blue california
Promise Health Plan

efgartigimod alfa-fcab (Vyvgart OR Vyvgart Hytrulo)

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 California Code of Regulations (CCR), Title 22, Section 51303 and 51313 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.

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

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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