UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Neurology – Vyvgart Hytrulo Utilization Management Medical Policy
- Vyvgart® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc subcutaneous injection – Argenx/Halozyme)

REVIEW DATE: 05/20/2026; selected revision 07/08/2026

OVERVIEW

Vyvgart Hytrulo, a neonatal Fc receptor blocker, is indicated for the treatment of adults with:[1]
- **Chronic inflammatory demyelinating polyneuropathy** (CIDP);
- **Generalized myasthenia gravis** (gMG).

Vyvgart Hytrulo is available in two presentations for subcutaneous use: single-use vials (1,008 mg efgartigimod alfa/11,200 units hyaluronidase), for administration with a winged infusion set by a healthcare professional; and single-use prefilled syringes (1,000 mg efgartigimod alfa/10,000 units hyaluronidase) that may be self-administered or administered by a caregiver after proper instruction in subcutaneous injection technique.[1]

Disease Overview

CIDP

CIDP is a chronic peripheral nervous system disorder with a prevalence of approximately 60,000 individuals in the US.[2] People of all ages can be diagnosed with CIDP, but onset usually occurs when patients are between 48 to 60 years of age. Symptoms generally consist of symmetric weakness in both proximal and distal muscles, numbness, fatigue, ambulating difficulties, falls, fine motor impairment, and paresthesia.[2,3] CIDP generally includes both motor and sensory dysfunction in the four limbs and it progresses over more than 8 weeks.[4] At present, there is no established biomarker to aid in diagnosis.[5] It is believed that an immune response directed at the components of the peripheral nerve causes demyelination and axonal damage, although the exact mechanisms are not yet clearly defined. The diagnosis of CIDP relies on clinical and electrophysiological criteria; electrodiagnostic evidence of peripheral nerve demyelination in motor nerves is required for diagnosis. Electrophysiological support is generally categorized as CIDP or possible CIDP.[4] Supportive diagnostic criteria may include cerebral spinal fluid protein level, nerve ultrasonography, magnetic resonance neuropathy, nerve pathology, and response to treatment. Since there are no established biomarkers for CIDP, clinical assessment remains the only evaluation tool. Treatment responses vary widely from one patient to another.

gMG

Myasthenia gravis is a chronic autoimmune neuromuscular disease that causes weakness in the skeletal muscles, which are responsible for breathing and moving parts of the body, including the arms and legs.[6] Myasthenia gravis is caused by the production of pathogenic immunoglobulin G autoantibodies against neuromuscular junction components (acetylcholine receptor [AChR], muscle-specific tyrosine kinase [MuSK], and low density lipoprotein receptor-related protein 4 [LRP4]).[7] Approximately 85% of patients with myasthenia gravis are anti-AChR antibody-positive and approximately 5% to 8% of patients are anti-MuSK antibody-positive.[8] The result of the antibodies at the junction is unsuccessful nerve transmission and deficiency or weakness of muscle contractions.[7] The hallmark of myasthenia gravis is muscle weakness that worsens after periods of activity and improves after periods of rest. Certain muscles such as those that control eye and eyelid movement, facial expression, chewing, talking, and swallowing are often involved in the disorder; however, the muscles that control breathing and neck and limb movements may also be

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affected. MuSK is rare and frequently more severe subtype of myasthenia gravis. Symptomatic treatment with acetylcholinesterase inhibitors (pyridostigmine) is generally unsatisfactory and may be deleterious in MuSK.[15]

Clinical Efficacy

CIDP

The efficacy of Vyvgart Hytrulo for the treatment of adults with CIDP was established in a two-stage, multicenter study.[1] The open-label phase identified responders to Vyvgart Hytrulo (Stage A) and these responders then entered a randomized, double-blind, placebo-controlled, withdrawal period (Stage B). All of the enrolled patients had a documented diagnosis of definite or probable CIDP using the European Federation of Neurological Societies/Peripheral Nerve Society (EFNS/PNS; 2010) criteria for progressing or relapsing forms. In Stage A, 322 patients received Vyvgart Hytrulo until evidence of improvement occurred at two consecutive study visits; treatment was for up to 12 weeks. Improvement was defined as an improvement of at least one point in the Inflammatory Neuropathy Cause and Treatment disability score (INCAT) [of note, efficacy of Vyvgart Hytrulo was assessed using the adjusted INCAT {aINCAT} disability score, which is identical to the INCAT disability score but with changes in the upper limb function from 0 (normal) to 1 (minor symptoms) excluded], improvement of at least 4 points on the Inflammatory Rasch-built Overall Disability Scale (I-RODS), or mean grip strength improvement of at least 8 kPa. Overall, 69% of patients (n = 221/322) who had documented improvement at two consecutive visits during Stage A entered Stage B. Patients were randomized to receive Vyvgart Hytrulo or placebo. Of the patients in Stage B, 146 patients were currently receiving standard of care and 75 patients who had either not received prior treatment for CIDP or were not treated with standard of care therapy for at least 6 months before study entry. The primary endpoint was the time to clinical deterioration defined as a 1-point increase in aINCAT at two consecutive visits or a ≥ 1 point increase in aINCAT at one visit. Patients with clinical deterioration or who completed Week 48 in Stage B without clinical deterioration were withdrawn from the placebo-controlled portion of the study. Patients who received Vyvgart Hytrulo experienced a longer time to clinical deterioration (i.e., increase of ≥ 1 point in aINCAT score) compared with patients who received placebo, which was statistically significant, as demonstrated by a hazard ratio of 0.394 (95% confidence interval [CI]: 0.253, 0.614; P < 0.0001).

gMG

Anti-AChR antibody positive. Non-inferiority of Vyvgart Hytrulo to Vyvgart Intravenous (IV) was demonstrated in the ADAPT-SC study, where patients were randomized to either Vyvgart Hytrulo or Vyvgart IV (n = 110).[9] The efficacy of Vyvgart IV was evaluated in a 26-week, multicenter, randomized, double-blind, placebo-controlled trial in adults with myasthenia gravis (n = 167).[10] Among other criteria, patients were on stable doses of myasthenia gravis therapy prior to screening (e.g., acetylcholinesterase inhibitors, steroids, or non-steroidal immunosuppressive therapies), either in combination or alone. In addition, patients had a Myasthenia Gravis Foundation of America (MGFA) clinical classification Class II to IV and a Myasthenia Gravis Activities of Daily Living (MG-ADL) total score of ≥ 5. MG-ADL assesses the impact of gMG on daily functions of eight signs or symptoms that are typically impacted by this disease. Each sign or symptom is assessed on a 4-point scale; a higher score indicates greater impairment. Patients were randomized to receive Vyvgart IV or placebo. At baseline, most patients had stable doses of acetylcholinesterase inhibitors (> 80%), steroids (> 70%), and/or non-steroidal immunosuppressive therapies (about 60%). The primary efficacy endpoint was comparison of the percentage of MG-ADL responders during the first treatment cycle between treatment groups in the anti-AChR antibody-positive population. An MG-ADL responder was defined as a patient with a 2-point or greater reduction in the total MG-ADL score compared to the treatment cycle baseline for at least 4 consecutive weeks, with the first reduction occurring no later than 1 week after the last infusion of the cycle. Overall, 67.7% of patients who received Vyvgart IV compared with 29.7% of patients who received placebo were considered MG-ADL responders (P < 0.0001).

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Anti-AChR antibody negative. The ADAPT SERON study enrolled adults patients with gMG who are anti-AChR antibody negative.[1,14] This included patients with antibody-positive muscle-specific tyrosine kinase (MuSK) [34%], antibody-positive low-density lipoprotein receptor-related protein (LRP4) [5%], and triple seronegative patients (with no detectable autoantibodies against AChR, MuSK, or LRP4) [61%]. Approximately 80% of patients were on baseline MG therapy with an acetylcholinesterase inhibitor. The trial was an 8-week, randomized, double-blind, placebo-controlled study which used Vyvgart IV for treatment. In Part A of the study, patients received once-weekly infusions for 4 weeks of either Vyvgart IV or placebo). Subsequent treatment cycles were administered in the open-label Part B of the study. Patients had MGFA clinical classification Class II to IV and a MG-ADL total score of at least 5. The primary efficacy endpoint was the comparison of the mean change from baseline at Week 4 between the treatment group in the MG-ADL total score. A statistically significant difference favoring Vyvgart IV was observed (least squares mean difference [95% CI] -1.46 [-2.50, -0.41; P = 0.0068]).[1]

Dosing Information

The recommended dose of Vyvgart Hytrulo for CIDP is one vial (1,008 mg efgartigimod alfa/11,200 units hyaluronidase) or one prefilled syringe (1,000 mg efgartigimod alfa/10,000 units hyaluronidase) administered subcutaneously (SC) once a week.[1]

The recommended dose of Vyvgart Hytrulo for gMG is one vial (1,008 mg efgartigimod alfa/11,200 units hyaluronidase) or one prefilled syringe (1,000 mg efgartigimod alfa/10,000 units hyaluronidase) administered SC once a week for 4 weeks.[1] Administer subsequent treatment cycles based on clinical evaluation.

Guidelines

CIDP

Use of Vyvgart Hytrulo for CIDP is not currently addressed in guidelines. The European Academy of Neurology (EAN)/PNS updated CIDP guidelines in 2021.[11] EAN/PNS strongly recommends that IV immune globulins or corticosteroids be used as initial treatment in typical CIDP and CIDP variants. Plasma exchange is strongly recommended if IV immune globulins and corticosteroids are ineffective. Guidelines also note that IV immune globulins should be considered first-line treatment in motor CIDP. For maintenance treatment, IV or SC immune globulins or corticosteroids are recommended. It is additionally recommended that if the maintenance dose is high on any of the first-line therapies, a combination of treatments or addition of an immunosuppressant may be warranted.

gMG

An international consensus guidance for the management of myasthenia gravis was published in 2016.[12] Pyridostigmine is recommended for the initial treatment in most patients with myasthenia gravis. The ability to discontinue pyridostigmine can indicate that the patient has met treatment goals and may guide the tapering of other therapies. Systemic corticosteroids or immunosuppressant therapy should be used in all patients with myasthenia gravis who have not met treatment goals after an adequate trial of pyridostigmine. Nonsteroidal immunosuppressant agents include azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, and tacrolimus. It is usually necessary to maintain some immunosuppression for many years, sometimes for life. Plasma exchange and IV immunoglobulin can be used as short-term treatments in certain patients. A 2020 update to these guidelines provides new recommendations for methotrexate, rituximab, and eculizumab IV infusion (Soliris®, biosimilars).[13] All recommendations should be considered extensions or additions to recommendations made in the initial international consensus guidance. Oral methotrexate may be considered as a steroid-sparing agent in patients with gMG who have not tolerated or responded to steroid-sparing agents. Rituximab should be considered as an early therapeutic option in patients with anti-MuSK antibody-positive myasthenia gravis

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who have an unsatisfactory response to initial immunotherapy. Eculizumab should be considered in the treatment of severe, refractory, anti-AChR antibody-positive gMG.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Vyvgart Hytrulo. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Vyvgart Hytrulo as well as the monitoring required for adverse events and long-term efficacy, approval requires Vyvgart Hytrulo to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Vyvgart Hytrulo is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Chronic Inflammatory Demyelinating Polyneuropathy (CIDP).** Approve for the duration noted if the patient meets ONE of the following (A or B):
   Note: Chronic inflammatory demyelinating polyneuropathy can also be referred to as chronic relapsing polyneuropathy or chronic inflammatory demyelinating polyradiculoneuropathy.
   - **A)** Initial Therapy. Approve for 3 months if the patient meets ALL of the following (i, ii, iii, and iv):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Diagnosis of CIDP was supported by electrodiagnostic studies; AND
     - **iii.** Patient meets ONE of the following (a or b):
       - **a)** Patient meets BOTH of the following ([1] and [2]):
         - **(1)** Patient has previously received treatment with an intravenous or subcutaneous immune globulin; AND
           Note: Examples of intravenous or subcutaneous immune globulin include: Gammagard Liquid, Gammaked, Gamunex-C, Panzyga, Privigen, Hizentra, and HyQvia.
         - **(2)** Patient has had inadequate efficacy or significant intolerance to an intravenous or subcutaneous immune globulin; OR
       - **b)** Patient has a contraindication to intravenous or subcutaneous immune globulin; AND
         Note: Examples of intravenous or subcutaneous immune globulin include: Gammagard Liquid, Gammaked, Gamunex-C, Panzyga, Privigen, Hizentra, and HyQvia.
     - **iv.** The medication is prescribed by or in consultation with a neurologist; OR
   - **B)** Patient is Currently Receiving Vyvgart Hytrulo. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** According to the prescriber, the patient has a clinically significant improvement in neurologic symptoms; AND

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Note. Examples of improvement in neurologic symptoms include improvement in disability: nerve conduction study results improved or stabilized; physical examination shows improvement in neurological symptoms, strength, and sensation.

iii. The medication is prescribed by or in consultation with a neurologist.

Dosing. Approve ONE of the following (A or B):

A) One single-dose vial (1,008 mg efgartigimod alfa and 11,200 units hyaluronidase) administered as a subcutaneous injection once weekly; OR

B) One single-dose prefilled syringe (1,000 mg efgartigimod and 10,000 units hyaluronidase) administered as a subcutaneous injection once weekly.

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2. Generalized Myasthenia Gravis. Approve for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, iv, and v):

i. Patient is ≥ 18 years of age; AND

ii. Patient meets BOTH of the following (a and b):

a) Myasthenia Gravis Foundation of America classification of II to IV; AND

b) Myasthenia Gravis Activities of Daily Living (MG-ADL) score of ≥ 5; AND

iii. Patient meets ONE of the following (a, b, or c):

a) Patient has received or is currently receiving pyridostigmine; OR

b) Patient has a contraindication to pyridostigmine; OR

c) Patient has anti-muscle-specific tyrosine kinase (MuSK) antibody-positive generalized myasthenia gravis; AND

iv. Patient has evidence of unresolved symptoms of generalized myasthenia gravis; AND
Note: Examples of unresolved symptoms include difficulty swallowing, difficulty breathing, or a functional disability resulting in the discontinuation of physical activity (e.g., double vision, talking, impairment of mobility).

v. The medication is being prescribed by or in consultation with a neurologist; OR

B) Patient is Currently Receiving Vyvgart Hytrulo (or Vyvgart Intravenous [efgartigimod alfa-fcab intravenous infusion]). Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):

i. Patient is ≥ 18 years of age; AND

ii. According to the prescriber, patient is continuing to derive benefit from Vyvgart Hytrulo (or Vyvgart Intravenous); AND
Note: Examples of derived benefit include reductions in exacerbations of myasthenia gravis; improvements in speech, swallowing, mobility, and respiratory function.

iii. The medication is being prescribed by or in consultation with a neurologist.

Dosing. Approve ONE of the following (A or B):

A) Single-Dose Vials: Approve one vial (1,008 mg efgartigimod alfa and 11,200 units hyaluronidase) administered as a subcutaneous injection once weekly for 4 weeks; OR

B) Single-Dose Prefilled Syringes: Approve one prefilled syringe (1,000 mg efgartigimod and 10,000 units hyaluronidase) administered as a subcutaneous injection once weekly for 4 weeks.
Note. Subsequent treatment cycles are administered based on clinical evaluation.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Vyvgart Hytrulo is not recommended in the following situations:

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1. **Concomitant Use with Another Neonatal Fc Receptor Blocker, a Complement Inhibitor, a Rituximab Product, or Uplizna® (inebilizumab-cdon intravenous infusion).** There is no evidence to support concomitant use of Vyvgart Hytrulo with another neonatal Fc receptor blocker, a complement inhibitor, a rituximab product, or Uplizna.
   Note: Examples of neonatal Fc receptor blockers are Imaavy (nipocalimab-aahu intravenous infusion), Rystiggo (rozanolixizumab-noli subcutaneous infusion), and Vyvgart (efgartigimod alfa-fcab intravenous infusion).
   Note: Examples of complement inhibitors are eculizumab intravenous infusion (Soliris, biosimilars), Ultomiris (ravulizumab-cwvz intravenous infusion), and Zilbrysq (zilucoplan subcutaneous injection).

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Chronic Inflammatory Demyelinating Polyneuropathy (CIDP):** This condition and criteria for approval were added to the policy. **Conditions Not Recommended for Approval, Concomitant Use with Another Neonatal Fc Receptor Blocker, a Complement Inhibitor, or a Rituximab Product:** Ultomiris subcutaneous injection was removed from the Note regarding examples of complement inhibitors.	07/17/2024
Annual Revision	**Chronic Inflammatory Dymelinating Polyneuropathy (CIDP):** For a patient who is currently receiving Vyvgart Hytrulo, the requirement that the medication be prescribed by or in consultation with a neurologist was added. Dosing information for the Vyvgart Hytrulo prefilled syringe was added to the dosing section. **Generalized Myasthenia Gravis:** Dosing information for the Vyvgart Hytrulo prefilled syringe was added to the dosing section. **Conditions Not Recommended for Approval, Concomitant Use with Another Neonatal Fc Receptor Blocker, a Complement Inhibitor, or a Rituximab Product:** Imaavy was added to the Note of examples of neonatal Fc receptor blockers. Biosimilars to Soliris were added to the Note of examples of complement inhibitors, where only Soliris was previously noted.	06/04/2025
Selected Revision	**Chronic Inflammatory Demyelinating Polyneuropathy (CIDP):** For a patient who is currently receiving Vyvgart Hytrulo, the requirement that the patient is ≥ 18 years of age was added.	06/11/2025
Selected Revision	**Generalized Myasthenia Gravis:** In initial therapy and for a patient currently receiving therapy, removed the requirement that treatment cycles are no more frequent than every 50 days from the start of the previous treatment cycle. **Dosing:** Removed the requirement that treatment cycles are no more frequent than every 50 days from the start of the previous treatment cycle. Added a Note that subsequent treatment cycles are administered based on clinical evaluation.	11/05/2025
Selected Revision	**Conditions Not Recommended for Approval:** The condition "Concomitant Use with Another Neonatal Fc Receptor Blocker, a Complement Inhibitor, a Rituximab Product" was revised to "Concomitant Use with Another Neonatal Fc Receptor Blocker, a Complement Inhibitor, a Rituximab Product, or Uplizna® (inebilizumab-cdon intravenous infusion)".	02/18/2026
Annual Revision	**Generalized Myasthenia Gravis:** Removed the criterion that the patient has confirmed anti-acetylcholine receptor antibody-positive generalized myasthenia gravis.	05/20/2026
Selected Revision	**Generalized Myasthenia Gravis**. Updated wording from "Patient received or is currently receiving pyridostigmine" to "Patient has received or is currently receiving pyridostigmine." Updated wording from "Patient has had inadequate efficacy, a contraindication, or significant intolerance to pyridostigmine" to "Patient has a contraindication to pyridostigmine." Added a criterion to bypass the trial of pyridostigmine if the patient has anti-muscle-specific tyrosine kinase (MuSK) antibody-positive generalized myasthenia gravis.	07/08/2026

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