Generic Name: efgartigimod alfa-fcab

Applicable Drugs: Vyvgart®

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/14/2025

Date Last Reviewed / Revised: 2/14/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met)

I. Documented diagnosis of one of the following conditions AND must meet ALL criteria listed:
   a. Generalized Myasthenia Gravis (gMG)
      i. MGFA clinical classification class II, III, or IV.
      ii. Documentation of a serologic test confirming the presence of acetylcholine receptor antibodies (AchR-Ab+).
      iii. Baseline Myasthenia Gravis-specific Activities of Daily Living scale (MG-ADL) total score of ≥ 5. See Other Criteria for MG-ADL scale criteria.
      iv. Patient has evidence of unresolved symptoms of gMG.
         1. Examples of unresolved symptoms include difficulty swallowing, difficulty breathing, or a functional disability resulting in the discontinuation of physical activity (e.g., double vision, talking, impairment of mobility).
      v. Member has documented treatment failure, intolerance, or contraindication to **both** of the following (1 and 2):
         1. Corticosteroids (at least 3 months of treatment)
         2. Nonsteroidal immunosuppressive therapy (at least one agent for at least 3 months of treatment) (e.g. azathioprine, cyclosporine, methotrexate, mycophenolate, etc.)

II. Patient is 18 years of age or older.

III. Treatment must be prescribed by or in consultation with a neurologist.

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- MGFA class I

- Active infection or sepsis
- Untreated hepatitis B, hepatitis C, or HIV with low CD4 count
- Coadministration with other immunomodulatory biologic therapies (e.g. rituximab, eculizumab, rozanolixizumab, zilucoplan, etc.)
- Coadministration with live vaccines
- Pregnancy
- Subsequent cycles initiated sooner than 50 days from the start of the previous treatment cycle.
- More than seven treatment cycles per year

OTHER CRITERIA

- The requested dosage must be appropriate based on the patient's weight. The recommended dosage is 10 mg/kg administered once weekly for 4 weeks, with a maximum dose of 1200 mg per infusion/injection. One cycle is equal to four weeks of treatment. Vyvgart for IV infusion is supplied in 400 mg/20 mL vials.
- The time between treatment cycles is customized based on patient response and clinical evaluation. Treatment cycles may not be more frequent than seven (7) cycles per year and a subsequent cycle may not be initiated sooner than 50 days from the start of the previous treatment cycle.

- MG-ADL Scoring Template:

Grade	0	1	2	3	Score
Talking	Normal	Intermittent slurring or nasal speech	Constant slurring or nasal, but can be understood	Difficult to understand speech	
Chewing	Normal	Fatigue with solid food	Fatigue with soft food	Gastric tube	
Swallowing	Normal	Rare episode of choking	Frequent choking necessitating changes in diet	Gastric tube	
Breathing	Normal	Shortness of breath with exertion	Shortness of breath at rest	Ventilator dependence	
Impairment of ability to brush teeth or comb hair	None	Extra effort, but no rest periods needed	Rest periods needed	Cannot do one of these functions	
Impairment of ability to arise from a chair	None	Mild, sometimes uses arms	Moderate, always uses arms	Severe, requires assistance	
Double vision	None	Occurs, but not daily	Daily, but not constant	Constant	
Eyelid droop	None	Occurs, but not daily	Daily, but not constant	Constant	
				Total Score:	

Wolfe GI, Herbelin L, Nations SP, Foster B, Bryan WW, Barohn RJ. Neurology 1999;52(7):1487-9

QUANTITY / DAYS SUPPLY RESTRICTIONS

- For patients < 120 kg: appropriate 10 mg/kg dose, not to exceed 12 vials (20 mL each) per 28-day cycle
- For patients ≥ 120 kg: 12 vials (20 mL each) per 28-day cycle
- For approved requests, quantity and supply limits will account for the time between treatment cycles. For example, if a patient's treatment plan includes a four-week cycle followed by a four-week break, the quantity and days supply limit will be calculated per 56-day period.

APPROVAL LENGTH

- **Authorization:** 6 months
- **Re-Authorization:** 6 months, with an updated letter of medical necessity or progress notes showing clinically significant improvement or maintenance with treatment and that the patient is adherent to treatment and the medication is tolerated. Clinical improvement or maintenance may be demonstrated by a ≥ 2-point reduction in MG-ADL score from baseline or by physician attestation that patient is continuing to derive benefit from treatment (as

evidenced by reductions in exacerbations, improvements in speech, swallowing, mobility, or respiratory function, etc.)

APPENDIX

N/A

REFERENCES

1. Vyvgart®. Prescribing information. argenx BV; Jan 2024. https://www.argenx.com/product/vyvgart-prescribing-information.pdf
2. Vyvgart® Hytrulo. Prescribing information. argenx BV; June 2024. https://www.argenx.com/product/vyvgart-hytrulo-prescribing-information.pdf
3. Howard JF,et. al., Safety, efficacy, and tolerability of efgartigimod in patients with generalized myasthenia gravis (ADAPT): a multicenter, randomized, placebo-controlled, phase 3 trial. *Lancet Neurol*. 2021 Jul;20(7):526-536. doi: 10.1016/S1474-4422(21)00159-9.
4. Narayanaswami P, International Consensus Guidance for Management of Myasthenia Gravis 2020 Update. *Neurology*. 2021; 96:114-122. doi:10.1212/WNL.0000000000011124
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6. argenx BV, Clinical Trial Protocol: A Randomized, Double-Blind, Placebo Controlled, Multicenter Phase 3 Trial to Evaluate the Efficacy, Safety and Tolerability of ARGX-113 in Patients with Myasthenia Gravis Having Generalized Muscle Weakness (ADAPT); 2018 Sep. https://classic.clinicaltrials.gov/ct2/show/ NCT03669588
7. argenx BV, argenx Reports Positive Topline Data from ADHERE Study of VYVGART Hytrulo in Patients with
8. Chronic Inflammatory Demyelinating Polyneuropathy. Press Release. Amsterdam, 2023. Accessed July 26, 2024. Available from https://www.argenx.com/sites/default/files/media-documents/Press-Release_ARGX_ADHERE_Data_Release.pdf
9. Muppidi S, Utilization of MG-ADL in myasthenia gravis clinical research and care. *Muscle Nerve*. 2022;65(6):630-639. doi:10.1002/mus.27476
10. Howard J, Supplemental to: Safety, efficacy, and tolerability of efgartigimod in patients with generalized myasthenia gravis (ADAPT): a multicenter, randomized, placebo-controlled, phase 3 trial. *Lancet Neurol* 2021; 20: 526–36.