

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.

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

- generalized myasthenia gravis (gMG)
- chronic inflammatory demyelinating polyneuropathy (CIDP)

Coverage Guidelines

Generalized Myasthenia Gravis (gMG)

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

- 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.

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.

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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