

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

Payers frequently require supplemental documentation to support a request for prior authorization (PA) or initial claim submission. Check the payer website to see if it requires you to complete a specific PA request form. You can also use the template letter of medical necessity on the next page to facilitate payer coverage for VYVGART® (efgartigimod alfa-fcab) or VYVGART® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc). A patient-specific letter of medical necessity explains the prescriber's rationale for choosing VYVGART or VYVGART Hytrulo for their adult patient with anti-AChR antibody positive gMG.

### Tips for drafting an efficient letter of medical necessity



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

#### Patient information:

- Full name
- Insurance ID/group number
- Date of birth
- Case ID number (if available)

#### The patient's diagnosis and date of diagnosis<sup>1</sup>

- G70.00, Myasthenia gravis without (acute) exacerbation
- G70.01, Myasthenia gravis with (acute) exacerbation

#### The severity of the patient's condition:

- Myasthenia Gravis-Activities of Daily Living (MG-ADL) score
- Myasthenia Gravis Foundation of America (MGFA) clinical classification
- Quantitative Myasthenia Gravis (QMG) score

#### A summary of the patient's previous tried and failed treatments, duration, and rationale for discontinuing each prior treatment

#### The clinical rationale for treatment with VYVGART or VYVGART Hytrulo, including clinical trial data supporting FDA approval, your preferred route of administration and site of care, dosing information, and prescribed course of therapy

#### Additional enclosures, including:

- Prescribing information
- Clinical notes/medical records
- FDA approval letter
- Diagnostic test results
- Relevant peer-reviewed articles



**To help avoid PA and claim processing delays or denials,** review the plan's specific coding and coverage guidelines for VYVGART or VYVGART Hytrulo.



**Be sure to know and meet all deadlines** for submitting a PA or claim. Once you receive a PA approval from the payer, verify the length of the authorization, as this can vary by health insurance plan or pharmacy benefit manager.

Key: AChR, acetylcholine receptor; FDA, Food and Drug Administration; gMG, generalized myasthenia gravis.

#### Reference:

1. CMS. 2024 ICD-10-CM tabular list of disease and injuries. Updated February 1, 2024. Accessed March 8, 2024. <https://www.cms.gov/medicare/coding-billing/icd-10-codes/2024-icd-10-cm>

## 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 demographic information. **The sample letter can be cut and pasted onto your practice's letterhead to submit to a payer to support a PA request or claim for VYVGART or VYVGART Hytrulo.** 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 ID 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<sup>®</sup> (efgartigimod alfa-fcab) or VYVGART<sup>®</sup> Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)]. 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 treatment with [VYVGART or VYVGART Hytrulo], NDC [list 11-digit NDC code. If applicable, you can also provide the HCPCS code (this is for medical claims only)].

### 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) (ICD-10-CM diagnosis code [enter ICD-10-CM diagnosis code]) as of [date of diagnosis].

[Summarize the rationale for treatment with [VYVGART or VYVGART Hytrulo]. Include a brief description of the severity of the patient's condition, disease progression, and relevant gMG clinical signs and symptoms of your patient's current presentation based on your medical opinion. Include history of prior tried and failed treatments, their duration, patient response, and rationale for discontinuing each. Detail other appropriate factors that demonstrate serious medical need and fully explain your prescribed course of treatment.]

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

Your plan 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 or VYVGART Hytrulo] vs other treatments. Include your professional opinion of your patient's likely prognosis or disease progression without treatment. Also list any contraindications or allergies to the plan's preferred therapies.]

### Summary

Based on the patient's medical and treatment history listed above and the supporting documentation enclosed, I strongly believe that [VYVGART or VYVGART Hytrulo] is indicated and medically necessary for my patient. Please find the enclosed additional documents [list enclosures such as patient chart notes, prescribing information, FDA approval letter, result tests, etc] that support my clinical decision. If you need additional information, 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 copy of the Full Prescribing Information for VYVGART

Download copy of the Full Prescribing Information for VYVGART Hytrulo

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

**Disclaimer:** This sample letter is provided for general reference 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.

## INDICATION

VYVGART<sup>®</sup> (efgartigimod alfa-fcab) for intravenous infusion and VYVGART<sup>®</sup> HYTRULO (efgartigimod alfa and hyaluronidase-qvfc) for subcutaneous injection are each indicated for the treatment of generalized myasthenia gravis in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

## IMPORTANT SAFETY INFORMATION

### CONTRAINDICATIONS

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

### WARNINGS AND PRECAUTIONS

#### Infection

VYVGART and VYVGART HYTRULO may increase the risk of infection. The most common infections observed in Study 1 were urinary tract infection (10% of efgartigimod alfa-fcab-treated patients vs 5% of placebo-treated patients) and respiratory tract infection (33% of efgartigimod alfa-fcab-treated patients vs 29% of placebo-treated patients). Patients on efgartigimod alfa-fcab 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 the administration of VYVGART or VYVGART HYTRULO 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 treatment with VYVGART or VYVGART HYTRULO until the infection has resolved.

#### Immunization

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

#### Hypersensitivity Reactions

In clinical trials, hypersensitivity reactions, including rash, angioedema, and dyspnea were observed in patients treated with VYVGART or VYVGART HYTRULO. Urticaria was also observed in patients treated with VYVGART HYTRULO. 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 intravenous efgartigimod alfa-fcab. Anaphylaxis and hypotension occurred during or within an hour of administration and led to infusion discontinuation and in some cases to permanent treatment discontinuation. Healthcare professionals should monitor patients during and for 1 hour after VYVGART administration, or for at least 30 minutes after VYVGART HYTRULO administration, 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 intravenous efgartigimod alfa-fcab 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. If a severe infusion-related reaction occurs with VYVGART HYTRULO, initiate appropriate therapy. Consider the risks and benefits of readministering VYVGART or VYVGART HYTRULO 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 ( $\geq 10\%$ ) adverse reactions in efgartigimod alfa-fcab-treated patients were respiratory tract infection, headache, and urinary tract infection. In Study 2, the most common ( $\geq 10\%$ ) adverse reactions in VYVGART HYTRULO-treated patients were injection site reactions and headache. Injection site reactions occurred in 38% of VYVGART HYTRULO-treated patients, including injection site rash, erythema, pruritus, bruising, pain, and urticaria. In Study 2 and its open-label extension, all injection site reactions were mild to moderate in severity and did not lead to treatment discontinuation. The majority occurred within 24 hours after administration and resolved spontaneously. Most injection site reactions occurred during the first treatment cycle, and the incidence decreased with each subsequent cycle.

### USE IN SPECIFIC POPULATIONS

#### Pregnancy

As VYVGART and VYVGART HYTRULO are 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 or VYVGART HYTRULO in utero.

#### Lactation

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

### Please see the full Prescribing Information for VYVGART and the full Prescribing Information for VYVGART HYTRULO

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** or **VYVGART Hytrulo**, 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](http://VYVGARTHCP.com/access).

