

## efgartigimod alfa-fcab (Vyvgart OR Vyvgart Hytrulo)

### Commercial Medical Benefit Drug Policy

#### Place of Service

Home Infusion Administration  
Infusion Center Administration  
Office Administration  
Outpatient Facility Administration

### Drug Details

**USP Category:** ANTIMYASTHENIC AGENTS

**Mechanism of Action:** Neonatal Fc receptor blocker

#### HCPCS:

J9332:Injection, efgartigimod alfa-fcab, 2mg

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

#### How Supplied:

Vyvgart: 400 mg/20 mL solution in a single-dose vial

Vyvgart Hytrulo: 1,008 mg efgartigimod alfa-11,200 units hyaluronidase/5.6 ml single dose vial

### Condition(s) listed in policy *(see coverage criteria for details)*

- Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) [Vyvgart Hytrulo ONLY]
- Generalized Myasthenia Gravis (gMG)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

### Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

**Vyvgart Hytrulo prefilled syringes:** Refer to the "Self-Administered Drugs" medical benefit drug policy for commercial plans.

**Vyvgart and Vyvgart Hytrulo vials** are managed under the Medical Benefit. Please submit clinical information for prior authorization review. For Vyvgart Hytrulo, please include medical rationale why medication cannot be home self-administered with the prefilled syringe.

Members with the following plans: PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct) may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

**CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION**

*MCG Care Guidelines, 19th edition, 2015*

ADMINISTRATION OF THIS DRUG IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted*)

1. Patient is starting new therapy with this drug (allowed for 4 doses). Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.
2. Patient is being re-initiated on this drug after being off therapy for at least 6 months (allowed for 4 doses). Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.
3. Additional clinical monitoring is required during administration as evidenced by one of the following:
  - a. Patient has experienced a previous severe adverse event on this drug based on documentation submitted.
  - b. Patient continues to experience moderate to severe adverse events on this drug based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
  - c. Patient is clinically unstable based on documentation submitted.
  - d. Patient is physically or cognitively unstable based on documentation submitted

**Coverage Criteria**

**The following condition(s) require Prior Authorization/Preservice.**

**Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) [Vyvgart Hytrulo ONLY]**

**Meets medical necessity if all the following are met:**

1. Age is consistent with the FDA-approved indication (18 years of age or older)
2. Prescribed by or in consultation with a neurologist
3. Inadequate response intolerable side effect, or contraindication to IVIG or SCIG
4. Not being used in combination with IVIG or SCIG
5. One of the following (a or b):
  - a. Typical chronic inflammatory demyelinating polyneuropathy (CIDP)
  - b. One of the following CIDP variants:
    - i. Multifocal acquired demyelinating polyneuropathy
    - ii. Distal chronic inflammatory demyelinating polyneuropathy
    - iii. Focal chronic inflammatory demyelinating polyneuropathy
    - iv. Motor chronic inflammatory demyelinating polyneuropathy
    - v. Sensory chronic inflammatory demyelinating polyneuropathy
6. One of the following (a or b):
  - a. Electrodiagnostic testing (nerve conduction studies) shows definite CIDP

- b. Electrodiagnostic testing shows possible CIDP, and two of the following to confirm the diagnosis: CSF examination, nerve biopsy, MRI, ultrasound

**Covered Doses:**

Vyvgart Hytrulo: 1,008 units/11,200 units given subcutaneously once weekly

**Coverage Period:**

Initial: 6 months

Reauthorization: Yearly as long as patient continues to respond to treatment (e.g., control of symptoms such as weakness, sensory loss, imbalance, pain) and/or improvement or maintenance of functional ability

**ICD-10:**

G61.81

**Generalized Myasthenia Gravis (gMG)**

**Meets medical necessity if all the following are met:**

Initial

1. Prescribed by or in consultation with a neurologist
2. Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score  $\geq 5$
3. Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV
4. Patient is on at least one treatment for generalized myasthenia gravis [i.e., acetylcholinesterase inhibitors, corticosteroids, or non-steroidal immunosuppressive therapies (NSISTs)]

Reauthorization

1. Patient's continued response to therapy as shown by one of the following:
  - a. Improvement of at least 2 points (reduction in score) in MG-ADL total score
  - b. Reduction in signs and symptoms of myasthenia gravis

**Covered Doses:**

one (1) treatment cycle (consists of 4 doses, one dose given weekly for 4 weeks) and subsequent cycles given no sooner than 28 days from the last administration of the previous treatment cycle

Vyvgart:

For patients < 120 kg: 10 mg/kg given intravenously

For patients  $\geq 120$  kg: 1,200 mg given intravenously

Vyvgart Hytrulo:

1,008 mg / 11,200 units given subcutaneously

**Coverage Period:**

Initial: 6 months

Reauthorization: one year

**ICD-10:**

G70.00, G70.01

### References

1. AHFS. Available by subscription at <http://www.lexi.com>
2. DrugDex. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
3. MCG Care Guidelines, 19th edition, 2015, Home Infusion Therapy, CMT: CMT-0009(SR)
4. Vyvgart (efgartigimod alfa) [prescribing information]. Boston, MA: Argenx US Inc; October 2025.
5. Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) [prescribing information]. Boston, MA: Argenx US Inc; November 2025.

### Review History

Date of Last Annual Review: 1Q2026

Changes from previous policy version:

- Clarify coverage period to include subsequent treatment cycles based on clinical evaluation. Rationale: Vyvgart and Vyvgart Hytrulo Prescribing Information

*Blue Shield of California Medication Policy to Determine Medical Necessity  
Reviewed by P&T Committee*