Vyvgart® (efgartigimod alfa-fcab)
Vyvgart® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)

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

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.

Vyvgart Hytrulo is indicated for the treatment of adult patients with:

- generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive
- chronic inflammatory demyelinating polyneuropathy (CIDP)

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.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) - *(Note: Applies to Vyvgart Hytrulo only)*

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

- Is 18 years of age or older;
- The diagnosis of CIDP is supported by electrodiagnostic studies;
- Had an inadequate efficacy or significant intolerance to previously tried intravenous or subcutaneous immune globulin (e.g., Gammagard Liquid, Gammaked, Gamunex-C, Privigen, Hizentra, HyQvia) unless contraindicated;
- Vyvgart Hytrulo is prescribed by or in consultation with a neurologist.

The individual must meet the following criterion for re-authorization:

- Has a clinically significant improvement in neurologic symptoms.

Approval duration (initial): gMG 6 months; CIDP 3 months
Approval duration (renewal): 12 months

Dosing Recommendations

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
Generalized myasthenia gravis (gMG)
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.

Chronic inflammatory demyelinating polyneuropathy (CIDP)
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 as once weekly injections.

References

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10. Van den Bergh PY, van Doorn PA, Hadden RD, et al. European Academy of Neurology/Peripheral Nerve Society guideline on diagnosis and treatment of chronic inflammatory demyelinating polyradiculoneuropathy: report of a joint task force – second revision. *J Peripher Nerv Syst*. 2021;26(3):242-368.
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