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

HOW TO ACQUIRE VYVGART HYTRULO

FOR CHRONIC INFLAMMATORY DEMYELINATING POLYNEUROPATHY

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

VYVGARTR HYTRULO (efgartigimod alfa and hyaluronidase-qvfc) is indicated for the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP).[1] **To acquire 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 Hytrulo

ACQUISITION

Once the specialty pharmacy receives a completed prescription, they will dispense 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)

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

REIMBURSEMENT

HCP submits reimbursement claims to payer for:

- Drug (HCPCS drug code [J9334] with a zero charge [$0.00 or $0.01])[2,3]
- 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

argenx

Purchasing through a specialty distributor?

argenx has contracted with a network of specialty distributors to service HCP offices choosing to purchase 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:

- Drug (HCPCS drug code [J9334] and charge amount)[3]
- 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

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)[4]	G61.81 - chronic inflammatory demyelinating polyneuritis
J-code[3]	J9334 (Injection, efgartigimod alfa, 2 mg and hyaluronidase-qvfc)
Package size[1]	1 single-dose vial
Quantity[1]	5.6 mL
Wholesale acquisition cost[5]	$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 as once-weekly injections over approximately 30 to 90 seconds.

Note: Refers to actual injection time of VYVGART Hytrulo. Allow for appropriate storage, preparation, and setup time before use.

Administration

VYVGART Hytrulo must be administered via a subcutaneous injection by a healthcare professional.

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.

How Supplied[1]

VYVGART Hytrulo injection is a preservative-free, sterile, yellowish, clear to opalescent solution supplied as one 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 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 of tubing, and a 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 or patients 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.

References
1. VYVGART Hytrulo. Prescribing information. argenx US Inc; 2024.
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3. CMS. April 2024 alpha-numeric HCPCS file. Updated March 7, 2024. Accessed March 13, 2024. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update
4. 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
5. 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

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.

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 (≥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 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).

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/vyvgarthytrulo-cidp/access

My VYVGART® Path

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.