efgartigimod alfa (Vyvgart®), efgartigimod alfa and hyaluronidase- human (Vyvgart® Hytrulo)

Medicare Advantage Medical Policy # 098
Original Effective Date: 06/01/2025
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Applies to all products administered or underwritten by the Health Plan, unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Generalized Myasthenia Gravis (gMG)

Based on review of available data, the Health Plan may consider efgartigimod alfa (Vyvgart®)‡ and efgartigimod alfa and hyaluronidase- human (Vyvgart Hytrulo) for the treatment of myasthenia gravis to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for efgartigimod alfa (Vyvgart) or efgartigimod alfa and hyaluronidase- human (Vyvgart Hytrulo) for the treatment of myasthenia gravis will be considered when the following criteria are met:

- Initial
    - Patient is greater than or equal to 18 years of age; AND
    - Patient has a diagnosis of generalized myasthenia gravis; AND
    - Patient has an anti-acetylcholine receptor autoantibody positive serologic test; AND
    - Patient has a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV; AND
    - Patient has a baseline IgG level of at least 6 g/L; AND
    - Patient has received or is currently receiving pyridostigmine unless there is clinical evidence or patient history that suggests the use of pyridostigmine will cause an adverse effect or inadequate response to the patient; AND
    - Patient has received or is currently receiving at least one nonsteroidal immunosuppressive therapy (NSIST) for at least 1 year unless there is clinical evidence or patient history that suggests NSISTs will be ineffective or cause an adverse reaction to the patient. Examples of NSISTs include azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus, and cyclophosphamide; AND
    - Patient has evidence of unresolved symptoms of generalized myasthenia gravis, such as difficulty swallowing, difficulty breathing, or a functional disability resulting in the discontinuation of physical activity (e.g., double vision, talking, impairment of mobility); AND

  - Dose does not exceed the lower of 10 mg/kg or 1200 mg once weekly for Vyvgart or 1,008 mg/11,200 units once weekly for Vyvgart Hytrulo
- Continuation
  - Patient has received an initial authorization for Vyvgart or Vyvgart Hytrulo from the plan OR has provided documentation of authorization from previous Medicare Advantage plan; AND
  - It has been at least 50 days since the start of the previous treatment cycle; AND
  - Patient has experienced improvement on therapy as evidenced by at least ONE of the following
    - Improvement in the Myasthenia Gravis Activities of Daily Living (MG-ADL) total score; OR
    - Improvement in Quantitative Myasthenia Gravis (QMG) total score; AND
  - Dose does not exceed the lower of 10 mg/kg or 1200 mg once weekly for Vyvgart or 1,008 mg/11,200 units once weekly for Vyvgart Hytrulo.

Chronic Inflammatory Demyelinating Polyradiculoneuropathy (CIDP)

Based on review of available data, the Health Plan may consider efgartigimod alfa and hyaluronidase- human (Vyvgart Hytrulo) for the treatment of chronic inflammatory demyelinating polyradiculoneuropathy to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for efgartigimod alfa and hyaluronidase- human (Vyvgart Hytrulo) for the treatment of chronic inflammatory demyelinating polyradiculoneuropathy will be considered when the following criteria are met:

- Initial
  - Patient is greater than or equal to 18 years of age; AND
  - Patient has a diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP); AND
  - Patient has tried and failed (e.g., intolerance or inadequate response) treatment with corticosteroids unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND
  - Patient has tried and failed (e.g., intolerance or inadequate response) treatment with intravenous or subcutaneous immune globulin unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient. Examples of intravenous or subcutaneous immune globulin include but are not limited to: Gammagard Liquid®‡, Gammaked™‡, Gamunex®-C‡, Panzyga®‡, Privigen®‡, Hizentra®‡, and HyQvia®‡; AND
  - Dose does not exceed 1,008 mg/11,200 units once weekly; AND
  - Requested drug is not used in combination with immune globulin or intravenous efgartigimod.

