Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:

Medical Benefit Drugs

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

Effective: July 1, 2026

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

Public Plans Products

☒ 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

Myasthenia gravis (MG) is an autoimmune disorder characterized by muscle weakness and fatigue. There are two classifications of MG: ocular and general. The degree of muscle weakness can fluctuate and vary in severity from person to person; however, it will generally improve with rest and worsen with physical activity. Most patients with MG develop autoantibodies that attack the acetylcholine receptor (AChR), blocking or destroying the receptors, which prevents muscles from contracting. Treatment decisions for generalized myasthenia gravis (gMG) are based on knowledge of the natural history of disease in each patient and the predicted response to a specific form of therapy. Goals are individualized based on disease severity, patient age and sex, and the degree of functional impairment. Approval of Vyvgart (efgartigimod afla-fcab) was based on the Phase 3 ADAPT trial in which treatment with Vyvgart resulted in clinically meaningful improvements in symptom severity compared with placebo as measured by the Myasthenia Gravis Activities of Daily Living (MG-ADL) score. Approval of Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-gvfc) was approved based on the results of the Phase 3 ADAPTsc trial which was a multicenter, randomized, open-label, parallel-group bridging study to the ADAPT trial. In ADAPTsc, patients were randomized to receive either Vyvgart Hytrulo or Vyvgart for one treatment cycle (one treatment cycle consisted of four doses at once-weekly intervals). The primary endpoint of noninferiority was met (mean total IgG reduction from baseline).

Chronic inflammatory demyelinating polyneuropathy (CIDP) is an acquired, immune-mediated neuropathy affecting peripheral nerves and nerve roots. CIPD is typically characterized by a relapsing-remitting or progressive course of symmetric weakness of proximal and distal muscles. CIDP is diagnosed by electrodiagnostic and/or pathologic features of demyelination and responsiveness to immunomodulatory treatments. Early administration of effective treatment is important, with the goal to stop the immune attack against the myelin sheath of the peripheral nerves. Ultimately, the treatment approach for an individual member will be influenced by severity and course of disease. Recommendations for initial treatments include intravenous immune globulin, plasma exchange or glucocorticoids. Among these options, intravenous immune globulin is easier to administer compared to plasma exchange and may be associated with a more rapid treatment response for disability improvement compared to glucocorticoids. Approval of Vyvgart Hytrulo for CIPD was based on a placebo-controlled trial in which treatment improved symptoms in treatment responders after 12 weeks and lowered the rate of clinical deterioration.

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 who are anti-acetylcholine receptor (AChR) antibody positive.

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 who are anti-acetylcholine receptor (AChR) antibody positive.
- 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. The prescribing physician is a neurologist

Reauthorization Criteria

1. Documented diagnosis of generalized myasthenia gravis

AND

2. The prescribing physician is a neurologist

AND

3. 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

- Initial coverage of Vyvgart/Vyvgart Hytrulo for generalized myasthenia gravis will be authorized for 6 months. Reauthorization of Vyvgart/Vyvgart Hytrulo will be provided for 12-month intervals.
- Initial coverage of Vyvgart Hytrulo for chronic inflammatory demyelinating polyneuropathy 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/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 NJ, et al. Treatment-refractory myasthenia gravis. J Clin Neuromuscul Dis. 2014;15(4):167.
4. 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
5. 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.
6. 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.
7. R, et al. When myasthenia gravis is deemed refractory: clinical signposts and treatment strategies. Ther Adv Neurol Disord. 2018;11:1756285617749134.
8. Narayanaswami P, Sanders D, Wolfe G, et al. International Consensus Guidance for Management of Myasthenia Gravis: 2020 Update. *Neurology*. 2021;96(3):114-122.
9. Silvestri
10. Oaklander AL, et al. Treatments for chronic inflammatory demyelinating polyradiculoneuropathy (CIDP): an overview of systematic reviews. Cochrane Database Syst Rev. 2017;1:CD010369.
11. Vyvgart (efgartigimod alfa-fcab). [package insert]. Boston, MA: argenx US, Inc.; Dec 2023.
12. Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) [package insert]. Boston, MA: argenx US, Inc.; June 2024.
13. 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.” Added Reauthorization Criteria, removed age requirements, added provider specialty requirements, and updated requirements for seropositive disease to read “Documentation of a positive serologic test for anti-acetylcholine antibodies.” Removed the Limitation “Any indications other than FDA-approved indications are considered experimental or investigational and will not be approved by the health plan.” (effective 12/1/23).
- January 1, 2024: Administrative Update: Added new J Code J9334.
- August 13, 2024: Added coverage criteria for Vyvgart Hytrulo’s supplemental indication in chronic inflammatory demyelinating polyneuropathy (eff 10/1/24).
- September 2024: Joint Medical Policy and Health Care Services UM Committee review (eff 10/1/24).
- September 2024: Updated Tufts Health Unify to Tufts Health One Care as part of the Rebranding.
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- December 9, 2025: No changes (eff 1/1/26)
- December 2025: Joint Medical Policy and Health Care Services UM Committee review (effective 1/1/26)
- June 2026: Joint Medical Policy and Health Care Services UM Committee review; Updated indication of generalized myasthenia gravis to include all serotypes of adult patients with gMG (effective 7/1/26)

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

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.