Vyvgart™ (efgartigimod alfa-fcab) & Vyvgart® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)

Humana

Pharmacy Coverage Policy

Effective Date: March 23, 2022
Revision Date: July 26, 2023
Review Date: July 19, 2023
Line of Business: Medicare, Commercial, Medicaid - South Carolina, Medicaid - Ohio
Policy Type: Prior Authorization

Products Affected

Vyvgart intravenous solution
Vyvgart Hytrulo subcutaneous solution

Listed Indications

Generalized Myasthenia Gravis (gMG)

Generalized Myasthenia Gravis (gMG)

Does the member meet all of the following criteria?	
Criteria #1	The member has a diagnosis of generalized myasthenia gravis
Criteria #2	The presence of anti-acetylcholine receptor (AChR) antibodies has been confirmed
Criteria #3	The member is being treated by, or under the supervision of, a specialist (e.g. neurologist) experienced in the management of generalized myasthenia gravis
Criteria #4	The member has had previous treatment, contraindication, or intolerance to:* • Pyridostigmine **AND** • At least one immunosuppressive therapy (e.g. azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) **Prior therapy requirements do not apply to Medicare medical (Part B) requests*
Approval Duration	
Initial	Plan year duration

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Background

This is a prior authorization policy about Vyvgart (efgartigamod alfa-fcab) and Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc). Please refer to each product's package insert for complete prescribing information.

Efgartigimod alfa is a human IgG1 antibody fragment that binds to the neonatal Fc receptor (FcRn), resulting in the reduction of circulating IgG, including autoantibodies that are present inpatients with generalized myasthenia gravis (gMG). Hyaluronidase increases permeability of the subcutaneous tissue by depolymerizing hyaluronan. This effect is transient and permeability of the subcutaneous tissue is restored within 24 to 48 hours.

Generalized myasthenia gravis (gMG) is a rare, chronic, autoimmune neuromuscular disease characterized by dysfunction and damage at the neuromuscular junction. This damage leads to fluctuating muscle weakness and fatigue throughout the body that worsens with activity and improves with rest. Autoantibodies against the acetylcholine receptor (AChR) are present in about 85% of people living with gMG, while muscle-specific tyrosine kinase (MuSK) autoantibodies occur in about 6% of patients making these the two most common subtypes of gMG.

Vyvgart (efgartigamod alfa-fcab) and Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) are indicated for the treatment of generalized

myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

Efgartigimod alfa is available as Vyvgart in a 400 mg/20 ml (20mg/ml) single-dose vial for intravenous use.
Efgartigimod alfa and hyaluronidase-qvfc is available as Vyvgart Hytrulo in a single-dose vial for subcutaneous use containing 1,008mg efgartigimod alfa and 11,200 units hyaluronidase per 5.6 mL.

Warnings & Precautions:

- Infections: Delay administration to patients with an active infection. Monitor for signs and symptoms of infection. If serious infection occurs, administer appropriate treatment and consider withholding treatment until the infection has resolved.
- Hypersensitivity Reactions: Angioedema, dyspnea, and rash have occurred. If a hypersensitivity reaction occurs, institute appropriate supportive measures.

Other Considerations:

- Vyvgart Hytrulo should be administered subcutaneously by a healthcare professional using a winged infusion set.
- Because Vyvgart and Vyvgart Hytrulo cause a reduction in IgG levels, vaccination with live-attenuated or live vaccines is not recommended during treatment with these agents.

Provider Claim Codes

For medically billed requests, please visit www.humana.com/PAL. Select applicable Preauthorization and Notification List(s) for medical and procedural coding information.

Medical Terms

Generalized myasthenia gravis; gMG; Vyvgart; efgartigamod alfa-fcab; intravenous; IV; pharmacy

References

1. Clinical Pharmacology [database online]. Philadelphia, PA: Elsevier, Inc.; URL: https://www.clinicalkey.com/pharmacology/. Updated periodically.
2. IBM Micromedex DRUGDEX® [database online]. Armonk, NY: IBM Corporation; URL: http://www.micromedexsolutions.com/. Updated periodically.
3. Narayanaswami P, Sanders DB, Wolfe G, et al. International Consensus Guidance for Management of Myasthenia Gravis: 2020 Update. *Neurology.* 2021 Jan 19;96(3):114-122. Epub 2020 Nov 3.
4. Vyvgart [package insert]. Boston, MA: Argenx US, Inc.; Dec 2021.
5. Vyvgart Hytrulo [package insert]. Boston, MA: Argenx US, Inc.; Jun 2023.

Disclaimer	State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, take precedence over clinical policy and must be considered first in determining eligibility for coverage. Coverage may also differ for our Medicare and/or Medicaid members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including National Coverage Determinations (NCD), Local Medical Review Policies (LMRP) and/or Local Coverage Determinations. See the CMS website at http://www.cms.hhs.gov/. The member's health plan benefits in effect on the date services are rendered must be used. Clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their

	medical judgment in rendering appropriate care. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically.