Mass General Brigham
Health Plan

Vyvgart (efgartigimod alfa-fcab)
Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase)
Effective 12/01/2023

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview
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
Authorization may be reviewed for members new to the plan 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, and documentation is provided:

1. Member has a diagnosis of generalized myasthenia gravis (gMG)
2. Positive serologic test for anti-acetylcholine receptor antibodies
3. Myasthenia Gravis Foundation of America (MGFA) clinical classification II to IV
4. Member is ≥ 18 years of age
5. Prescriber by or in consultation with a neurologist
6. MG activities of daily living (MG-ADL) total score of 5 or more with at least 50% of the score due to non-ocular symptoms
7. 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)

Continuation of Therapy
Reauthorization requires physician attestation that member demonstrates a positive response to therapy (e.g., improvement in MG-ADL score, changes compared to baseline in Quantitative Myasthenia Gravis (QMG) total score).

Limitations

1. Initial approvals and reauthorizations will be granted for 6 months.

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

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; June 2023.