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

HOW TO ACQUIRE VYVGART OR VYVGART HYTRULO

FOR GENERALIZED MYASTHENIA GRAVIS

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

VYVGART® (efgartigimod alfa-fcab) and VYVGART® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) are each indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.[1,2] **To acquire VYVGART or VYVGART Hytrulo, please use the following specialty pharmacies or specialty distributors.**

Acquiring through a specialty pharmacy?

argenx has contracted with a network of authorized specialty pharmacies to dispense the drug and help healthcare providers (HCPs) acquire VYVGART or VYVGART Hytrulo

ACQUISITION

Once the specialty pharmacy receives a completed prescription, they will dispense VYVGART or VYVGART Hytrulo directly to the HCP's office

ADMINISTRATION

HCP administers the drug in the office or at an alternate site of care (depending on payer requirements)

For VYVGART Hytrulo HCP training resources are available through Naven Health at 1-877-330-7766 ext 171

REIMBURSEMENT

HCP submits reimbursement claims to payer for:

- **VYVGART Hytrulo** (HCPCS drug code [J9334] with a zero charge [$0.00 or $0.01])[3,4]
- **VYVGART** (HCPCS drug code [J9332] with a zero charge [$0.00 or $0.01])[3,4]
- Drug administration

Key: HCPCS, Healthcare Common Procedure Coding System.

Specialty Pharmacies	P: PHONE F: FAX	EMAIL	WEBSITE
Accredo Specialty Pharmacy	P: 888-200-2811 F: 877-773-9233	N/A	accredo.com
Option Care Health	P: 833-812-0669 F: 855-211-5843	oc-argenxreferral@optioncare.com	optioncarehealth.com
Soleo Health	P: 844-503-0912 F: 844-506-6185	mgtherapy@soleohealth.com	soleohealth.com
CVS Specialty	P: 800-237-2767 F: 800-323-2445	N/A	cvsspecialty.com
AcariaHealth Pharmacy	P: 800-511-5144 F: 877-541-1503	N/A	acariahealth.envolvehealth.com
Optum	P: 855-427-4682 F: 877-342-4596	N/A	specialty.optumrx.com
AllianceRx Walgreens Pharmacy	P: 855-244-2555 F: 800-874-9179	N/A	walgreens.com
CenterWell Specialty Pharmacy	P: 800-486-2668 F: 877-405-7940	N/A	centerwellspecialtypharmacy.com

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Purchasing through a specialty distributor?

argenx has contracted with a network of specialty distributors to service HCP offices choosing to purchase VYVGART or VYVGART Hytrulo through the buy-and-bill model

DISTRUBUTION

HCP purchases the drug from a specialty distributor, allowing the product to be available on hand vs acquiring from a specialty pharmacy

ADMINISTRATION

HCP administers the drug in the office or at an alternate site of care (depending on payer requirements)

REIMBURSEMENT

HCP submits reimbursement claim to payer for:

- **VYVGART Hytrulo** (HCPCS drug code [J9334] and charge amount)[4]
- **VYVGART** (HCPCS drug code [J9332] and charge amount)[4]
- Drug administration

Specialty Distributors	P: PHONE F: FAX	EMAIL	WEBSITE
McKesson Plasma Biologic	P: 877-625-2566 F: 888-752-7626	mpborders@mckesson.com	connect.mckesson.com
McKesson Specialty Health (for multi-specialty customers)	P: 855-477-9800 F: 800-800-5673	mshcustomercare-mspl@mckesson.com	mscs.mckesson.com
McKesson Specialty Health (for oncology customers)	P: 800-482-6700 F: 855-824-9489	oncologycustomersupport@mckesson.com	mscs.mckesson.com
CuraScript SD	P: 877-599-7748 F: 800-862-6208	customer.service@curascript.com	curascript.com
Cardinal Health Specialty Pharmaceutical Distribution	P: 866-476-1340 F: 614-553-6301	gmb-spd-csorderentry@cardinalhealth.com	orderexpress.cardinalhealth.com or specialtyonline.cardinalhealth.com
AmerisourceBergen Specialty Distribution	P: 800-746-6273 F: 800-547-9413	service@asdhealthcare.com	asdhealthcare.com
Oncology Supply	P: 800-633-7555 F: 800-248-8205	service@oncologysupply.com	oncologysupply.com
Besse Medical	P: 800-543-2111 F: 800-543-8695	service@besse.com	besse.com
BioCareSD	P: 800-304-3064 F: 602-850-6215	order@biocaresd.com	biocaresd.com

Healthcare provider training resource for VYVGART Hytrulo

If you have additional questions or would like to request in-office training support, please contact **Naven Health** at **1-877-330-7766 ext 171**.