- Continuation
  - Patient has received an initial authorization for Vyvgart Hytrulo from the plan OR has provided documentation of authorization from previous Medicare Advantage plan; AND
  - Patient has experienced clinically significant improvement in neurological symptoms while on therapy; AND
  - Dose does not exceed 1,008 mg/11,200 units once weekly; AND
  - Requested drug is not used in combination with immune globulin or intravenous efgartigimod.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Health Plan considers the use of efgartigimod alfa (Vyvgart) or efgartigimod alfa and hyaluronidase- human (Vyvgart Hytrulo) for myasthenia gravis that is not MGFA class II to IV, when the patient does not have a baseline IgG level of at least 6 g/dL, has not tried and failed pyridostigmine in addition to at least one NSIST, or does not have evidence of unresolved symptoms of generalized myasthenia gravis to be **not medically necessary.****

Based on review of available data, the Health Plan considers the use of efgartigimod alfa and hyaluronidase- human (Vyvgart Hytrulo) for CIDP when the patient has NOT tried and failed corticosteroids or intravenous or subcutaneous immune globulin to be **not medically necessary.****

Based on review of available data, the Health Plan considers the continued use of efgartigimod alfa (Vyvgart) or efgartigimod alfa and hyaluronidase- human (Vyvgart Hytrulo) when the patient has not experienced improvement while on therapy to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Health Plan considers the use of efgartigimod alfa (Vyvgart) or efgartigimod alfa and hyaluronidase- human (Vyvgart Hytrulo) when the patient selection criteria are not met (except those denoted above as **not medically necessary****) to be **investigational.***

Policy Guidelines

Myasthenia Gravis Foundation of America (MGFA) Clinical Classification

Class	***Description***
I	Any ocular muscle weakness; may have weakness of eye closure. All other muscle strength is normal
IIa	Mild weakness affecting muscles other than ocular muscles. Predominantly affecting limb, axial muscles, or both. May also have lesser involvement of oropharyngeal muscles

IIb	Mild weakness affecting muscles other than ocular muscles. Predominantly affecting oropharyngeal, respiratory muscles, or both. May also have lesser or equal involvement of limb, axial muscles, or both.
IIIa	Moderate weakness affecting muscles other than ocular muscles. Predominantly affecting limb, axial muscles, or both. May also have lesser involvement of oropharyngeal muscles.
IIIb	Moderate weakness affecting muscles other than ocular muscles. Predominantly affecting oropharyngeal, respiratory muscles, or both. May also have lesser or equal involvement of limb, axial muscles, or both.
IVa	Severe weakness affecting muscles other than ocular muscles. Predominantly affecting limb, axial muscles, or both. May also have lesser involvement of oropharyngeal muscles.
IVb	Severe weakness affecting muscles other than ocular muscles. Predominantly affecting oropharyngeal, respiratory muscles, or both. May also have lesser or equal involvement of limb, axial muscles, or both.
V	Intubation with or without mechanical ventilation except when employed during routine postoperative management.

Myasthenia Gravis Activities of Daily Living (MG-ADL) profile

Grade	***0***	***1***	***2***	***3***	***Score***
1. Talking	Normal	Intermittent slurring or nasal speech	Constant slurring or nasal, but can be understood	Difficult to understand speech	
2. Chewing	Normal	Fatigue with solid food	Fatigue with soft food	Gastric tube	
3. Swallowing	Normal	Rare episode of choking	Frequent choking necessitating changes in diet	Gastric tube	
4. Breathing	Normal	Shortness of breath with exertion	Shortness of breath at rest	Ventilator dependence	
5. Impairment of ability to brush teeth or comb hair	None	Extra effort, but no rest periods needed	Rest periods needed	Cannot do one of these functions	
6. Impairment of ability to arise from a chair	None	Mild, sometimes uses arms	Moderate, always uses arms	Severe, requires assistance	

7. Double vision	None	Occurs, but not daily	Daily, but not constant	Constant	
8. Eyelid droop	None	Occurs, but not daily	Daily, but not constant	Constant	
				MG-ADL score total (items 1-8)=	

Quantitative Myasthenia Gravis (QMG) Score

Test Item	***None***	***Mild***	***Moderate***	***Severe***	***Score***
Grade	***0***	***1***	***2***	***3***	
Double vision on lateral gaze (secs)	61	11-60	1-10	Spontaneous	
Ptosis (upward gaze)	61	11-60	1-10	Spontaneous	
Facial muscles	Normal lid closure	Complete, weak, some resistance	Complete without resistance	Incomplete	
Swallowing 4 oz water	Normal	Minimal coughing or throat clearing	Severe coughing/choking or nasal congestion	Cannot swallow (test not attempted)	
Speech after counting aloud from 1 to 50 (onset of dysarthria)	None at 50	Dysarthria at 30-49	Dysarthria at 10-29	Dysarthria at 9	
Right arm outstretched (90 degrees sitting), seconds	240	90-239	10-89	0-9	
Left arm outstretched (90 degrees sitting), seconds	240	90-239	10-89	0-9	
Forced Vital Capacity	≥80	65-79	50-64	≤50	
Rt-hand grip, kg Men Women	 ≥45 ≥30	 15-44 10-29	 5-14 5-9	 0-4 0-4	
Lt-hand grip, kg	≥35	15-34	5-14	0-4	

