VYVGART® Hytrulo
(efgartigimod alfa and hyaluronidase-qvfc)

Subcutaneous Injection
180 mg/mL and 2000 U/mL vial

# PRIOR AUTHORIZATION GUIDE

Before starting VYVGART Hytrulo, it may be necessary to obtain prior authorization (PA) for coverage. Contact the individual payer for PA requirements and clinical coverage guidelines for VYVGART Hytrulo, if available. This checklist is provided as an educational resource for healthcare providers (HCPs) regarding common PA requirements for VYVGART Hytrulo.

*A common reason for denial is incomplete or missing information on the PA request form. The following list provides information on submitting a PA request form to ensure comprehensive communication with plans.*

## Included below are some examples of commonly requested information in a PA for VYVGART Hytrulo:

### Indicate whether patient is newly initiating therapy or continuing ongoing therapy.

*For patients initiating therapy continue reading below*

*For patients continuing ongoing therapy only, provide quantitative value where applicable:*

- Change in gMG symptoms
- Change in MG-ADL score from pre-treatment baseline
- Change in QMG score from pre-treatment baseline
- Patient not taking concurrently with other biologics for gMG

### Verification that the patient meets clinical criteria for the use of VYVGART Hytrulo (include all that apply):

- Anti-AChR+ serology
- MGFA clinical classification class II, III, or IV
- MG-ADL total score of ≥5 (>50% non ocular) at baseline
- Adult patients ≥18 years of age

### Prescribed by or in consultation with neurologist or other specialist for the treatment of gMG in adult patients who are anti-AChR antibody positive

### Patient-specific information regarding the diagnosis of gMG

*Your office may need to coordinate with other providers to gather all necessary information to submit a PA*

- gMG ICD-10-CM diagnosis code (G70.00, G70.01)
- Signs and symptoms (date of onset, severity, progression, comorbidities, etc)
- Diagnostic results possibly including: (chart notes, laboratory tests, clinical improvement on oral cholinesterase inhibitors, anticholinesterase test results, SFEMG or repetitive nerve stimulation test, etc)

Key: AChR – acetylcholine receptor; gMG – generalized myasthenia gravis; ICD-10-CM – International Classification of Diseases, 10th Revision, Clinical Modification; MG-ADL – Myasthenia Gravis-Activities of Daily Living; MGFA – Myasthenia Gravis Foundation of America; PA – prior authorization; QMG – Quantitative Myasthenia Gravis; SFEMG – single-fiber electromyography.

Disclaimer: This guide is for general reference and is not comprehensive of all possible or required clinical criteria for 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 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.





argenx

## Patient-specific treatment plan for VYVGART Hytrulo:

- Cycle 1 and subsequent treatment schedule: the safety of initiating subsequent cycles sooner than 4 weeks from the last injection of the previous treatment cycle has not been established

## Attestation that patient is not taking VYVGART Hytrulo concurrently with other biologics for gMG or live vaccines

## Letter of Medical Necessity – Some payers may require a letter of medical necessity in addition to a PA request. The letter establishes the patient-specific need for VYVGART Hytrulo to treat gMG.

## Plans may require a previous trial of 1 or 2 commonly prescribed therapies.

*It is important to include start and end date (if applicable), response to, and clinical factors preventing use.*

- **Acetylcholinesterase inhibitors**
- **Oral corticosteroids**
- **Non-steroidal immunosuppressants**

Additionally, HCPs should consider attaching, as appropriate, documents that provide additional clinical information to support the VYVGART Hytrulo PA request, such as:

- Patient-specific medical records, chart notes
- Payer-recognized gMG clinical guidelines or published peer-reviewed medical literature
- VYVGART Hytrulo full prescribing information

Key: AChR – acetylcholine receptor; gMG – generalized myasthenia gravis; ICD-10-CM – International Classification of Diseases, 10th Revision, Clinical Modification; MG-ADL – Myasthenia Gravis-Activities of Daily Living; MGFA – Myasthenia Gravis Foundation of America; PA – prior authorization; QMG – Quantitative Myasthenia Gravis; SFEMG – single-fiber electromyography.

Disclaimer: This guide is for general reference and is not comprehensive of all possible or required clinical criteria for 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 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.

## 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