

PHARMACY POLICY STATEMENT

Marketplace

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| DRUG NAME | Vyvgart (efgartigimod alfa-fcab) and Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) |
| BENEFIT TYPE | Medical |
| STATUS | Prior Authorization Required |

Vyvgart, approved by the FDA in December 2021, is indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive. Vyvgart is a first-in-class IgG1 antibody Fc fragment designed to reduce pathogenic IgG autoantibody levels by inhibiting IgG recycling via the neonatal Fc receptor (FcRn) and increasing IgG degradation. In the phase 3 ADAPT trial, Vyvgart intravenously administered met its primary endpoint, demonstrating clinically meaningful improvements in symptom severity compared with placebo and was generally well-tolerated. Vyvgart Hytrulo is a combination of efgartigimod and hyaluronidase for subcutaneous administration.

Myasthenia gravis is an autoimmune disorder affecting the neuromuscular junction. It is characterized by muscle weakness and fatigue. The cause is an antibody-mediated immunologic attack directed at proteins in the postsynaptic membrane of the neuromuscular junction, most commonly the acetylcholine receptor (90%). Autoantibodies attack the AChR, blocking or destroying the receptors and damaging the neuromuscular junction, which impairs neuromuscular transmission and prevents muscles from contracting, as acetylcholine is unable to activate its receptor. Ocular motility, swallowing, speech, mobility, and respiratory function can all be affected.

Pyridostigmine, an acetylcholinesterase inhibitor, is the initial drug of choice prescribed for MG. It eases symptoms by slowing the breakdown of acetylcholine. If control is inadequate, immunosuppressive treatment is added, such as prednisone and/or azathioprine. Other drugs are used in cases of severe or refractory MG or myasthenic crisis, which is an emergency.

Vyvgart (efgartigimod alfa-fcab) and Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) will be considered for coverage when the following criteria are met:

Generalized Myasthenia Gravis (gMG)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Member has a documented diagnosis of MGFA class II-IV myasthenia gravis (see appendix); AND
4. Lab result in chart notes shows the member is seropositive for AChR antibodies; AND
5. Member has tried and failed at least 1 conventional therapy:
 - A. pyridostigmine
 - B. corticosteroid for at least 3 months
 - C. non-steroid immunosuppressant (e.g., azathioprine) for at least 6 months.
6. **Dosage allowed/Quantity limit:**
 IV infusion (Vyvgart) or SubQ injection (Vyvgart Hytrulo) once weekly for 4 weeks (1 cycle).
 Subsequent treatment cycles may take place no sooner than 50 days from the start of the previous cycle.

Vyvgart-- Weight <120 kg: 10 mg/kg; Weight 120 kg or greater: 1200 mg (3 vials)

QL: 12 vials per 28 days; (1 vial= 20 mL).

Vyvgart Hytrulo-- 1,008 mg / 11,200 units (1,008 mg efgartigimod alfa and 11,200 units hyaluronidase)
QL: 4 vials per 28 days

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes must document clinically meaningful improvement in symptom severity and daily functioning compared to pre-treatment baseline (e.g., improved MG-ADL or QMG scores); AND
2. Treatment cycles are being prescribed at least 50 days apart.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Vyvgart (efgartigimod alfa-fcab) and Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

| DATE | ACTION/DESCRIPTION |
|------------|--|
| 01/19/2022 | New policy for Vyvgart created. |
| 07/03/2023 | Added Vyvgart Hytrulo to policy. Added reference. Split list of conventional drug trials. Added treatment cycle spacing to reauth. |

Appendix:

| MG Foundation of America (MGFA) Clinical Classification | |
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| Class I | any ocular weakness; all other muscle strength is normal |
| Class II | mild weakness affecting other than ocular muscles; may also have ocular weakness at any level |
| Class III | moderate weakness affecting other than ocular muscles; may also have ocular weakness at any level |
| Class IV | severe weakness affecting other than ocular muscles; may also have ocular weakness at any level |
| Class V | defined by intubation, with or without mechanical ventilation |

References:

1. Vyvgart [prescribing information]. argenx US, Inc.; 2022.
2. Howard JF Jr, Bril V, Vu T, et al. Safety, efficacy, and tolerability of efgartigimod in patients with generalised myasthenia gravis (ADAPT): a multicentre, randomised, placebo-controlled, phase 3 trial [published correction appears in Lancet Neurol. 2021 Aug;20(8):e5]. *Lancet Neurol.* 2021;20(7):526-536. doi:10.1016/S1474-4422(21)00159-9
3. Narayanaswami P, Sanders DB, Wolfe G, et al. International Consensus Guidance for Management of Myasthenia Gravis: 2020 Update. *Neurology.* 2021;96(3):114-122. doi:10.1212/WNL.0000000000001124
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6. Vyvgart Hytrulo [prescribing information]. argenx BV; 2023.
7. Alhaidar MK, Abumurad S, Soliven B, Rezania K. Current Treatment of Myasthenia Gravis. *J Clin Med.* 2022;11(6):1597. Published 2022 Mar 14. doi:10.3390/jcm11061597

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