Men Women	≥25	10-24	5-9	0-4	
Head lifted (45 degrees supine), seconds	120	30-119	1-29	0	
Right leg outstretched (45 degrees supine), seconds	100	31-99	1-30	0	
Left leg outstretched (45 degrees supine), seconds	100	31-99	1-30	0	
				Total QMG Score:	

Background/Overview

Vyvgart and Vyvgart Hytrulo contain a first-in-class human immunoglobulin G1 (IgG1) antibody fragment and are both indicated for the treatment of generalized myasthenia gravis in adults with anti-acetylcholine receptor antibodies. Vyvgart Hytrulo is also indicated for the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP). The active ingredient in both products is efgartigimod alfa and it works by binding to the neonatal Fc receptor (FcRn) causing the antibodies to stay in circulation and preventing FcRn from recycling IgG back into the blood. This leads to a reduction in the overall levels of IgG, including the abnormal AChR antibodies that are present in most patients with generalized myasthenia gravis. Vyvgart is administered as a 10 mg/kg intravenous infusion over 1 hour once weekly for 4 weeks. In patients weighing 120 kg or more, the recommended dose is 1200 mg per infusion. If subsequent treatment cycles are needed (determined based on clinical evaluation), they should be initiated no sooner than 50 days from the start of the previous treatment cycle. Vyvgart Hytrulo is formulated with hyaluronidase which allows it to be administered subcutaneously. Vyvgart Hytrulo should be administered as a 1,008 mg subcutaneous infusion over approximately 30 to 90 seconds. In CIDP, Vyvgart Hytrulo is administered as one injection once a week. The dosing in myasthenia gravis is administered in cycles of once weekly injections for 4 weeks. Both products must be administered by a healthcare professional. It should be noted that these drugs cause a reduction in IgG levels, so immunization with live-attenuated or live vaccines is not recommended during treatment. If indicated, these vaccines should be administered prior to initiation of a Vyvgart or Vyvgart Hytrulo treatment cycle.

Generalized Myasthenia Gravis (gMG)

Myasthenia gravis is a chronic autoimmune neuromuscular disease that causes weakness in the skeletal muscles. The hallmark of the condition 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. Acquired myasthenia gravis results from the binding of autoantibodies to components of the neuromuscular junction, most commonly the acetylcholine receptor (AChR). However, antibodies to other proteins, such as the muscle-specific kinase (MuSK) protein, can also lead to impaired transmission at the neuromuscular junction. Myasthenia gravis most commonly occurs in young adult women (<40 years of age) and older men (>60 years of age), but it can occur at any age, including childhood. The incidence ranges from 0.3 to 2.8 per 100,000, and it is estimated to affect more than 700,000 people worldwide. Various clinical scoring systems are available to assess the severity of disease and include the Myasthenia Gravis Foundation of America (MGFA) clinical classification system, Myasthenia Gravis Activities of Daily Living (MG-ADL), and Quantitative Myasthenia Gravis (QMG) test.

Medications to treat myasthenia gravis include anticholinesterase agents (e.g., pyridostigmine), which slow the breakdown of acetylcholine at the neuromuscular junction and thereby improve neuromuscular transmission and increase muscle strength. Immunosuppressive drugs improve muscle strength by suppressing the production of abnormal antibodies and may include prednisone, azathioprine, mycophenolate mofetil, tacrolimus, and rituximab. Plasmapheresis and intravenous immunoglobulin (IVIG) may be options in severe cases to remove the destructive antibodies; however, their effectiveness frequently lasts only a few weeks to months. Additionally, the Food and Drug Administration (FDA) recently approved eculizumab (Soliris®)‡, ravulizumab (Ultomiris™)‡, and zilucoplan (Zilbrysq®)‡, all complement inhibitors, as well as rozanolixizumab (Rystiggo), an IgG4 monoclonal antibody that binds to the neonatal Fc receptor for the treatment of generalized myasthenia gravis. Although Soliris, Ultomiris, Vyvgart, Vyvgart Hytrulo, Zilbrysq and Rystiggo are the only agents with FDA approval for the condition, the other agents have been used off-label and are still recommended as first-line therapy in clinical practice guidelines. Available guidelines have not been updated to address Vyvgart.

Chronic Inflammatory Demyelinating Polyradiculoneuropathy (CIDP)
CIDP is a group of related neuropathies that all have chronicity, demyelination, inflammation, and immune mediation in common. The disorder is caused by damage to the myelin sheath of the peripheral nerves. The disease is difficult to diagnose due to its heterogeneous presentation (both clinical and electrophysiological). Symptoms generally consist of symmetric weakness in both proximal and distal muscles, numbness, fatigue, ambulating difficulties, falls, fine motor impairment, and paresthesia. In the classic form of the condition, motor involvement is greater than sensory, and the course is slowly progressive. However, a relapsing-remitting course occurs in at least one-third of patients and is more common in the pediatric age group. CIDP generally responds to immunosuppressive or immunomodulatory treatment with glucocorticoids, IVIG, or plasma exchange. Use of Vyvgart Hytrulo for CIDP is not currently addressed in guidelines.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Vyvgart was approved in December 2021 for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive. Vyvgart Hytrulo was approved in June 2023 for the same indication as Vyvgart. In June of 2024, Vyvgart Hytrulo was approved for the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP).

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The efficacy of Vyvgart for the treatment of generalized myasthenia gravis in adults who are AChR antibody positive was established in a 26-week, multicenter, randomized, double-blind, placebo-controlled trial. Included patients had a Myasthenia Gravis Foundation of America (MGFA) clinical classification class II to IV, MG-ADL total score of $\geq$5, and were on a stable dose of myasthenia gravis therapy prior to screening that included acetylcholinesterase (AChE) inhibitors, steroids, or NSISTs, either in combination or alone. Additionally, patients had IgG levels of at least 6 g/L. A total of 167 patients were enrolled and were randomized to receive either Vyvgart 10 mg/kg (1200 mg for those weighing 120 kg or more) (n=84) or placebo (n=83). At baseline, over 80% of patients in each group received AChE inhibitors, over 70% in each group received steroids, and approximately 60% in each treatment group received NSISTs, at stable doses.

The efficacy of Vyvgart was measured using the Myasthenia Gravis-Specific Activities of Daily Living (MG-ADL) scale, which assesses the impact of generalized myasthenia gravis on daily functions of 8 signs or symptoms that are typically affected in the condition. Each item is assessed on a 4-point scale where a score of 0 represents normal function and a score of 3 represents loss of ability to perform that function. A total score ranges from 0 to 24, with the higher scores indicating more impairment. In this study, an MG-ADL responder was defined as 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. The primary efficacy endpoint was the comparison of the percentage of MG-ADL responders during the first treatment cycle between treatment groups in the AChR-Ab positive population. A statistically significant difference favoring Vyvgart was observed in the MG-ADL responder rate during the first treatment cycle [67.7% in the Vyvgart-treated group vs 29.7% in the placebo-treated group ($p<0.0001$)].

The efficacy of Vyvgart Hytrulo was based on a study demonstrating comparable pharmacodynamic effect on AChR antibody reduction as compared to the Vyvgart intravenous formulation.

The efficacy of Vyvgart Hytrulo for the treatment of adults with CIDP was established in a two stage, multicenter study. The open-label phase identified responders to Vyvgart Hytrulo (Stage A) who then entered a randomized, double-blind, placebo-controlled, withdrawal period (Stage B). All enrollees 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 up to 12 once weekly subcutaneous injections of Vyvgart Hytrulo until evidence of improvement occurred at two consecutive study visits. Improvement was defined as an improvement of at least one point in the Inflammatory Neuropathy Cause and Treatment disability score (INCAT), 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. 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. Overall, 69% of patients (n = 221/322) who had documented improvement at two consecutive visits during Stage A then entered Stage B. In 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).

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03/18/2025 UM Committee Review. New Policy
Next Scheduled Review Date: 03/2026

Coding

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No code
HCPCS	J9332, J9334
ICD-10 Diagnosis	All related Diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and

whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient's health insurance contract contains language that differs from the Health Plan Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Health plan recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

Medicare Advantage Members

Established coverage criteria for Medicare Advantage members can be found in Medicare coverage guidelines in statutes, regulations, National Coverage Determinations (NCD)s, and Local Coverage Determinations (LCD)s. To determine if a National or Local Coverage Determination addresses coverage for a specific service, refer to the Medicare Coverage Database at the following link: https://www.cms.gov/medicare-coverage-database/search.aspx. You may wish to review the Guide to the MCD Search here: https://www.cms.gov/medicare-coverage-database/help/mcd-bene-help.aspx.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, internal coverage criteria may be developed. This policy is to serve as the summary of evidence, a list of resources and an explanation of the rationale that supports the adoption of this internal coverage criteria.