Efgartigimod alfa-fcab (Vyvgart®) Efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo)	Place of Service Office Administration Home Infusion Administration Infusion Center Administration Outpatient Facility Administration HCPCS • **Vyvgart** (IV injection): **J9332** per 2 mg • **Vyvgart Hytrulo** (SC): **J9334** per 2 mg

Conditions listed in policy (*see criteria for details*)

- Generalized myasthenia gravis (gMG)

AHFS therapeutic class: Antimyasthenic Agents

Mechanism of action: Neonatal Fc receptor blocker

(1) Special Instructions and pertinent Information

Covered under the Medical Benefit: Please submit clinical information for prior authorization review.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Vyvgart® (efgartigimod alfa-fcab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Generalized myasthenia gravis (gMG)

1. Prescribed by or in consultation with a neurologist, **AND**
2. Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score ≥ 5, **AND**
3. Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV, **AND**
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

Intravenous:
For patients < 120 kg: 10 mg/kg IV once weekly for 4 weeks
For patients ≥ 120 kg: 1,200 mg IV once weekly for 4 weeks
Subcutaneous:
1,008 mg / 11,200 units (1,008 mg efgartigimod alfa and 11,200 units hyaluronidase) SC once weekly injections 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, OR
2. Reduction in signs and symptoms of myasthenia gravis

ICD-10:
G70.00, G70.01

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Vyvgart® (efgartigimod alfa-fcab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

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 in a single-dose vial

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- MCG™ Care Guidelines, 19th edition, 2015, Home Infusion Therapy, CMT: CMT-0009(SR)
- Vyvgart (efgartigimod alfa-fcab) [Prescribing information]. Boston, MA: Argenx; 12/2023.
- Vyvgart hytrulo (efgartigimod alfa-fcab and hyaluronidase-qvfc) [Prescribing information]. Boston, MA: Argenx, 12/2023.

(7) Policy Update

Date of last review: 1Q2024
Date of next review: 1Q2025
Changes from previous policy version:

- Generalized myasthenia gravis: Clarified reauthorization requirement to include clinical response (i.e., MG-ADL total score, signs and symptoms). *Rationale: Published literature supports MG-ADL score to assess clinical treatment response in myasthenia gravis.*

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee