Medical Necessity Guidelines

Medical Benefit Drugs

Vyvgart (efgartigimod alfa-fcab), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)

Effective: August 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☒ Tufts Health Plan Commercial products; Fax 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☐ Tufts Health Together – MassHealth Accountable Care Partnership Plans; Fax 617-673-0939

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual-eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration-Approved Indications

Vyvgart (efgartigimod alfa-fcab) is a neonatal Fc receptor blocker indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients.

Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-gvfc) is a combination of efgartigimod alfa, a neonatal Fc receptor blocker, and hyaluronidase, an endoglycosidase, indicated for the treatment of adult patients with:

- Generalized myasthenia gravis (gMG) in adult patients
- Chronic inflammatory demyelinating polyneuropathy (CIPD)

Clinical Guideline Coverage Criteria

Generalized Myasthenia Gravis

The plan may authorize coverage of Vyvgart or Vyvgart Hytrulo for Members when **ALL** of the following criteria are met:

Initial Authorization Criteria

1. Documented diagnosis of generalized myasthenia gravis

AND

2. Documentation of one (1) of the following:
    a. Positive serologic test for anti-acetylcholine antibodies
    b. Positive serologic test for anti-muscle-specific tyrosine kinase antibodies
    c. Positive serologic test for anti-low-density lipoprotein receptor-related protein 4
    d. Triple seronegative test (i.e., anti-AChR, anti-MuSK, and anti-LRP4 antibodies negative)

AND

3. Documentation of Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV generalized myasthenia gravis

AND

4. Documentation of Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score of at least 5

AND

5. The prescribing physician is a neurologist

AND

6. Documentation of **one (1)** of the following:
    a. Persistent symptoms that limit function following a previous trial of immunosuppressive therapy consisting of a glucocorticoid in combination with at least one other immunotherapeutic agent (e.g., azathioprine, mycophenolate, cyclosporine, tacrolimus)
    b. Ongoing rescue therapy with intravenous immunoglobulin or plasma exchange while receiving immunosuppressive therapy
    c. Clinical rationale to avoid immunosuppressive therapy with glucocorticoids and other immunotherapeutic agents (e.g., azathioprine, mycophenolate, cyclosporine, tacrolimus)

Reauthorization Criteria

1. Documented diagnosis of generalized myasthenia gravis

AND

2. Documentation of one (1) of the following:
    a. Positive serologic test for anti-acetylcholine antibodies
    b. Positive serologic test for anti-muscle-specific tyrosine kinase antibodies
    c. Positive serologic test for anti-low-density lipoprotein receptor-related protein 4
    d. Triple seronegative test (i.e., anti-AChR, anti-MuSK, and anti-LRP4 antibodies negative)

AND

3. The prescribing physician is a neurologist

AND

4. Documentation the Member has experienced a therapeutic response as defined by an improvement of Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score from baseline

Chronic Inflammatory Demyelinating Polyneuropathy

The plan may authorize coverage of Vyvgart Hytrulo for Members when **ALL** of the following criteria are met:

Initial Authorization Criteria

1. Documented diagnosis of chronic inflammatory demyelinating polyneuropathy supported by electrodiagnostic studies

AND

2. The prescribing physician is a neurologist

AND

3. Documentation of inadequate response, contraindication, or clinical inappropriateness with immunoglobulin therapy

Reauthorization Criteria

1. Documented diagnosis of chronic inflammatory demyelinating polyneuropathy supported by electrodiagnostic studies

AND

2. The prescribing physician is a neurologist

AND

3. Documentation the patient has experienced a therapeutic response as defined by provider attestation of clinically significant improvement in neurologic symptoms (e.g., improvement in disability; improved or stabilized nerve conduction study results; improved neurological symptoms, strength, and sensation upon physical examination)

Limitations

- For generalized myasthenia gravis, initial coverage of Vyvgart or Vyvgart Hytrulo will be authorized for 6 months. Reauthorization of Vyvgart or Vyvgart Hytrulo will be provided in 12-month intervals.
- For chronic inflammatory demyelinating polyneuropathy, initial coverage of Vyvgart Hytrulo will be authorized for 3 months. Reauthorization of Vyvgart Hytrulo will be provided in 12-month intervals.
- Members new to the plan stable on Vyvgart or Vyvgart Hytrulo should be reviewed against Reauthorization Criteria.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J9332	Injection, efgartigimod alfa-fcab, 2 mg
J9334	Injection, efgartigimod alfa, 2 mg and hyaluronidase-QVFC

References

1. Gilhus N, Verschuuren J. Myasthenia gravis: subgroup classification and therapeutic strategies. *Lancet Neurol.* 2015;14(10):1023-36. doi: 10.1016/S1474-4422(15)00145-3.
2. Howard Jr J, 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(7):526-536. doi: 10.1016/S1474-4422(21)00159-9.
3. Mantegazza R, et al. When myasthenia gravis is deemed refractory: clinical signposts and treatment strategies. Ther Adv Neurol Disord. 2018;11:1756285617749134.
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5. Silvestri NJ, et al. Treatment-refractory myasthenia gravis. J Clin Neuromuscul Dis. 2014;15(4):167.
6. Tice JA, Touchette DR, Nikitin D, Campbell JD, Lien P-W, Moradi A, et al. Eculizumab and efgartigimod for the treatment of myasthenia gravis: effectiveness and value; final evidence report. October 20, 2021. Accessed January 12, 2022. https://icer.org/wp-content/uploads/2021/03/ICER_Myasthenia-Gravis_Final-Report_102021-1.pdf
7. Van den Bergh PY, van Doorn PA, Hadden RD, et al. European Academy of Neurology/Peripheral Nerve Society guideline on diagnosis and treatment of chronic inflammatory demyelinating polyradiculoneuropathy: report of a joint task force – second revision. J Peripher Nerv Syst. 2021;26(3):242-368.
8. Patwa HS, et al. Evidence-based guideline: intravenous immunoglobulin in the treatment of neuromuscular disorders: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology. 2012;78(13):1009.
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11. Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) [package insert]. Boston, MA: argenx US, Inc.; May 2026.
12. Muley SA, Parry GJ. Inflammatory demyelinating neuropathies. Curr Treat Options Neurol 2009; 11:221

Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)

Subsequent endorsement date(s) and changes made:

- September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)
- September 12, 2023: Added Vyvgart Hytrulo to the Medical Necessity Guideline. Updated the title of the Medical Necessity Guideline from “Vyvgart” to “Vyvgart and Vyvgart Hytrulo” (effective 10/1/23).
- January 1, 2024: Administrative updated: Added new J Code J9334 to Medical Necessity Guideline.
- August 13, 2024: Updated requirements to establish refractory disease of generalized myasthenia gravis. Added coverage criteria for Vyvgart Hytrulo’s supplemental indication in chronic inflammatory demyelinating polyneuropathy (eff 1/1/25).
- September 10, 2024: Updated requirements to establish refractory disease of generalized myasthenia gravis (eff 1/1/25).
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- September 9, 2025: no changes
- July 14, 2026: Updated Vyvgart and Vyvgart Hytrulo’s expanded indication for all generalized myasthenia subtypes in adults. Updated documentation of a positive serological test for anti-acetylcholine antibodies, anti-muscle-specific tyrosine kinase antibodies, anti-low-density lipoprotein receptor-related protein 4, or documentation of triple seronegative disease. Administrative updates: Template updated to remove CareLink from the Medical Necessity Guideline template. Template updated from “Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans” to “Tufts Health Together- MassHealth Accountable Care Partnership Plans.” (eff 8/1/26).

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member’s benefit document, and in coordination with the Member’s physician(s) on a case-by-case basis

considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.