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

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

PRIOR AUTHORIZATION CHECKLIST

FOR GENERALIZED MYASTHENIA GRAVIS

Before starting your adult patient with anti-AChR antibody positive gMG on VYVGART® (efgartigimod alfa-fcab) or VYVGART® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc), it may be necessary to obtain a prior authorization (PA) for coverage. PA requirements may vary by insurer, so check with your patient's health plan to determine PA requirements and coverage guidelines before you submit a claim.

This checklist is an educational resource for healthcare providers (HCPs) regarding common PA requirements for VYVGART or VYVGART Hytrulo.

- ☐ **Obtain the appropriate PA form after initiating your patient through one of the following:**
  - ☐ My VYVGART Path ☐ Insurance provider ☐ Site of care/specialty pharmacy
- ☐ **Ensure you document the most recent clinical notes and submit all requested and appropriate information, which may include:**
  - Patient diagnosis, using appropriate **ICD-10-CM diagnosis code** (G70.00, G70.01)
  - Patient's **current age** (≥18 years)
  - **MGFA Clinical Classification** (Class II-IV)
  - **MG-ADL score at baseline**
    - May require documentation of MG-ADL score ≥5 at baseline and/or >50% of total MG-ADL score non-ocular
    - Limited plans may also require documentation of QMG score
  - Signs and symptoms of gMG (date of onset, severity, progression, comorbidities, etc) – **may require submission of clinical notes**
  - **Diagnostic** and **laboratory** results confirming gMG with **anti-AChR antibody positive serology**
  - **List of all current and previously tried gMG therapies,** including names, doses, durations, outcome, and rationale for therapies that are deemed inappropriate for use (if applicable), such as:
    - AChE inhibitors
    - Corticosteroids
    - Non-steroidal immunosuppressive therapies
- ☐ **Fill out all required patient and provider information on the appropriate PA form**
- ☐ **Attach a Letter of Medical Necessity, if required**
- ☐ **Sign all necessary forms. Any and all forms may be rejected if a signature is missing**

Incomplete information may often **lead to a denial** for VYVGART or VYVGART Hytrulo

It is important that you **double-check your documentation** prior to submitting your initial PA request to **avoid common reasons for denial**

Common reasons for coverage denial

Lack of supporting documentation

- MGFA Clinical Classification Criteria and MG-ADL scores are commonly missed
- Documentation does not support health plan authorization criteria
- Patient not treated with required therapies per health plan

Missing treatment information

- Previous therapies tried/failed, reason for discontinuation, and/or duration of use not included

Reminder, most plans will require reauthorization at 6 months:

Some plans may require additional documentation for reauthorization (eg, attestation of response to therapy and/or MG-ADL score improvement ≥2 points from baseline)

HCPs should consider attaching any additional documentation relevant to patient's diagnosis and therapy

Key: AChE, acetylcholinesterase; AChR, acetylcholine receptor; gMG, generalized myasthenia gravis; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; HCP, healthcare provider; MG-ADL, Myasthenia Gravis-Activities of Daily Living; MGFA, Myasthenia Gravis Foundation of America; PA, prior authorization; QMG, Quantitative Myasthenia Gravis.

Disclaimer: This guide is for educational purposes and is not comprehensive of all possible or required clinical criteria for VYVGART or VYVGART Hytrulo and is not intended to provide legal advice. Including the recommendations in this guide represents no guarantee, promise, or statement of coverage or reimbursement for VYVGART or VYVGART Hytrulo by argenx. It is the responsibility of the HCP to refer to, check, and comply with payer-specific policies regarding coverage and billing requirements.

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INDICATION

VYVGART® (efgartigimod alfa-fcab) for intravenous infusion and VYVGART® 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 (≥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 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.

My VYVGART® Path

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