Mass General Brigham
Health Plan

Vyvgart (efgartigimod alfa-fcab)
Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase)
Effective 01/01/2025

<table>
<tr><td>Plan</td><td>☐ MassHealth UPPL
☒Commercial/Exchange</td><td rowspan="2">Program Type</td><td rowspan="2">☒ Prior Authorization
☐ Quantity Limit
☐ Step Therapy</td></tr>
<tr><td>Benefit</td><td>☒ Pharmacy Benefit
☒ Medical Benefit</td></tr>
<tr><td>Specialty Limitations</td><td colspan="3">This medication has been designated specialty and must be filled at a contracted specialty pharmacy.</td></tr>
<tr><td rowspan="2">Contact Information</td><td colspan="3">Specialty Medications
All Plans | Phone: 877-519-1908 | Fax: 855-540-3693</td></tr>
<tr><td colspan="3">Non-Specialty Medications
All Plans | Phone: 800-711-4555 | Fax: 844-403-1029</td></tr>
<tr><td>Exceptions</td><td colspan="3">N/A</td></tr>
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Overview
Vyvgart (efgartigimod alfa-fcab) and Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) are indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

Additionally, Vyvgart Hytrulo is approved for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) in adults.

Coverage Guidelines
Authorization may be reviewed for members new to the plan within the past 90 days who are currently receiving treatment with requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
OR
Authorization may be granted for members when all the following criteria are met:

Generalized Myasthenia Gravis – Vyvgart and Vyvgart Hytrulo
1. Member has a diagnosis of generalized myasthenia gravis (gMG) with both of the following:
    a. Myasthenia Gravis Foundation of America (MGFA) clinical classification II to IV
    b. MG-Activities of Daily Living (MG-ADL) total score of ≥ 5
2. Anti-acetylcholine receptor (AchR) antibody positive
3. Member is currently on a stable dose of at least ONE of the following:
    a. Acetylcholinesterase inhibitors (e.g., pyridostigmine)
    b. Corticosteroids
    c. Nonsteroidal immunosuppressive therapy (NSIST) (e.g., azathioprine, mycophenolate mofetil)

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) – Vyvgart Hytrulo

1. Member has a diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP) confirmed by electrodiagnostic tests (e.g., electromyography, nerve conduction studies)
2. Member has had an inadequate response, adverse reaction, or contraindication to immunoglobulin (IVIG or SCIG)

Continuation of Therapy

Generalized Myasthenia Gravis – Vyvgart and Vyvgart Hytrulo

Reauthorization requests will be approved when the following criteria are met:

1. Provider submits documentation of a positive response to therapy (e.g., improvement in MG-ADL score, changes compared to baseline in Quantitative Myasthenia Gravis (QMG) total score).

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) – Vyvgart Hytrulo

Reauthorizations requests will be approved when the following criteria are met:

1. Provider submits documentation of clinical improvement in neurologic symptoms or stabilization of disease (e.g., nerve conduction studies, Inflammatory Neuropathy Case and Treatment [INCAT], Medical Research Council [MRC] sum score, grip strength)

Limitations

1. Approvals for CIDP are limited to Vyvgart Hytrulo only.
2. Initial approvals and reauthorizations will be granted for 6 months.

References

1. Vyvgart [package insert]. Boston, MA: Argenx US, Inc.; December 2021.
2. Sanders D, Wolfe G, Benatar M et al. International consensus guidance for management of myasthenia gravis. *Neurology*. 2021; 96 (3) 114-122.
3. Howard JF, 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. *Lancet Neurol*. 2021. 20:526-536.
4. Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase) [prescribing information]. Boston, MA: Argenx US Inc; August 2024.

Review History

07/20/22 – Reviewed and created for July P&T. Effective 09/01/2022
10/11/2023 – Reviewed and Updated for Oct P&T; Added new drug Vyvgart Hytrulo to criteria. Effective 12/1/23
10/09/2024 – Reviewed and approved for October P&T. Added approval criteria for CIDP for Vyvgart Hytrulo. Updated Limitations section to clarify that only Vyvgart Hytrulo will be approved for CIDP. Removed age and specialist prescriber requirements from gMG approval criteria. Effective 1/1/2025.