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

VYVGART Hytrulo
UNCLASSIFIED HCPCS CODE BILLING & CODING GUIDE

VYVGART® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) is indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive. VYVGART Hytrulo is administered subcutaneously in cycles of once-weekly injections for 4 weeks.[1]

Please see Important Safety Information on the last page and 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. 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, but is subject to change.

This guide should only be referenced if a patient received VYVGART Hytrulo (efgartigimod alfa and hyaluronidase-qvfc).
Do not use this guide if a patient received intravenously administered VYVGART (Injection, efgartigimod alfa-fcab, 2 mg).

Coding for VYVGART Hytrulo

At launch and until it is assigned a product-specific billing code, VYVGART Hytrulo can be reported with a miscellaneous (unclassified) billing code:

Code Type	Code	Description	Place of Service
HCPCS code[2]	J3490	Unclassified drugs	Physician office (most payers), HOPD (most private commercial payers)
	J3590	Unclassified biologics	
	C9399	Unclassified drugs or biologicals	HOPD (Medicare and some private commercial payers)
HCPCS modifier[3]	JZ	Zero drug amount discarded/not administrated to any patient	Physician office, HOPD
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	Physician office, HOPD
CPT[4,a]	96372[b]	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	Physician office, HOPD
ICD-10-CM diagnosis code[5]	G70.00	Myasthenia gravis without (acute) exacerbation	Physician office, HOPD
	G70.01	Myasthenia gravis with (acute) exacerbation	
Revenue code[6]	0636	Drugs requiring detailed coding	HOPD
	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 2022 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association.
[b] Other codes may apply based on payer.

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 Form: For the physician office setting[7]

Item 19: Enter drug-identifying information as required by the payer: eg, drug name, dose, amount administered and discarded (if applicable), route of administration, 11-digit NDC (with no dashes or other punctuation).

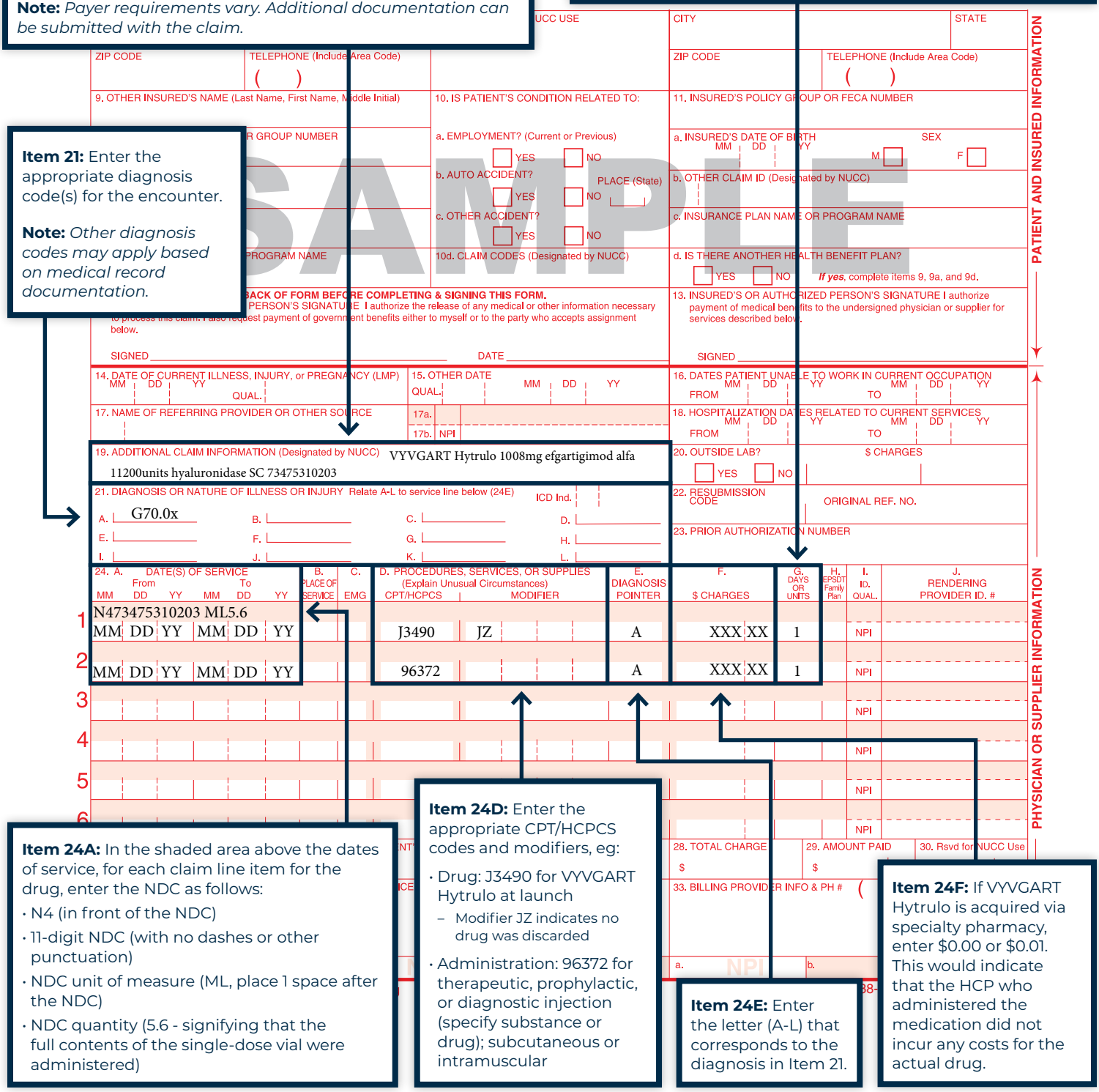
Note: *Payer requirements vary. Additional documentation can be submitted with the claim.*

Item 24G: Enter the appropriate number of billing units for each line item. When billing with miscellaneous codes, a billing unit of 1 is commonly reported for each single-dose vial.

