UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2377-1
Program	Prior Authorization/Medical Necessity
Medication	*Vyvgart Hytrulo® (efgartigimod alfa and hyaluronidase-qvfc) *This program applies to the prefilled syringe formulation for self-administered subcutaneous use
P&T Approval Date	9/2025
Effective Date	12/1/2025

1. Background:

Vyvgart Hytrulo is a combination of efgartigimod alfa, a neonatal Fc receptor (FcRn) blocker, and hyaluronidase, an endoglycosidase, indicated for the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive and chronic inflammatory demyelinating polyneuropathy (CIDP).

2. Coverage Criteria[a]:

A. Generalized Myasthenia Gravis

1. **Initial Authorization**

a. **Vyvgart Hytrulo** will be approved based on **all** of the following criteria:

(1) Diagnosis of generalized Myasthenia Gravis (gMG)

-AND-

(2) Positive serologic test for anti-AChR antibodies

-AND-

(3) Patient has a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of class II, III, or IV at initiation of therapy

-AND-

(4) Patient has a Myasthenia Gravis Activities of Daily Living scale (MG-ADL) total score ≥ 5 at initiation of therapy

-AND-

(5) **One** of the following:

(a) History of failure of a minimum of two immunosuppressive agents over the course of at least 12 months (e.g., azathioprine, corticosteroids, cyclosporine, methotrexate, mycophenolate, etc.)

-OR-

(b) **Both** of the following:

i. History of failure of at least one immunosuppressive therapy

ii. Patient has required four or more courses of plasmapheresis/plasma exchanges and/or immune globulin over the course of at least 12 months without symptom control

-AND-

(6) Patient is **not** receiving Vyvgart Hytrulo in combination with **any** of the following for treatment of the same indication:

(a) A complement inhibitor [e.g., eculizumab, Ultomiris (ravulizumab), Zilbrysq (zilucoplan)]
(b) Another FcRn blocker [e.g., Imaavy (nipocalimab), Rystiggo (rozanolixizumab)]
(c) Immune globulin (e.g., Gammagard, Privigen, Hizentra)

-AND-

(7) Prescribed by or in consultation with a neurologist

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Vyvgart Hytrulo** will be approved based on **all** of the following criteria:

(1) Submission of medical records (e.g., chart notes, laboratory tests) demonstrating **all** of the following:

(a) Improvement and/or maintenance of at least a 2-point improvement (reduction in score) in the MG-ADL score from pre-treatment baseline
(b) Reduction in signs and symptoms of myasthenia gravis
(c) Maintenance, reduction, or discontinuation of dose(s) of baseline immunosuppressive therapy (IST) prior to starting Vyvgart Hytrulo. Note: Add on, dose escalation of IST, or additional rescue therapy from baseline to treat myasthenia gravis or exacerbation of symptoms while on Vyvgart Hytrulo therapy will be considered as treatment failure

-AND-

(2) Patient is **not** receiving Vyvgart Hytrulo in combination with **any** of the following for treatment of the same indication:

(a) A complement inhibitor [e.g., eculizumab, Ultomiris (ravulizumab), Zilbrysq (zilucoplan)]
(b) Another FcRn blocker [e.g., Imaavy (nipocalimab), Rystiggo (rozanolixizumab)]

(c) Immune globulin (e.g., Gammagard, Privigen, Hizentra)

-AND-

(3) Prescribed by or in consultation with a neurologist

Authorization will be issued for 12 months.

B. Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

1. **Initial Authorization**

a. **Vyvgart Hytrulo** will be approved based on **all** of the following criteria:

(1) Diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP)

-AND-

(2) **All** of the following:

(a) Progressive symptoms present for at least 2 months

-AND-

(b) Symptomatic polyradiculoneuropathy as indicated by progressive or relapsing motor or sensory impairment of more than one limb

-AND-

(c) Electrodiagnostic findings (consistent with EFNS/PNS guidelines for definite CIDP) indicating the presence of at least **one** of the following:

i. Motor distal latency prolongation in 2 nerves
ii. Reduction of motor conduction velocity in 2 nerves
iii. Prolongation of F-wave latency in 2 nerves
iv. Absence of F-waves in at least 1 nerve
v. Partial motor conduction block of at least 1 motor nerve
vi. Abnormal temporal dispersion in at least 2 nerves
vii. Distal CMAP duration increase in at least 1 nerve

-AND-

(3) Trial and failure (after a trial of at least two months [b]), contraindication, or intolerance to a corticosteroid (e.g., prednisone, methylprednisolone)

-AND-

(4) **One** of the following:

(a) Trial and failure (after a trial of at least three months [b]) to an immune globulin (e.g., Gammagard, Privigen, Hizentra) with the maximally allowable and/or tolerated dose

-OR-

(b) **Both** of the following:

i. Intolerance to **all** immune globulins (e.g., Gammagard, Privigen, Hizentra)

ii. Dose has been adjusted or escalated to the maximally allowable and/or tolerated dose

-OR-

(c) Contraindication to **all** immune globulins (e.g., Gammagard, Privigen, Hizentra)

-AND-

(5) Patient is not receiving Vyvgart Hytrulo in combination with an immune globulin (e.g., Gammagard, Privigen, Hizentra) for treatment of the same indication

-AND-

(6) Prescribed by or in consultation with a neurologist

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Vyvgart Hytrulo** will be approved based on **all** of the following criteria:

(1) Documentation of a positive clinical response to Vyvgart Hytrulo as measured by an objective scale [e.g., Rankin, Modified Rankin, Medical Research Council (MRC) scale]

-AND-

(2) Patient is not receiving Vyvgart Hytrulo in combination with an immune globulin (e.g., Gammagard, Privigen, Hizentra) used for treatment of the same indication

-AND-

(3) Prescribed by or in consultation with a neurologist

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

[b] For Connecticut, Kentucky and Mississippi business, only a 30-day trial will be required.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Medical Necessity may be in place.

4. References:

1. Vyvgart Hytrulo® [prescribing information]. Boston, MA: Argenx US, Inc.; April 2025
2. Howard JF, Jr., Bril V, Vu T, et al. Safety, efficacy, and tolerability of efgartigimod in patients with generalized myasthenia gravis (ADAPT): a multicenter, randomized, placebo-controlled, phase 3 trial. The Lancet Neurology. 2021;20(7):526-536.
3. Bird S. Overview of the treatment of myasthenia gravis. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA.
4. Narayanaswami P, Sanders DB, Wolfe G, et al. International Consensus Guidance for Management of Myasthenia Gravis: 2020 Update. Neurology. 2021;96(3):114-122.
5. Muppidi S, Silvestri NJ, Tan R, Riggs K, Leighton T, Phillips GA. Utilization of MG-ADL in myasthenia gravis clinical research and care. Muscle Nerve. 2022;65(6):630-639. doi:10.1002/mus.27476.
6. Van den Bergh PYK, van Doorn PA, Hadden RDM, 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 [published correction appears in J Peripher Nerv Syst. 2022 Mar;27(1):94. doi: 10.1111/jns.12479.] [published correction appears in Eur J Neurol. 2022 Apr;29(4):1288. doi: 10.1111/ene.15225.]. *J Peripher Nerv Syst*. 2021;26(3):242-268. doi:10.1111/jns.12455

Program	Prior Authorization/Medical Necessity - Vyvgart Hytrulo® (efgartigimod alfa and hyaluronidase-qvfc))
Change Control	
9/2025	New program.