Drug Coverage Policy

Effective Date 5/1/2026
Coverage Policy Number.....IP0574
Policy Title.....Vyvgart Hytrulo

Neurology – Vyvgart Hytrulo

- Vyvgart® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc subcutaneous injection – Argenx/Halozyme)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW

Vyvgart Hytrulo, a neonatal Fc receptor blocker, is indicated for the following use:[1]

- **Chronic inflammatory demyelinating polyneuropathy** (CIDP), treatment in adults;

- **Generalized myasthenia gravis** (gMG), treatment of adults who are anti-acetylcholine receptor antibody-positive (AChR).

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 (IgG) autoantibodies against neuromuscular junction components (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 affected.

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

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-acetylcholine receptor 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).

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-muscle specific kinase antibody positive myasthenia gravis who have an unsatisfactory response to initial immunotherapy. Eculizumab should be considered in the treatment of severe, refractory, anti-acetylcholine receptor antibody positive gMG.

Coverage Policy

POLICY STATEMENT

Prior Authorization is required for 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.

Documentation: Documentation is required where noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, laboratory tests, claims records, prescription receipts and/or other information. All documentation must include patient-specific identifying information.

Vyvgart Hytrulo is considered medically necessary when ONE of the following is met:

FDA-Approved Indications

1. **Chronic Inflammatory Demyelinating Polyneuropathy (CIDP).** Approve for the duration noted below 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 has a contraindication to intravenous or subcutaneous immune globulin; OR
    Note: Examples of intravenous or subcutaneous immune globulin include: Gammagard Liquid, Gammaked, Gamunex-C, Panzyga, Privigen, Hizentra, and HyQvia.
  - **b)** 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; AND
- **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 ii):
- **i.** Patient is ≥ 18 years of age; AND
- **ii.** According to the prescriber, the patient has a clinically significant improvement in neurologic symptoms; AND
  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.

2. Generalized Myasthenia Gravis. Approve 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, v, and vi):
- **i.** Patient is ≥ 18 years of age; AND
- **ii.** Patient has confirmed anti-acetylcholine receptor antibody-positive generalized myasthenia gravis **[documentation required]**; AND
- **iii.** 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
- **iv.** Patient meets ONE of the following (a or b):
  - **a)** Patient received or is currently receiving pyridostigmine; OR
  - **b)** Patient has had inadequate efficacy, a contraindication, or significant intolerance to pyridostigmine; AND
- **v.** 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).
- **vi.** 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 Covered

Vyvgart Hytrulo for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

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 or subcutaneous injection), and Zilbrysq (zilucoplan subcutaneous injection).

Coding Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J9334	Injection, efgartigimod alfa, 2 mg and hyaluronidase-qvfc

References

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3. Gogia B, Rocha Cabrero F, Khan Suheb MZ, et al. Chronic Inflammatory Demyelinating Polyradiculoneuropathy. March 4, 2024. In: StatPearls [Internet]. Available at: https://www.ncbi.nlm.nih.gov/books/NBK563249/. Accessed on May 28, 2025.
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5. Mathey EK, Park SB, Hughes R, et al. Chronic inflammatory demyelinating polyradiculoneuropathy: from pathology to phenotype. *J Neurol Neurosurg Psychiatry.* 2015;86:973-985.
6. National Institute of Neurological Disorders and Stroke (NINDS). Myasthenia Gravis Fact Sheet. National Institutes of Health (NIH) Publication No. 17-768. Publication last updated: March 2020. Available at: https://www.ninds.nih.gov/sites/default/files/migrate-documents/myasthenia_gravis_e_march_2020_508c.pdf Accessed on May 23, 2025.
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12. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis. *Neurology*. 2016;87:419–425.
13. Narayanaswami P, Sanders DB, Wolfe G, et al. International Consensus Guidance for Management of Myasthenia Gravis: 2020 Update. *Neurology*. 2021;96(3):114-122.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	**Generalized Myasthenia Gravis:** **Updated "**Treatment cycles are no more frequent than every 50 days from the start of the previous treatment cycle" **from** Dosing section **to** criteria under Generalized Myasthenia Gravis. **Added "**Patient is Currently Receiving Vyvgart Hytrulo (or Vyvgart Intravenous [efgartigimod alfa-fcab intravenous infusion])" criteria **Chronic Inflammatory Demyelinating Polyneuropathy (CIDP):** This condition and criteria for approval were added to the policy. **Updated Coding:** **Removed** C9399, J3490, J3590 **Added** J9334 (effective 1/1/2024)	10/15/2024

Annual Revision	**Added** documentation instructions **Chronic Inflammatory Dymelinating Polyneuropathy (CIDP):** For a patient who is currently receiving Vyvgart Hytrulo, the requirement that the patient is ≥ 18 years of age was added and 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. **Updated from** "Documentation that the patient has confirmed anti-acetylcholine receptor antibody positive generalized myasthenia gravis" **to** "patient has confirmed anti-acetylcholine receptor antibody positive generalized myasthenia gravis **[documentation required**]" **Conditions Not Covered, 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.	8/15/2025
Selected Revision	**Updated** policy template.	11/1/2025
Selected Revision	**Chronic Inflammatory Demyelinating Polyneuropathy (CIDP).** **Added** Note: Chronic inflammatory demyelinating polyneuropathy can also be referred to as chronic relapsing polyneuropathy or chronic inflammatory demyelinating polyradiculoneuropathy. **Added** Note: Examples of intravenous or subcutaneous immune globulin include: Gammagard Liquid, Gammaked, Gamunex-C, Panzyga, Privigen, Hizentra, and HyQvia. **Generalized Myasthenia Gravis.** **Initial Therapy and Patient is Currently Receiving Vyvgart Hytrulo (or Vyvgart Intravenous [efgartigimod alfa intravenous infusion]):** Removed the requirement that treatment cycles are no more frequent than every 50 days from the start of the previous treatment	01/15/2026

	cycle; this stipulation was removed from the prescribing information. **Dosing:** Removed the requirement that treatment cycles are no more frequent than every 50 days from the start of the previous treatment cycle; this stipulation was removed from the prescribing information. Added a Note that subsequent treatment cycles are administered based on clinical evaluation.	
Selected Revision	**Updated** documentation statement **from** "Documentation: Documentation is required where noted in the criteria as [documentation required]. Documentation may include, but is not limited to, chart notes, laboratory tests, claims records and/or other information. All documentation must include patient-specific identifying information" **to** "Documentation: Documentation is required where noted in the criteria as [documentation required]. Documentation may include, but is not limited to, chart notes, laboratory tests, claims records, prescription receipts and/or other information. All documentation must include patient-specific identifying information." **Conditions Not Covered** The condition "Concomitant Use with Another Complement Inhibitor, a Neonatal Fc Receptor Blocker, or a Rituximab Product" was revised to "Concomitant Use with Another Complement Inhibitor, a Neonatal Fc Receptor Blocker, a Rituximab Product, or Uplizna® (inebilizumab-cdon intravenous infusion)."	5/1/2026

The policy effective date is in force until updated or retired.