Product Description

NDC (National Drug Code)[1]	73475-3102-3
Description[1]	VYVGART Hytrulo (1,008 mg efgartigimod alfa and 11,200 units hyaluronidase) per 5.6 mL
ICD-10 (International Classification of Diseases, 10th Revision)[5]	G70.00 Myasthenia gravis without (acute) exacerbation G70.01 Myasthenia gravis with (acute) exacerbation
J-code[4]	J9334 (Injection, efgartigimod alfa, 2 mg and hyaluronidase-qvfc)
Package size[1]	1 single-dose vial
Quantity[1]	5.6 mL
Wholesale acquisition cost[6]	$15,773

Dosing and Administration[1]

Recommended dose

The recommended dosage of VYVGART Hytrulo is 1,008 mg/11,200 units (1,008 mg efgartigimod alfa and 11,200 units hyaluronidase) administered subcutaneously over approximately 30 to 90 seconds[a] in cycles of once-weekly injections for 4 weeks.

[a]Refers to actual injection time of VYVGART Hytrulo. Allow for appropriate storage, preparation, and setup time before use.

For subcutaneous injection only

VYVGART Hytrulo is to be administered subcutaneously only.

Administration

VYVGART Hytrulo must be administered via a subcutaneous injection by an HCP (see Preparation and Administration instructions on page 4).

Subsequent treatment

Administer subsequent treatment cycles of VYVGART Hytrulo based on clinical evaluation. The safety of initiating subsequent cycles sooner than 4 weeks from the last injection of the previous treatment cycle has not been established.

Missed dose

If a scheduled injection is missed, VYVGART Hytrulo may be administered up to 3 days after the scheduled time point. Thereafter, resume the original dosing schedule until the treatment cycle is completed.

How Supplied[1]

VYVGART Hytrulo injection is a preservative-free, sterile, yellowish, clear to opalescent solution supplied as 1 single-dose vial per carton.

Storage and Handling Requirements[1]

Store VYVGART Hytrulo vials refrigerated at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light until time of use. Unopened vials may be stored in the original carton for up to 3 days at room temperature at 20°C to 25°C (68°F to 78°F) for a single period before administration or returned to refrigeration. Do not freeze. Do not shake.

Do not store the vial at room temperature more than one time. Record the date removed from and the date returned to the refrigerator on the carton.

Supplies Needed for Administration

Alcohol swabs	One winged infusion set 25G x 12 inches	Adhesive bandage	One 18G transfer needle (1.5 to 2 inches in length)
One 10 mL syringe	1 sterile gauze	1 FDA-cleared sharps container	

Key: FDA, Food and Drug Administration.

Preparation[1]

- Take the VYVGART Hytrulo vial out of the refrigerator at least 15 minutes before injecting to allow it to reach room temperature. Do not use external heat sources.
- Check that the VYVGART Hytrulo solution is yellowish, clear to opalescent.
- Parenteral medicine products should be inspected visually for particulate matter prior to administration, whenever solution and container permit. Do not use if opaque particles or other foreign particles are present.
- Withdraw the entire content of VYVGART Hytrulo from the vial using a polypropylene syringe and an 18G stainless steel transfer needle.
- Remove large air bubbles, if present.
- Each vial contains overfill to compensate for liquid loss during preparation and to compensate for the priming volume of the winged infusion set.
- VYVGART Hytrulo does not contain preservatives. Administer immediately after preparation.

Administration[1]

- To administer VYVGART Hytrulo, use a winged infusion set made of polyvinyl chloride (PVC), 25G, 12 inches tubing, maximum priming volume of 0.4 mL.
- Remove the transfer needle from the syringe and connect the syringe to the winged infusion set.
- Prior to administration, fill the tubing of the winged infusion set by gently pressing the syringe plunger until the plunger is at 5.6 mL. There should be solution at the end of the winged infusion set needle.
- Choose an injection site on the abdomen (at least 2 to 3 inches away from the navel).
  - Do not inject on areas where the skin is red, bruised, tender, hard, or into areas where there are moles or scars.
  - Rotate injection sites for subsequent administrations.
- Inject VYVGART Hytrulo subcutaneously into a pinched skin area at an angle of about 45 degrees over 30 to 90 seconds.
- Localized injection site reactions may occur after VYVGART Hytrulo is administered.
- Discard any unused portions of medicine remaining in the vial, the syringe, and the winged infusion set.
- 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.

Product Description

NDC (National Drug Code)[2]	73475-3041-5
Description[2]	400 mg of efgartigimod alfa-fcab in 20 mL (20 mg/mL)
ICD-10 (International Classification of Diseases, 10th Revision)[5]	G70.00 Myasthenia gravis without (acute) exacerbation G70.01 Myasthenia gravis with (acute) exacerbation
J-code[4]	J9332; Injection, efgartigimod alfa-fcab, 2 mg
Package size[2]	1 single-dose vial
Quantity[2]	20.0 mL
Wholesale acquisition cost[7]	$6,190.38

Dosing and Administration[2]

Recommended dose

The recommended dosage of VYVGART is 10 mg/kg administered as an intravenous infusion over 1 hour once weekly for 4 weeks. In patients weighing 120 kg or more, the recommended dose of VYVGART is 1,200 mg (3 vials) per infusion.

