VYVGART®
(efgartigimod alfa-fcab)
Injection for Intravenous Use
400 mg/20 mL vial

SUBMITTING A LETTER OF MEDICAL NECESSITY

This information is current as of the date of publication, but is subject to change.

Payers may require prior authorization (PA), supporting documentation, or a letter of medical necessity to support coverage of VYVGART. A letter of medical necessity will help to explain the physician's rationale and clinical decision-making in choosing a therapy.

You can use the sample letter of medical necessity on the next page as a starting point to provide reasons that the prescribed medication is necessary for your patient. A letter of medical necessity typically explains why you have prescribed the medication and gives health plans patient-specific information they can use to assess the request for VYVGART.

Tips for drafting an efficient letter of medical necessity

To help avoid denials when you submit the PA request to the payer, familiarize yourself with the plan's specific guidelines.

Be sure to know and meet all deadlines for submitting the PA form and other required documents. Once you have received the PA, check with the payer to determine the length of the authorization, as this can vary.

Be detailed and thorough. Recommended information for a letter of medical necessity typically includes:

1. **Patient information:**
   - Full name
   - Date of birth
   - Insurance ID / group number
   - Case ID number (if available)
2. **The patient's diagnosis and the indication for the intended use of VYVGART.**
3. **The severity of the patient's condition:**
   - Myasthenia Gravis-Activities of Daily Living (MG-ADL) score
   - Quantitative Myasthenia Gravis (QMG) score
   - Myasthenia Gravis Foundation of America (MGFA) clinical classification
4. **A summary of the patient's previous treatments, the duration of each and the rationale for discontinuation (if applicable).**
5. **The clinical rationale for treatment, including trial data supporting the FDA approval, administration, and dosing information.**
6. **A summary of your recommendation.**
7. **Additional enclosures, including:**
   - Prescribing information
   - Clinical notes/medical records
   - Diagnostic test results
   - Relevant peer-reviewed articles

Disclaimer: This sample letter is provided for educational purposes only. Use of the information in this template letter does not guarantee that the insurance company will provide coverage or reimbursement for the prescribed medication. This sample letter is not intended to be a substitute for, or an influence on, the independent medical judgment of the physician.

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Sample letter of medical necessity

The following is a sample letter of medical necessity that can be customized based on your patient's medical history and identifiable information. You can use the sample letter of medical necessity on this page as a starting point to provide reasons that the prescribed medication is necessary for your patient. It is recommended the letter be drafted onto your practice's letterhead before submitting to a payer. Some payers may have specific forms that must be completed to document medical necessity.

[Physician letterhead]
[Date]
[Contact Name], [Title] [Payer Name]
[Payer Address]

RE: [Patient Full Name]

Date of Birth: [Patient Birth Date]

Member ID: [Patient Member ID Number], Policy or Group Number: [Patient Policy or Group Number]

To Whom it May Concern,

I am writing on behalf of my patient, [Patient Full Name], to provide information supporting medical necessity for VYVGART® (efgartigimod alfa-fcab) treatment. In this letter, I am providing my patient's medical history, diagnosis, and a summary of their treatment plan. I have also provided a brief description of the patient's previous treatments and a clinically based treatment rationale supporting the medical necessity for VYVGART.

Patient's Clinical / Medical History

[Patient Name] is a[n] [age] year-old patient who has been diagnosed with acetylcholine receptor (AChR) antibody-positive generalized myasthenia gravis (gMG) as of [date of diagnosis].

[Provide a summary of rationale for treatment with VYVGART. This includes a brief description of the severity of the patient's condition and disease progression, relevant gMG clinical signs and symptoms of your patient's current presentation based on your medical opinion. Include history of prior treatments, the duration of each, responses to those treatments, the rationale for discontinuation and/or addition of this treatment, as well as other factors that have affected your treatment selection demonstrating serious medical need]

If Policy Requires Step Therapy/Trial or Failure of Recommended Therapy (OPTIONAL)

Your policy requires a step edit through [recommended therapy per clinical policy]. In my medical opinion, [recommended therapy per clinical policy] is not an appropriate step for my patient. [Discuss rationale for using VYVGART. Include your professional opinion of your patient's likely prognosis or disease progression without treatment.]

Summary

Based on the patient's medical and treatment history listed above and the supporting documentation enclosed, I strongly believe that VYVGART is indicated and medically necessary for this patient. Please find the enclosed additional documents [list enclosures such as supporting clinical documentation, prescribing Information, clinical notes/medical records, etc.] that support my clinical decision. If you need additional information for a timely approval, please contact my office at [insert office phone number].

