



Original Effective Date: 04/27/2022
 Current Effective Date: 10/25/2023
 Last P&T Approval/Version: 10/25/2023
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 Policy Number: C23127-A

Vyvgart (efgartigimod)

PRODUCTS AFFECTED

Vyvgart (efgartigimod), Vyvgart Hytrulo (efgartigimod alfa-hyaluronidase-qvfc)

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. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

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

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3. Documentation member is currently on a stable dose of at least 1 treatment for generalized myasthenia gravis (acetylcholinesterase (AChE) inhibitors [pyridostigmine], steroids, immunosuppressive therapy)
AND
4. Documentation of member's Myasthenia Gravis-Specific Activities of Daily Living (MG-ADL) total score (or other means for treatment plan efficacy monitoring)
AND
5. Documentation of inadequate response, serious side effects, or labeled contraindication to ONE or more immunosuppressive drugs used alone or in combination for at least 12 months [i.e., azathioprine, mycophenolate mofetil, cyclosporine, cyclophosphamide, methotrexate, tacrolimus, steroids]
AND
6. Prescriber attests efgartigimod will not be used concurrently with Rystiggo (rozanolixizumab), Soliris (eculizumab), or Ultomiris (ravulizumab)

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
AND
2. Prescriber attests to or clinical reviewer has found no evidence of 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 as evidenced 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 OR
 - (b) Reduction in signs and symptoms of myasthenia gravis OR
 - (c) Stabilization, reduction, 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 with initial request and reauthorization requests]

AGE RESTRICTIONS:

18 years of age and older

QUANTITY:

Vyvgart:

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.

Vyvgart Hytrulo:

1,008 mg/11,200 units once weekly for 4 weeks; subsequent cycles to be administered no sooner than 50 days from the start of the previous treatment cycle

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PLACE OF ADMINISTRATION:

The recommendation is that injectable medications in this policy will be for pharmacy or medical benefit coverage and the subcutaneous injectable products administered in a place of service that is a non-hospital facility-based location.

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 [Specialty Medication Administration Site of Care Coverage Criteria \(molinamarketplace.com\)](https://molinamarketplace.com)

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

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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.

Vyvgart Hytrulo is the first FcRn blocker administered as a subcutaneous injection that is FDA-approved for the treatment of gMG. Vyvgart Hytrulo was approved based on the results of the Phase 3 ADAPTsc trial (NCT04735432), a multicenter, randomized, open-label, parallel-group bridging study to the Phase 3 ADAPT study (NCT03669588), which resulted in the approval of Vyvgart in December 2021. In ADAPTsc, 110 patients were randomized in a 1:1 ratio to receive Vyvgart Hytrulo or Vyvgart for one treatment cycle (one treatment cycle consisted of four doses at once-weekly intervals). The primary endpoint of noninferiority was met, and Vyvgart Hytrulo demonstrated a mean total IgG reduction of 66.4% from baseline at Day 29, compared to 62.2% with Vyvgart ($P < 0.0001$). Of note, the efficacy and safety of Vyvgart Hytrulo were also established through the ADAPT trial. Myasthenia Gravis Activities of Daily Living (MG-ADL) and Quantitative Myasthenia Gravis (QMG) measures showed consistent responses between Vyvgart and Vyvgart Hytrulo-treated groups. Vyvgart Hytrulo's safety profile is consistent with Vyvgart's, with the exception of injection site reactions (ISRs), which were higher with Vyvgart Hytrulo in clinical trials, but these were mild to moderate in severity and resolved over time.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

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

OTHER SPECIAL CONSIDERATIONS:

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

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.

VYVGART HYTRULO is for subcutaneous use only and administered by a healthcare professional only. If a scheduled infusion or dose is missed, VYVGART and VYVGART HYTRULO may be administered up to 3 days after the scheduled time point. Thereafter, resume the original dosing schedule until the treatment cycle is completed.

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

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Drug and Biologic Coverage Criteria

HCPCS CODE	DESCRIPTION
J9332	Injection, efgartigimod alfa-fcab, 2mg
J3590	Unclassified biologic (Vyvgart Hytrulo)

AVAILABLE DOSAGE FORMS:

Vyvgart Hytrulo SOLN 180-2000MG-UNIT/ML

Vyvgart SOLN 400MG/20ML

REFERENCES

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Products Affected Required Medical Information Continuation of Therapy Quantity Place of Administration Background Other Special Considerations Coding/Billing Information Available Dosage Forms References	Q4 2023
New Development	Q2 2022