Patient Weight (kg) and Number of Vials	
40 kg or less	1 vial
41 kg-80kg	2 vials
81 kg or more	3 vials

For injection only

VYVGART is to be administered as an intravenous infusion only.

Administration

Each injection should be administered by an HCP. Prior to administration, VYVGART single-dose vials require dilution in 0.9% sodium chloride injection, USP to make a total volume to be administered of 125 mL (see Preparation and Administration instructions on page 6).

Subsequent treatment

Administer subsequent treatment cycles based on clinical evaluation. The safety of initiating subsequent cycles sooner than 4 weeks from the last infusion of the previous treatment cycle has not been established.

Missed dose

If a scheduled infusion is missed, VYVGART may be administered up to 3 days after the scheduled time point. Thereafter, resume the original dosing schedule until the treatment cycle is completed.

How Supplied[2]

VYVGART injection is a preservative-free, sterile, colorless to slightly yellow, clear to slightly opalescent solution supplied in 1 single-dose vial per carton.

Storage and Handling Requirements[2]

Store VYVGART vials refrigerated at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light until time of use.

Do not freeze. Do not shake.

Supplies Needed for Administration

Alcohol swabs	**PE, PVC, EVA, or polyurethane/polypropylene infusion lines**	**Adhesive bandage**	**PE, PVC, EVA, or ethylene/polypropylene copolymer bags (polyolefins bags)**
One 20 mL syringe	**1 sterile gauze**	**1 FDA-cleared sharps container**	**0.2 micron in-line filter**

Key: EVA, ethylene vinyl acetate; FDA, Food and Drug Administration; PE, polyethylene; PVC, polyvinyl chloride.

Preparation[2]

- Check that the VYVGART solution is clear to slightly opalescent and colorless to slightly yellow. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.
- Do not use if opaque particles, discoloration, or other foreign particles are present. Use aseptic technique when preparing the VYVGART diluted solution for intravenous infusion. Each vial is for single-dose only. Discard any unused portion.
- Calculate the dose (mg), total drug volume (mL) of VYVGART solution required, and the number of vials needed based on the recommended dose according to the patient's body weight. Each vial contains a total of 400 mg of VYVGART at a concentration of 20 mg per mL.
- Gently withdraw the calculated dose of VYVGART from the vial(s) with a sterile syringe and needle. Discard any unused portion of the vials.
- Dilute the withdrawn VYVGART with 0.9% sodium chloride injection, USP to make a total volume of 125 mL for intravenous infusion.
- Gently invert the infusion bag containing the diluted VYVGART without shaking to ensure thorough mixing of the product and the diluent.
- The diluted solution can be administered using PE, PVC, EVA, or ethylene/polypropylene copolymer bags (polyolefins bags), and with PE, PVC, EVA, or polyurethane/polypropylene infusion lines.

Storage Conditions of the Diluted Solution[2]

- VYVGART does not contain preservatives. Administer immediately after dilution and complete the infusion within 4 hours of dilution.
- If immediate use is not possible, the diluted solution may be stored refrigerated at 2°C to 8°C (36°F to 46°F) for up to 8 hours. Do not freeze. Protect from light. Allow the diluted drug to reach room temperature before administration. Complete the infusion within 4 hours of removal from the refrigerator. Do not heat the diluted drug in any manner other than via ambient air.

Administration[2]

- Visually inspect the VYVGART diluted solution for particles or discoloration prior to administration. Do not use if it is discolored, or if opaque or foreign particles are seen.
- Infuse the total 125 mL of diluted solution intravenously over 1 hour via a 0.2 micron in-line filter.
- After administration of VYVGART, flush the entire line with 0.9% sodium chloride injection, USP.
- Monitor patients during administration and for 1 hour thereafter for clinical signs and symptoms of hypersensitivity reactions. If a hypersensitivity reaction occurs during administration, discontinue administration of VYVGART and institute appropriate supportive measures.
- Other medications should not be injected into infusion side ports or mixed with VYVGART.

References: 1. VYVGART Hytrulo. Prescribing information. argenx US Inc; 2024. **2.** VYVGART. Prescribing information. argenx US Inc; 2024. **3.** CMS. May 2024. Billing and coding: drugs and biologicals. Updated January 11, 2024. Accessed March 15, 2024. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=52855. **4.** CMS. April 2024 alpha-numeric HCPCS file. Updated March 7, 2024. Accessed March 8, 2024. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update. **5.** 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 **6.** Active Ingredient: VYVGART Hytrulo. RED BOOK Online. IBM Micromedex [database online]. Truven Health Analytics/IBM Watson Health; 2020. Accessed April 4, 2024. https://www.micromedexsolutions.com **7.** Active Ingredient: VYVGART. RED BOOK Online. IBM Micromedex [database online]. Truven Health Analytics/IBM Watson Health; 2020. Accessed April 4, 2024. https://www.micromedexsolutions.com

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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

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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