VYVGART® Hytrulo
(efgartigimod alfa and hyaluronidase-qvfc)
Subcutaneous Injection
180 mg/mL and 2000 U/mL vial

SUBMITTING A
LETTER OF MEDICAL NECESSITY

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 Hytrulo. A patient-specific letter of medical necessity explains the prescriber's rationale for choosing VYVGART Hytrulo.

Tips for drafting an efficient letter of medical necessity

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

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)
   - Route of administration
   - Diagnosis
2. **The patient's diagnosis and date of diagnosis.**
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 tried and failed treatments, duration, and rationale for discontinuing each prior treatment.**
5. **The clinical rationale for treatment with 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.**
6. **Additional enclosures, including:**
   - Prescribing information
   - Clinical notes/medical records
   - FDA approval letter
   - Diagnostic test results
   - Relevant peer-reviewed articles

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.

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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 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 VVGART 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 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® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) 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 treatment with 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 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 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 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 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® HYTRULO (efgartigimod alfa and hyaluronidase-qvfc) 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 HYTRULO is contraindicated in patients with serious hypersensitivity to efgartigimod alfa products, to hyaluronidase, or to any of the excipients of VYVGART HYTRULO. Reactions have included anaphylaxis and hypotension leading to syncope.

WARNINGS AND PRECAUTIONS

Infection

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 infections (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 VYVGART HYTRULO 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 HYTRULO until the infection has resolved.

Immunization

Immunization with vaccines during VYVGART HYTRULO 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 HYTRULO causes a reduction in immunoglobulin G (IgG) levels, vaccination with live-attenuated or live vaccines is not recommended during VYVGART HYTRULO treatment. Evaluate the need to administer age-appropriate vaccines according to immunization guidelines before initiation of a new treatment cycle with VYVGART HYTRULO.

Hypersensitivity Reactions

In clinical trials, hypersensitivity reactions, including rash, angioedema, and dyspnea were observed in patients treated with VYVGART HYTRULO or intravenous efgartigimod alfa-fcab. 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 for clinical signs and symptoms of hypersensitivity reactions for at least 30 minutes after administration. 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, initiate appropriate therapy. Consider the risks and benefits of readministering 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 (≥10%) adverse reactions in efgartigimod alfa-fcab-treated patients were respiratory tract infection, headache, and urinary tract infection. In Study 2, the most common (≥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 HYTRULO 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 HYTRULO in utero.

Lactation

There is no information regarding the presence of efgartigimod alfa or hyaluronidase, from administration of VYVGART HYTRULO, 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 HYTRULO and any potential adverse effects on the breastfed infant from VYVGART HYTRULO 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 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.

My VYVGART® Path