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

Billing and Coding Guide
for **VYVGART Hytrulo**
in chronic inflammatory demyelinating polyneuropathy

VYVGART® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) is indicated for the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP). VYVGART Hytrulo is administered subcutaneously as once-weekly injections.[1]

Please see Important Safety Information for VYVGART Hytrulo in tab below or click here for full Prescribing Information.

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.

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Coding
for VYVGART Hytrulo in CIDP

VYVGART Hytrulo has been assigned a drug-specific Healthcare Common Procedure Coding System (HCPCS) billing code that can be reported on outpatient medical claims for dates of service on or after January 1, 2024.

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	✓	✓
	JG[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	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.

[a]CPT Copyright 2023 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association.
[b]340B-covered entities may report modifier JG or TB through December 31, 2024. 340B-covered entities must report modifier TB starting with services on January 1, 2025. Modifier TB represents a *drug or biological acquired with 340B Drug Pricing Program discount, reported for informational purposes for select entities.*[7]

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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Sample CMS-1500 Claim Form
for VYVGART Hytrulo in the physician office[8]

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.

A. G61.81 B. C. D.
E. F. G. H.
I. J. K. L.

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
N473475310203 ML5.6											
MM DD YY	MM DD YY			J9334	JZ	A	XXX XX	504		NPI	
MM DD YY	MM DD YY			96372		A	XXX XX	1		NPI	

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.

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Sample CMS-1450 (UB-04) Claim Form

for VYVGART Hytrulo in the hospital outpatient department[9]

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	A	B	C	D	E	F	G	H	68
G61.81									
I	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.

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Important Safety Information

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).

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