UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Neurology – Vyvgart Intravenous Utilization Management Medical Policy
- Vyvgart® (efgartigimod alfa-fcab intravenous infusion – Argenx)

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

OVERVIEW

Vyvgart Intravenous (IV), a neonatal Fc receptor blocker, is indicated for the treatment of adult patients with **generalized myasthenia gravis**.[1]

Disease Overview

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.[2] Myasthenia gravis is caused by the production of pathogenic immunoglobulin G (IgG) autoantibodies against neuromuscular junction components (acetylcholine receptor [AChR], muscle-specific tyrosine kinase [MuSK], and low density lipoprotein receptor-related protein 4 [LRP4]).[3] Approximately 85% of patients with myasthenia gravis are anti-AChR antibody-positive and approximately 5% to 8% of patients are anti-MuSK antibody-positive.[4] The result of the antibodies at the junction is unsuccessful nerve transmission and deficiency or weakness of muscle contractions.[3] 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, neck and limb movements may also be 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.[8]

Clinical Efficacy

Anti-AChR antibody-positive

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).[1] 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 generalized myasthenia gravis 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 ($P < 0.0001$).

Anti-AChR antibody-negative

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The ADAPT SERON study enrolled adults patients with gMG who are anti-AChR antibody negative.[1,7] This included patients with antibody positive MuSK (34%), antibody positive 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 infusion 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 squared [LS] mean difference [95% confidence interval] = -1.46 [-2.50 to -0.41]; p = 0.0068).[1]

Dosing Information

For patients weighing < 120 kg, the recommended dose is 10 mg/kg administered as an IV infusion over one hour once weekly for 4 weeks.[1] For patients weighing ≥ 120 kg, the recommended dose is 1200 mg per infusion. Administer subsequent treatment cycles based on clinical evaluation.

Guidelines

An international consensus guidance for the management of myasthenia gravis was published in 2016.[5] 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).[6] 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 generalized myasthenia gravis 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 tyrosine 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 generalized myasthenia gravis.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Vyvgart IV. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. 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 IV as well as the monitoring required for adverse events and long-term efficacy, approval requires Vyvgart IV to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

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RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

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1. **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, 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 Intravenous (or Vyvgart Hytrulo [efgartigimod alfa and hyaluronidase-qvfc subcutaneous injection]). 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 Intravenous (or Vyvgart Hytrulo); 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 if the patient meets ONE of the following dosing regimens (A or B):
   - **A)** Patient weighs < 120 kg: The dose is 10 mg/kg administered by intravenous infusion once weekly for 4 weeks; OR
   - **B)** Patient weighs ≥ 120 kg: The dose is 1,200 mg administered by intravenous infusion once weekly for 4 weeks.
     Note. Subsequent treatment cycles are administered based on clinical evaluation.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

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

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 Intravenous with another neonatal Fc receptor blocker, a complement inhibitor, a rituximab product, or Uplizna.

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Note: Examples of neonatal Fc receptor blockers are Imaavy (nipocalimab-aahu intravenous infusion), Rystiggo (rozanolixizumab-noli subcutaneous infusion), and Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc subcutaneous injection).
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.

REFERENCES

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8. Rodolico C, Bonanno C, Toscano A, et al. MuSK-associated myasthenia gravis: Clinical features and management. *Front Neurol.* 2020;11:660.

HISTORY

Type of Revision	Summary of Changes	Review Date
Selected Revision	**Generalized Myasthenia Gravis:** "Treatment cycles are no more frequent than every 50 days from the start of the previous treatment cycle" was added to the Dosing section.	02/28/2024
Annual Revision	**Conditions Not Recommended for Approval, Concomitant Use with Another Neonatal Fc Receptor Blocker, a Complement Inhibitor, or a Rituximab Product:** Removed Ultomiris subcutaneous injection from the Note of examples of complement inhibitors.	07/24/2024
Annual Revision	**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	**Generalized Myasthenia Gravis.** **Initial Therapy and Patient is Currently Receiving Vyvgart Intravenous (or Vyvgart Hytrulo [efgartigimod alfa and hyaluronidase-qvfc subcutaneous injection]):** 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. **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.	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"	02/18/2026

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	was revised to "Concomitant Use with Another Neonatal Fc Receptor Blocker, a Complement Inhibitor, a Rituximab Product, or Uplizna® (inebilizumab-cdon intravenous infusion)".	
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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