

Vyvgart® (efgartigimod alfa-fcab) injection

Vyvgart® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)

When requesting efgartigimod alfa products (Vyvgart® and Vyvgart® Hytrulo) the individual requiring treatment must be diagnosed with an FDA-approved indication and meets the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indication

Vyvgart and Vyvgart Hytrulo are 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;
- Has 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);
- Has Myasthenia Gravis Foundation of America classification of II to IV;
- Has Myasthenia Gravis Activities of Daily Living (MG-ADL) score of 5 or greater;
- Vyvgart or Vyvgart Hytrulo is prescribed by or in consultation with a neurologist.

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

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

Approval duration (initial): 6 months

Approval duration (renewal): 12 months

Dosing Recommendation

Vyvgart

The recommended dosage is 10 mg/kg administered as an intravenous infusion over one hour once weekly for 4 weeks. In patients weighing 120 kg or more, 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.

Vyvgart Hytrulo

The recommended dosage is 1,008 mg/11,200 units (1,008 mg efgartigimod alfa and 11,200 units hyaluronidase) administered subcutaneously over approximately 30 to 90 seconds in cycles of once weekly for 4 weeks.

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; April 2022.
2. Vyvgart® Hytrulo subcutaneous injection. Boston, MA and San Diego, CA: Argenx and Halozyme; June 2023.
3. National Institute of Neurological Disorders and Stroke (NINDS). Myasthenia Gravis Fact Sheet. National Institutes of Health (NIH) Publication No. 17-768. Publication last updated: March 2020. Available at: https://www.ninds.nih.gov/sites/default/files/migrate-documents/myasthenia_gravis_e_march_2020_508c.pdf Accessed on June 12, 2023.
4. National Institute of Neurological Disorders and Stroke (NINDS). Myasthenia Gravis Fact Sheet. National Institutes of Health (NIH) Publication No. 17-768. Publication last updated: July 25, 2022. Available at: <https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Myasthenia-Gravis-Fact-Sheet>. Accessed on November 11, 2022.
5. Data on File. ADAPT-SC – Argenx. Received June 13, 2023.
6. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis. *Neurology*. 2016;87:419–425.
7. 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.