

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

Before starting 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 Hytrulo in patients with chronic inflammatory demyelinating polyneuropathy (CIDP).**

**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** (G61.81)<sup>1</sup>
- Diagnosis confirmed by **electrodiagnostic test results** (eg, electromyography (EMG) or nerve conduction studies)
- Patient's **current age** (≥18 years)<sup>2</sup>
- Documentation of **strength or weakness using a clinical measurement tool** (eg, Inflammatory Neuropathy Cause and Treatment (INCAT), Medical Research Council (MRC) muscle strength, 6-minute walk test (6-MWT), Rankin, Modified Rankin, etc)
- Documentation of **current and previously tried treatments** (eg, corticosteroids, immunoglobulins, etc)
- Demonstration of **disease course as progressive or relapsing/remitting for 2 months or greater**
- Some plans may require documentation of **moderate to severe functional disability**

**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 lead to a denial for 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

- 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



**Once approved, initial authorizations typically last 3 to 6 months.**

**Some plans may require documentation of clinical improvement with a clinical measurement tool or physical exam for reauthorization.**



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

Key: CIDP, chronic inflammatory demyelinating polyneuropathy; HCP, healthcare provider; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; PA, prior authorization.

References: 1. CMS. 2024 ICD-10-CM tabular list of disease and injuries. Updated February 1, 2024. Accessed February 23, 2024. <https://www.cms.gov/medicare/coding-billing/icd-10-codes/2024-icd-10-cm>. 2. VYVGART Hytrulo. Prescribing information. argenx US Inc; June 2024.

# VYVGART® Hytrulo

(efgartigimod alfa and hyaluronidase-qvfc)

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

## INDICATION

VYVGART® HYTRULO (efgartigimod alfa and hyaluronidase-qvfc) is indicated for the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive.

VYVGART® HYTRULO (efgartigimod alfa and hyaluronidase-qvfc) is indicated for the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP).

## 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 in patients with gMG 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 in gMG. 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.

## 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/vyvgarthyrulo-cidp/access](http://vyvgarthcp.com/vyvgarthyrulo-cidp/access)

**Disclaimer:** This guide is for educational purposes 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.

## 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

Patients with gMG: 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 in patients with gMG, 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.

Patients with CIDP: In Study 3 stage B, the overall safety profile observed in patients with CIDP treated with VYVGART HYTRULO was consistent with the known safety profile of VYVGART HYTRULO and of efgartigimod alfa-fcab administered intravenously. In Study 3, injection site reactions occurred in 15% of patients treated with VYVGART HYTRULO compared to 6% of patients who received placebo. The most common of these injection site reactions were injection site bruising and injection site erythema. All injection site reactions were mild to moderate in severity. Most injection site reactions occurred during the first 3 months of treatment.

## 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 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).

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