

Vyvgart[®] (efgartigimod alfa-fcab) injection

When requesting Vyvgart[®] (efgartigimod alfa-fcab injection) the individual requiring treatment must be diagnosed with a FDA-approved indication or approved compendial use and meets the specific coverage guidelines.

FDA-approved Indication

Vyvgart is indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

Coverage Guidelines

Generalized Myasthenia Gravis (gMG)

The individual must meet **all** of the following criteria for initial authorization:

- Has a confirmed diagnosis of anti-acetylcholine receptor (AChR) antibody positive generalized myasthenia gravis;
- Is 18 years of age or older;
- Received or is currently receiving pyridostigmine unless failed, contraindicated or intolerant to pyridostigmine;
- Has evidence of unresolved symptoms of generalized myasthenia gravis, such as difficulty swallowing, difficulty breathing, or a functional disability resulting in the discontinuation of physical activity (e.g., double vision, talking, impairment of mobility); AND
- Meets the following criteria:
 - Myasthenia Gravis Foundation of America classification of II to IV; AND
 - Myasthenia Gravis Activities of Daily Living (MG-ADL) score ≥ 5 ; AND
- Vyvgart is prescribed by or in consultation with a neurologist.

For re-authorization:

- Is 18 years of age or older;
- The individual is continuing to receive benefits from Vyvgart therapy (e.g., reductions in exacerbations of myasthenia gravis; improvement in speech, swallowing, mobility, and respiratory function).
- Vyvgart is prescribed by or in consultation with a neurologist.

Approval duration (initial): 6 months

Approval duration (renewal): 12 months

Dosing Recommendations

For patients weighing < 120 kg, the recommended dose is 10 mg/kg administered as an intravenous infusion over one hour once weekly for 4 weeks.

For patients weighing ≥ 120 kg, the recommended dose is 1200 mg per infusion.

Administer subsequent treatment cycles based on clinical evaluation. The safety of initiating subsequent cycles sooner than 50 days from the start of the previous treatment cycle has not been established.

References

1. Vyvgart® intravenous infusion [prescribing information]. Boston, MA: Argenx; December 2021.
2. National Institute of Neurological Disorders and Stroke (NINDS). Myasthenia Gravis Fact Sheet. National Institutes of Health (NIH) Publication No. 17-768. Publication last updated: November 15, 2021. Available at: <https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Myasthenia-Gravis-Fact-Sheet>. Accessed on December 20, 2021.
3. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis. *Neurology*. 2016;87:419–425.
4. Narayanaswami P, Sanders DB, Wolfe G, et al. International Consensus Guidance for Management of Myasthenia Gravis: 2020 Update. *Neurology*. 2021 Jan 19;96(3):114-122.