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## DRUG POLICY

# Vyvgart (efgartigimod alfa-fcab) Vyvgart Hytrulo (efgartigimod alfa/hyaluronidase-qvfc)

### NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

### BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

### DESCRIPTION

The intent of the Vyvgart (efgartigimod alfa-fcab)/Vyvgart Hytrulo (efgartigimod alfa/hyaluronidase-qvfc) drug policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

#### FDA-Approved Indication

Vyvgart and Vyvgart Hytrulo are indicated for the treatment of adult patients with generalized myasthenia gravis (gMG).

Vyvgart Hytrulo is indicated for the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP).

### POLICY

#### Documentation

Submission of the following information is necessary to initiate the prior authorization review:

A. Myasthenia gravis

1. For initial requests: Chart notes, medical records, or claims history documenting:
  - i. Clinical classification of myasthenia gravis score
  - ii. MG activities of daily living score (MG-ADL)
  - iii. Use of an acetylcholinesterase (AChE) inhibitor, steroid, non-steroidal immunosuppressive therapy (NSIST), and/or intravenous immunoglobulin (IVIG) where applicable
  - iv. Prior chronic treatment with plasmapheresis or plasma exchange (if applicable)
2. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

B. Chronic inflammatory demyelinating polyneuropathy (CIDP) (Vyvgart Hytrulo Only)

1. For initial requests: Chart notes, medical records, or claims history documenting:
  - i. Pre-treatment electrodiagnostic studies (electromyography [EMG] or nerve conduction studies [NCS])
  - ii. Previous therapies tried (e.g., immunoglobulins, corticosteroids, or plasma exchange), including response to therapy. If therapy is not advisable, documentation of clinical reasons to avoid therapy.
2. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

Criteria for Initial Approval

A. Vyvgart (efgartigimod alfa-fcab) and Vyvgart Hytrulo (efgartigimod alfa/hyaluronidase-qvfc) may be considered **medically necessary** for the treatment of generalized myasthenia gravis (gMG) when all of the following criteria are met:

1. Member has Myasthenia Gravis Foundation of America (MGFA) clinical classification II to IV
2. Member has a MG activities of daily living (MG-ADL) total score of greater than or equal to 5
3. Member had an inadequate response with two or more conventional therapies (e.g., pyridostigmine, corticosteroids, immunosuppressant such as azathioprine, cyclosporine, mycophenolate, etc.) OR member required chronic treatment with plasmapheresis, plasma exchange (PE) or intravenous immunoglobulin (IVIG) in addition to immunosuppressant therapy
4. Member is on a stable dose of at least one of the following:
  - a. Acetylcholinesterase inhibitors (e.g., pyridostigmine)
  - b. Steroids (at least 3 months of treatment)
  - c. Nonsteroidal immunosuppressive therapy (NSIST) (at least 6 months of treatment) (e.g., azathioprine, mycophenolate mofetil)
5. The requested medication will not be used in combination with another neonatal Fc receptor blocker (e.g., Rystiggo) or complement inhibitor (e.g., Soliris, Ultomiris, Zilbrysq)

**Approval is for 6 months.**

B. Vyvgart Hytrulo (efgartigimod alfa/hyaluronidase-qvfc) may be considered **medically necessary** for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) when all of the following criteria are met:

1. Disease course is progressive or relapsing/remitting for 2 months or longer

2. The diagnosis was confirmed by electrodiagnostic studies (consistent with EFNS/PNS guidelines)
3. Member meets one of the following:
  - a. Member has had an inadequate response or intolerable adverse event to immunoglobulins, corticosteroids, or plasma exchange
  - b. Member has a documented clinical reason to avoid therapy with immunoglobulins, corticosteroids, or plasma exchange

**Approval is for 6 months.**

#### Continuation of Therapy

- A. Vyvgart (efgartigimod alfa-fcab) and Vyvgart Hytrulo (efgartigimod alfa/hyaluronidase-qvfc) may be considered **medically necessary** for the continued treatment of generalized myasthenia gravis (gMG) when there is no evidence of unacceptable toxicity or disease progression while on the current regimen and member demonstrates a positive response to therapy (e.g., improvement in MG-ADL score, changes compared to baseline in Quantitative Myasthenia Gravis (QMG) total score).

