

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	
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.
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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.00000000000011124
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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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