Sincerely,
[Physician Name]
[Physician Address]
[Physician Phone]

Provide relevant medical information and attach patient's medical records and/or supporting documents for payers to review

Download a copy of the Full Prescribing Information

Check with the payer to identify specific documentation that needs to be submitted with a letter of medical necessity

It may be beneficial to submit a letter of medical necessity, even if it is not explicitly asked for, to avoid delay

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INDICATION

VYVGART® (efgartigimod alfa-fcab) is indicated for the treatment of generalized myasthenia gravis in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

VYVGART is contraindicated in patients with serious hypersensitivity to efgartigimod alfa products or to any of the excipients of VYVGART. Reactions have included anaphylaxis and hypotension leading to syncope.

WARNINGS AND PRECAUTIONS

Infection

VYVGART may increase the risk of infection. The most common infections observed in Study 1 were urinary tract infection (10% for VYVGART vs 5% for placebo) and respiratory tract infections (33% for VYVGART vs 29% for placebo). Patients on VYVGART vs placebo had below normal levels for white blood cell counts (12% vs 5%, respectively), lymphocyte counts (28% vs 19%, respectively), and neutrophil counts (13% vs 6%, respectively). The majority of infections and hematologic abnormalities were mild to moderate in severity. Delay VYVGART administration in patients with an active infection until the infection has resolved; monitor for clinical signs and symptoms of infections. If serious infection occurs, administer appropriate treatment and consider withholding VYVGART until the infection has resolved.

Immunization

Immunization with vaccines during VYVGART treatment has not been studied; the safety with live or live-attenuated vaccines and the response to immunization with any vaccine are unknown. Because VYVGART causes a reduction in immunoglobulin G (IgG) levels, vaccination with live-attenuated or live vaccines is not recommended during VYVGART treatment. Evaluate the need to administer age-appropriate vaccines according to immunization guidelines before initiation of a new treatment cycle with VYVGART.

Hypersensitivity Reactions

In clinical trials, hypersensitivity reactions, including rash, angioedema, and dyspnea were observed in VYVGART-treated patients. Hypersensitivity reactions were mild or moderate, occurred within 1 hour to 3 weeks of administration, and did not lead to treatment discontinuation. Anaphylaxis and hypotension leading to syncope have been reported in postmarketing experience with VYVGART. Anaphylaxis and hypotension occurred during or within an hour of administration and led to infusion discontinuation and in some cases to permanent treatment discontinuation. Monitor patients during administration and for 1 hour thereafter for clinical signs and symptoms of hypersensitivity reactions. If a hypersensitivity reaction occurs, the healthcare professional should institute appropriate measures if needed or the patient should seek medical attention.

Infusion-Related Reactions

Infusion-related reactions have been reported with VYVGART in postmarketing experience. The most frequent symptoms and signs were hypertension, chills, shivering, and thoracic, abdominal, and back pain. Infusion-related reactions occurred during or within an hour of administration and led to infusion discontinuation. If a severe infusion-related reaction occurs during administration, discontinue VYVGART infusion and initiate appropriate therapy. Consider the risks and benefits of readministering VYVGART following a severe infusion-related reaction. If a mild to moderate infusion-related reaction occurs, patients may be rechallenged with close clinical observation, slower infusion rates, and pre-medications.

ADVERSE REACTIONS

In Study 1, the most common (≥10%) adverse reactions with VYVGART were respiratory tract infection, headache, and urinary tract infection.

USE IN SPECIFIC POPULATIONS

Pregnancy

As VYVGART is expected to reduce maternal IgG antibody levels, reduction in passive protection to the newborn is anticipated. Risks and benefits should be considered prior to administering live or live-attenuated vaccines to infants exposed to VYVGART in utero.

Lactation

There is no information regarding the presence of efgartigimod alfa-fcab in human milk, the effects on the breastfed infant, or the effects on milk production. Maternal IgG is known to be present in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for VYVGART and any potential adverse effects on the breastfed infant from VYVGART or from the underlying maternal condition.

Please see the full Prescribing Information.
You may report side effects to the US Food and Drug Administration by visiting http://www.fda.gov/medwatch or calling 1-800-FDA-1088. You may also report side effects to argenx US, Inc, at 1-833-argx411 (1-833-274-9411).

Additional Resources

If you have additional questions about **VYVGART**, please contact **My VYVGART Path** at **1-833-MY-PATH-1 (1-833-697-2841)** where you can be connected to the appropriate resource.

You can access downloadable resources by visiting VYVGARTHCP.com/access.

My VYVGART® Path

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