

BILLING AND CODING GUIDE

FOR **VYVGART Hytrulo** IN CHRONIC INFLAMMATORY DEMYELINATING POLYNEUROPATHY

VYVGART Hytrulo[®]
(efgartigimod alfa and hyaluronidase-qvfc)

VYVGART Hytrulo[®] vial (180 mg/mL efgartigimod alfa and 2,000 U/mL hyaluronidase) for subcutaneous injection is indicated for the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP). VYVGART Hytrulo is administered as once-weekly injections.¹

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Please note: This guide is specific to VYVGART Hytrulo vial for HCP administration. For any questions or information on VYVGART Hytrulo prefilled syringe for self-injection, contact your argenx Field Reimbursement Manager.

Please see Important Safety Information for VYVGART Hytrulo in tab below and full [Prescribing Information for VYVGART HYTRULO](#).

This guide is provided as an educational resource for healthcare providers (HCPs) regarding billing and coding for VYVGART Hytrulo for CIDP. This guide does not include all possible or required billing and coding options for VYVGART Hytrulo and is not intended to provide reimbursement or legal advice. Following 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 coding, coverage, and billing prior to submitting claims. This information is current as of the date of publication and is subject to change.



Coding

CMS-1500 Claim Form

CMS-1450 Claim Form

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

VYVGART Hytrulo has been assigned a drug-specific Healthcare Common Procedure Coding System (HCPCS) billing code that can be reported on outpatient medical claims.

Please review the table below for this and other codes that may be appropriate to report services associated with VYVGART Hytrulo.

Code Type	Code	Description	Physician office	HOPD
HCPCS code ²	J9334	Injection, efgartigimod alfa, 2 mg and hyaluronidase-qvfc	✓	✓
HCPCS modifier ^{2,3}	JZ	Zero drug amount discarded/not administered to any patient	✓	✓
	TB ^b	Drug or biological acquired with 340B Drug Pricing Program discount, reported for informational purposes	—	✓
NDC ¹	73475-3102-03	1,008 mg efgartigimod alfa and 11,200 units hyaluronidase in a 5.6 mL (180 mg/2,000 units per mL) single-dose vial	✓	✓
CPT ^{4,a}	96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	✓	✓
ICD-10-CM diagnosis code ⁵	G61.81	Chronic inflammatory demyelinating polyneuritis	✓	✓
Revenue code ⁶	0636	Drugs requiring detailed coding	—	✓
	0940	Other therapeutic services: General		
	0510 ^c	Clinic: General		

Key: CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; HOPD, hospital outpatient department; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; NDC, National Drug Code.

^aCPT Copyright 2023 American Medical Association. All rights reserved. CPT[®] is a registered trademark of the American Medical Association.

^b340B-covered entities must report modifier TB starting with services on January 1, 2025.⁷

^cOther revenue codes may apply.

Do not use HCPCS code J9332 (Injection, efgartigimod alfa-fcab, 2 mg) to report use of VYVGART Hytrulo (efgartigimod alfa and hyaluronidase-qvfc).

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Coding

CMS-1500 Claim Form

CMS-1450 Claim Form

Item Number 21

Enter the appropriate diagnosis code(s) based on HCP documentation.

ICD-10-CM: G61.81 for chronic inflammatory demyelinating polyneuritis

Item Number 24G

Enter the appropriate number of billing units for each line item. Each single-use vial of VYVGART Hytrulo contains 1,008 mg. There are a total of 504 units per single-use vial.

- For J9334, 1 billing unit is equal to 2 mg of VYVGART Hytrulo
- For 96372, 1 unit represents a single subcutaneous injection

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.										22. RESUBMISSION CODE		ORIGINAL REF. NO.							
A. G61.81 B. _____ C. _____ D. _____										23. PRIOR AUTHORIZATION NUMBER									
E. _____ F. _____ G. _____ H. _____										F. \$ CHARGES		G. DAYS OR UNITS		H. EPSDT Family Plan		I. ID. QUAL.		J. RENDERING PROVIDER ID. #	
I. _____ J. _____ K. _____										XXX XX		504				NPI			
24. A. DATE(S) OF SERVICE From To B. PLACE OF SERVICE C. EMG D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS MODIFIER E. DIAGNOSIS POINTER										XXX XX		1				NPI			
N473475310203 ML5.6																			
MM DD YY MM DD YY																			
MM DD YY MM DD YY																			
J9334 JZ A																			
96372 A																			

Item Number 24A

In the shaded area above the dates of service, for each claim line item for the drug, enter the NDC as follows:

- N4 (in front of the NDC)
- 11-digit NDC (with no dashes or other punctuation)
- NDC unit of measure (ML, place 1 space after the NDC)
- NDC quantity (5.6 – signifying that the full contents of the single-dose vial were administered)

Note: Check payer requirements and format for reporting NDC.

Item Number 24D

Enter the appropriate CPT/HCPCS codes and modifiers, eg:

- Drug: J9334 for VYVGART Hytrulo
 - Modifier JZ indicates no amount of drug was discarded
- Administration: 96372 for therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular

Item Number 24E

Enter the letter (A-L) that corresponds to the diagnosis in Item Number 21.

If VYVGART Hytrulo is acquired via specialty pharmacy, enter \$0.00 or \$0.01 in Item Number 24F to indicate that the HCP who administered the medication did not incur any costs for the actual drug.

Key: CMS, Centers for Medicare & Medicaid Services; CPT, Current Procedural Terminology; HCP, healthcare provider; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; NDC, National Drug Code.



Coding

CMS-1500 Claim Form

CMS-1450 Claim Form

FL 42

Enter the appropriate revenue code, eg:

- 0636 for VYVGART Hytrulo
- 0940 for subcutaneous injection

Note: Other revenue codes may apply.

FL 43

Enter the corresponding description for the billing codes listed in FL 44. For VYVGART Hytrulo, enter the NDC as follows:

- N4 (in front of the NDC)
- 11-digit NDC (with no dashes or other punctuation)
- NDC unit of measure (ML, place 1 space after the NDC)
- NDC quantity (5.6 – signifying that the full contents of the single-dose vial were administered)

Note: Check payer requirements and format for reporting NDC.

FL 44

Enter the appropriate CPT/HCPCS codes and modifiers, eg:

- Drug: J9334 for VYVGART Hytrulo
 - Modifier JZ indicates no amount of drug was discarded
- Administration: 96372 for therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
0636	N473475310203 ML5.6 VYVGART Hytrulo	J9334 JZ	MM DD YY	504	XXX XX		
0940	Subcutaneous injection	96372	MM DD YY	1	XXX XX		

FL 46

Enter the appropriate number of billing units for each line item. Each single-use vial of VYVGART Hytrulo contains 1,008 mg. There are a total of 504 units per single-use vial.

- For J9334, 1 billing unit is equal to 2 mg of VYVGART Hytrulo
- For 96372, 1 unit represents a single subcutaneous injection

⁶⁶ DX	G61.81	A	B	C	D	E	F	G	H	⁶⁸
		J	K	L	M	N	O	P	Q	

FL 67 and 67A-67Q

Enter the appropriate diagnosis code(s) based on HCP documentation.
ICD-10-CM: G61.81 for chronic inflammatory demyelinating polyneuritis

If VYVGART Hytrulo is acquired via specialty pharmacy, enter \$0.00 or \$0.01 in FL 47 to indicate that the HCP who administered the medication did not incur any costs for the actual drug.

Key: CMS, Centers for Medicare & Medicaid Services; CPT, Current Procedural Terminology; FL, Form Locator; HCP, healthcare provider; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; NDC, National Drug Code.



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

Infections

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

Evaluate the need to administer age-appropriate vaccines according to immunization guidelines before initiation of a new treatment cycle with VYVGART HYTRULO. The safety of immunization with live vaccines and the immune response to vaccination during treatment with VYVGART HYTRULO are unknown. Because VYVGART HYTRULO causes a reduction in immunoglobulin G (IgG) levels, vaccination with live vaccines is not recommended during treatment 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. 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. 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/Injection-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/injection-related reaction occurs, initiate appropriate therapy. Consider the risks and benefits of readministering VYVGART HYTRULO following a severe infusion/injection-related reaction. If a mild to moderate infusion/injection-related reaction occurs, patients may be rechallenged with close clinical observation, slower infusion/injection 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. Risk and benefits should be considered prior to administering live 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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1. VYVGART Hytrulo. Prescribing information. argenx US, Inc; 2025.
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3. CMS. Medicare program: discarded drugs and biologicals – JW modifier and JZ modifier policy. Accessed November 22, 2024. <https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf>
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9. CMS. Medicare claims processing manual: chapter 25 – completing and processing the Form CMS-1450 data set. Updated December 20, 2023. Accessed November 22, 2024. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c25.pdf>