Effective Date: 04/27/2022
Last P&T Approval/Version: 04/27/2022
Next Review Due By: 04/2023
Policy Number: C23127-A

Vyvgart (efgartigimod)

PRODUCTS AFFECTED

Vyvgart (efgartigimod)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive

DIAGNOSIS:
generalized myasthenia gravis (gMG)

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review

A. GENERALIZED MYASTHENIA GRAVIS
1. Documentation of a diagnosis of generalized myasthenia gravis
   AND
2. Documentation of a positive serological test for anti-AChR antibodies
   AND
3. Documentation member is currently on a stable dose of at least 1 treatment for generalized myasthenia gravis (acetylcholinesterase (AChE) inhibitors, steroids, immunosuppressive therapy)
   AND
4. Documentation of members Myasthenia Gravis-Specific Activities of Daily Living (MG-ADL) total score (or other means for treatment plan efficacy monitoring)

5. (a) Documentation of inadequate response to, is intolerant of, or has a labeled contraindication to ONE or more immunosuppressive drug agents used alone or in combination for at least 6 months one year [i.e., azathioprine (Imuran), mycophenolate mofetil (Cellcept), cyclosporine (Sandimmune), cyclophosphamide, methotrexate, tacrolimus, rituximab (Rituxan), steroids]

CONTINUATION OF THERAPY:

A. GENERALIZED MYASTHENIA GRAVIS:

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation (documentation required)
   AND
2. Documentation of no intolerable adverse effects or drug toxicity
   AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms by ONE of the following: (a) Improvement of at least 3 points (reduction in score) from pre-treatment baseline on the Myasthenia Gravis-Specific Activities of Daily Living (MG-ADL) assessment, (b) reduction in signs and symptoms of myasthenia gravis and stabilization, reduction, or discontinuation of dose(s) of baseline immunosuppressive therapy (IST) prior to starting Vyvgart.

DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a board-certified immunologist, neurologist, or rheumatologist [If prescribed in consultation, consultation notes must be submitted within initial request and reauthorization requests]

AGE RESTRICTIONS:

18 and older

QUANTITY:

10 mg/kg once weekly for 4 weeks; patients weighing 120 kg or more, the recommended dose is 1200 mg per infusion; subsequent cycles to be administered no sooner than 50 days from the start of the previous treatment cycle.

PLACE OF ADMINISTRATION:

The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-hospital facility-based location as per the Molina Health Care Site of Care program.

Note: Site of Care Utilization Management Policy applies for Vyvgart (efgartigimod). For information on site of care, see https://www.molinamarketplace.com/marketplace/-/media/Molina/PublicWebsite/PDF/Common/Specialty-Medication-Administration-Site-of-Care-Coverage-Criteria-Policy_v2

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intravenous infusion

DRUG CLASS:
Neonatal Fc Receptor (FcRn) Antagonists

FDA-APPROVED USES:
Indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive

COMPENDIAL APPROVED OFF-LABELED USES: None

APPENDIX

APPENDIX:

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Myasthenia gravis is a chronic autoimmune, neuromuscular disease that causes weakness in the skeletal muscles (also called voluntary muscles) that worsens after periods of activity and improves after periods of rest. Myasthenia gravis affects voluntary muscles, especially those that are responsible for controlling the eyes, face, mouth, throat, and limbs. In myasthenia gravis, the immune system produces AChR antibodies that interfere with communication between nerves and muscles, resulting in weakness. Severe attacks of weakness can cause breathing and swallowing problems that can be life-threatening.

Vyvgart is the first approval of a new class of medication. It is an antibody fragment that binds to the neonatal Fc receptor (FcRn), preventing FcRn from recycling immunoglobulin G (IgG) back into the blood. The medication causes a reduction in overall levels of IgG, including the abnormal AChR antibodies that are present in myasthenia gravis.

The application is supported by data from the multicenter, randomized, double-blind phase 3 ADAPT trial (ClinicalTrials.gov: NCT03669588) that evaluated the efficacy and safety of efgartigimod in 167 adults with gMG. In the 26-week study 167 Patients were randomly assigned 1:1 to receive efgartigimod 10mg/kg via intravenous infusion or placebo.

The primary endpoint was the percentage of responders on the Myasthenia Gravis Activities of Daily Living (MG-ADL) score among acetylcholine receptor-antibody positive (AChR-Ab+) generalized myasthenia gravis patients. Responders were defined as having at least a 2-point improvement on the MG-ADL score for at least 4 consecutive weeks.

Findings showed that a significantly greater proportion of AChR-Ab+ patients treated with efgartigimod met the primary end point compared with placebo (67.7% vs 29.7%, respectively; P <.0001). Additionally, a greater proportion of efgartigimod-treated AChR-Ab+ patients responded on the Quantitative Myasthenia Gravis (QMG) score compared with placebo (63.1% vs 14.1%, respectively; P <.0001); a responder was defined as having at least a 3-point improvement for at least 4 consecutive weeks.

The most common adverse reactions reported with efgartigimod were respiratory tract infections, headache, and urinary tract infection. As Vyvgart causes a reduction in IgG levels, the risk of infections may increase. Hypersensitivity reactions such as eyelid swelling, shortness of breath, and rash have

occurred. If a hypersensitivity reaction occurs, discontinue the infusion and institute appropriate therapy. Patients using Vyvgart should monitor for signs and symptoms of infections during treatment.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Vyvgart (efgartigimod) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. There are no contraindications to Vyvgart (efgartigimod) on current FDA label.

OTHER SPECIAL CONSIDERATIONS:

Because VYVGART causes transient reduction in IgG levels, immunization with live-attenuated or live vaccines is not recommended during treatment with VYVGART. Evaluate the need to administer age appropriate immunizations according to immunization guidelines before initiation of a new treatment cycle with VYVGART

VYVGART should be administered via intravenous infusion by a healthcare professional. Infuse the total 125 mL of diluted solution intravenously over one hour via a 0.2 micron in-line filter

CODING/BILLING 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

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:

Vyvgart: Efgartigimod alfa-fcab 400 mg/20 mL (20 mL)

REFERENCES

1. Vyvgart (efgartigimod alfa) [prescribing information]. Boston, MA: Argenx US, Inc; December 2021.
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4. Garzón-Orjuela N, et al. Quality of life in refractory generalized myasthenia gravis: A rapid review of the literature. Intractable Rare Dis Res. 2019;8(4):231–238. doi:10.5582/irdr.2019.01121
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SUMMARY OF REVIEW/REVISIONS	DATE
New Development	Q2 2022