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 receiving their first course (4 doses in a course) of Vyvgart or is being re-initiated on Vyvgart after at least 6 months off therapy. *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

OR

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. Patient has experienced a previous severe adverse event on Vyvgart based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on Vyvgart based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
4. Patient is clinically unstable based on documentation submitted.
5. 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:
1. Prescribed by or in consultation with a neurologist
2. Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score ≥ 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)]

Covered Doses:
Vyvgart:
For patients < 120 kg: 10 mg/kg given intravenously once weekly for 4 weeks
For patients ≥ 120 kg: 1,200 mg given intravenously once weekly for 4 weeks
Vyvgart Hytrulo:
1,008 mg / 11,200 units given subcutaneously once weekly for 4 weeks

Coverage Period:
Initial: 1 treatment course (Consist of 4 doses; one dose given weekly for 4 weeks) as often as every 50 days for 6 months
Reauthorization: Yearly, based upon patient's continued response to therapy as shown by ONE of the following:
1. Improvement of at least 2 points (reduction in score) in MG-ADL total score
2. Reduction in signs and symptoms of myasthenia gravis

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; April 2025.
5. Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) [prescribing information]. Boston, MA: Argenx US Inc; April 2025.

Review History

Date of Last Annual Review: 1Q2025
Changes from previous policy version:

- Add coverage sensory chronic inflammatory demyelinating polyneuropathy CIDP variant - ***Rationale:*** 2021 European Academy of Neurology/ Peripheral Nerve Society guideline on diagnosis and treatment of CIDP
- Remove requirements for motor or sensory dysfunction and for tendon reflexes or gait ataxia involvement - ***Rationale:*** 2021 European Academy of Neurology/ Peripheral Nerve Society guideline on diagnosis and treatment of CIDP 14

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