**Approval is for 12 months.**

- B. Vyvgart Hytrulo (efgartigimod alfa/hyaluronidase-qvfc) may be considered **medically necessary** for the continued treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) when there is no evidence of unacceptable toxicity or disease progression while on the current regimen and member demonstrates a positive response to therapy (e.g., improvement in disability or maintenance of improvement since initiation of therapy)

**Approval is for 12 months.**

Vyvgart (efgartigimod alfa-fcab) and Vyvgart Hytrulo (efgartigimod alfa/hyaluronidase-qvfc) are considered **not medically necessary** for members who do not meet the criteria set forth above.

#### Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

| Medication                                                                                                                                                                                                                     | FDA-recommended dosing                                                                                                                                                                                                                                                                                                              |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Vyvgart (efgartigimod alfa-fcab) 400 mg/20 mL single-dose vial                                                                                                                                                                 | <ul style="list-style-type: none"> <li>The recommended dosage is 10 mg/kg administered as an intravenous infusion over one hour once weekly for 4 weeks. In patients weighing 120 kg or more, the recommended dose is 1200 mg per infusion.</li> <li>Administer subsequent treatment cycles based on clinical evaluation</li> </ul> |
| <p>Vyvgart Hytrulo (efgartigimod alfa/hyaluronidase-qvfc) 1,008 mg/11,200 units per 5.6 mL single-dose vial</p> <p>Vyvgart Hytrulo (efgartigimod alfa/hyaluronidase-qvfc) 1,000 mg/10,000 units per 5 mL prefilled syringe</p> | <p><u>Myasthenia gravis:</u></p> <ul style="list-style-type: none"> <li>The recommended dosage is 1,008 mg/11,200 units administered subcutaneously over approximately 30 to 90 seconds in cycles of once weekly injections for 4 weeks.</li> <li>Administer subsequent treatment cycles based on clinical evaluation</li> </ul>    |
| <p>Vyvgart Hytrulo (efgartigimod alfa/hyaluronidase-qvfc) 1,008 mg/11,200 units per 5.6 mL single-dose vial</p> <p>Vyvgart Hytrulo (efgartigimod alfa/hyaluronidase-qvfc) 1,000 mg/10,000 units per 5 mL prefilled syringe</p> | <p><u>Chronic inflammatory demyelinating polyneuropathy:</u></p> <ul style="list-style-type: none"> <li>The recommended dosage is 1,008 mg/11,200 units administered subcutaneously over approximately 30 to 90 seconds as once weekly injections.</li> </ul>                                                                       |

## PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT\* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J9332 – Injection, efgartigimod 2mg
- J9934 – Injection, efgartigimod alfa, 2 mg and hyaluronidase-qvfc (effective 1/1/24)
- J3590 – Unclassified biologic (when specified as [Vygart Hytrulo] (efgartigimod alfa and hyaluronidase-qvfc))
- C9399 – Unclassified drugs or biologicals (when specified as [Vygart Hytrulo] (efgartigimod alfa and hyaluronidase-qvfc))

## REFERENCES

- Vyvgart [package insert]. Boston, MA: Argenx US, Inc.; January 2024.

- Vyvgart Hytrulo [package insert]. Boston, MA: Argenx US. Inc.; June 2024.
- Sanders D, Wolfe G, Benatar M et al. International consensus guidance for management of myasthenia gravis. *Neurology*. 2021; 96 (3) 114-122.
- Howard JF, Bril V, Vu T, et al. Safety, efficacy, and tolerability of efgartigimod in patients with generalised myasthenia gravis (ADAPT): a multicentre, randomised, placebo-controlled, phase 3 trial. *Lancet Neurol*. 2021. 20:526-536.

\*Some content reprinted from CVSHealth

## POLICY HISTORY

**Policy #:** 05.04.56

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**Reviewed:** June 2026

**Revised:** June 2026

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