigimod alfa-fcab (Vyvgart)*
	  ▪ The recommended dosage is 10 mg/kg administered as an intravenous infusion over 1 hour once weekly for 4 weeks.
	  ▪ In individuals weighing 120 kg or more, 1200 mg per infusion.
	  ○ Efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo)* once weekly injections for 4 weeks:
	
	  ▪ Prefilled syringe: 1000 mg efgartigimod alfa and 10,000 units hyaluronidase
	  ▪ Vial: 1008 mg efgartigimod alfa and 11,200 units hyaluronidase
	
	All of the ICD-10 CM codes have been removed from this policy. Report on the most appropriate diagnosis code in support of medically necessary criteria as listed in the policy.

Revisions From MA08.142d:

12/15/2025	This policy has been reissued in accordance with the Company's annual review process.

12/16/2024	This version of the policy will become effective 12/16/2024. This policy has been updated to communicate the Company's coverage position and criteria for efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo) for chronic inflammatory demyelinating polyneuropathy (CIDP). The following have been **added** to this policy: NOTE: Evio has been selected by the Company to administer clinical outcomes monitoring for individuals receiving certain high-cost drug therapies. Vygart and Vyvgart Hytrulo are included in the portfolio of high-cost drug/biologic therapies for which Evio will be tracking clinical outcomes. If an individual meets all medical policy criteria, the requesting profecional provider and/or individual being treated must agree to providing clinical outcomes data and information via Evio's secure web portal as requested. This language was approved by Medical Claim Payment Policy management and the Legal team. The following ICD-10 code has been **added** to this policy: G61.81 Chronic inflammatory demyelinating polyneuritis

Revisions From MA08.142c:

01/02/2024	This policy has been identified for the HCPCS code update, effective 01/02/2024. The following HCPCS codes **termed** from this policy: C9399 Unclassified drugs or biologics J3590 Unclassified biologics The following HCPCS code has been **added** to this policy: J9334 Injection, efgartigimod alfa, 2 mg and hyaluronidase-qvfc

Revisions From MA08.142b:

10/09/2023	This version of the policy will become effective 10/09/2023. This policy has been updated to communicate the Company's coverage position and criteria for hyaluronidase-qvfc (Vyvgart Hytrulo). The following HCPCS codes have been **added** to this policy: THE FOLLOWING CODES ARE USED TO REPRESENT HYALURONIDASE-QVFC (VYVGART HYTRULO®): C9399 Unclassified drugs or biologics J3590 Unclassified biologics

Revisions From MA08.142a:

09/05/2023	This policy has been reissued in accordance with the Company's annual review process.
07/01/2022	This policy has been identified for the HCPCS code update, effective 07/01/2022. The following HCPCS codes **termed** from this policy: C9399 Unclassified drugs or biologics J3590 Unclassified biologics The following HCPCS codes have been **added** to this policy:

	J9332 Injection, efgartigimod alfa-fcab, 2mg

Revisions From MA08.142:

3/14/2022	This version of the policy will become effective 3/14/2022. This new policy has been issued to communicate the Company's coverage position and criteria for efgartigimod-alfa (Vyvgart).

Version Effective Date:
03/20/2026
Version Issued Date:
03/20/2026
Version Reissued Date:
N/A