Note: *Payer requirements may vary.*

Item 21: Enter the appropriate diagnosis code(s) for the encounter.

Note: *Other diagnosis codes may apply based on medical record documentation.*



Item 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)

Item 24D: Enter the appropriate CPT/HCPCS codes and modifiers, eg:

- Drug: J3490 for VYVGART Hytrulo at launch
  - Modifier JZ indicates no drug was discarded
- Administration: 96372 for therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular

Item 24E: Enter the letter (A-L) that corresponds to the diagnosis in Item 21.

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

Key: CMS, Centers for Medicare and Medicaid Services; CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; HCP, healthcare provider; NDC, National Drug Code.

Sample CMS-1450 (or UB-04) Form: For the hospital outpatient department[8]

FL 42: Enter the appropriate 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.

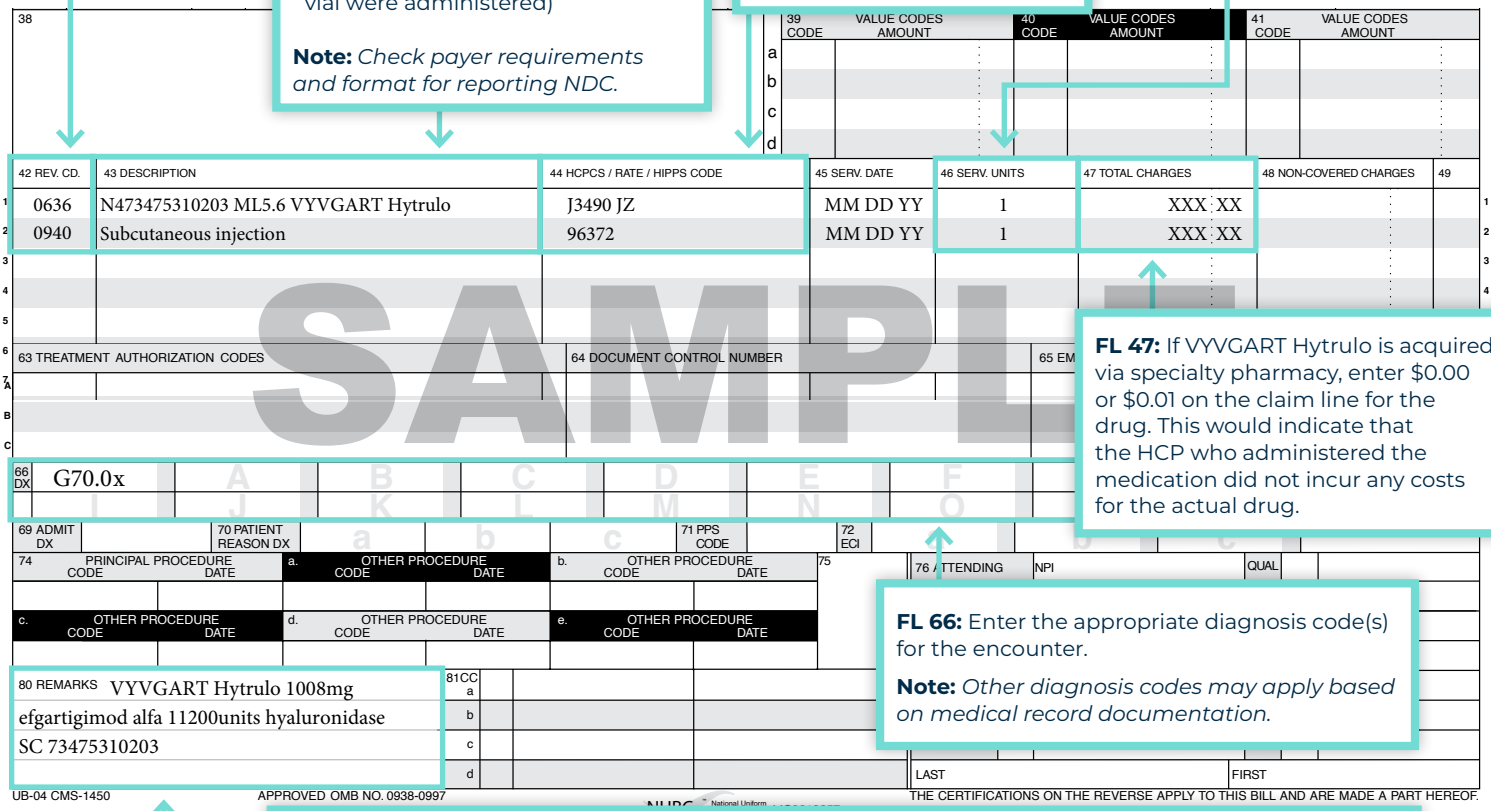
For VYVGART Hytrulo, enter the NDC as follows:
- N4 (in front of the NDC)
- 11-digit NDC (with no dashes or other punctuation)
- NDC unit of measure (ML, place 1 space after the NDC)
- NDC quantity (5.6 - signifying that the full contents of the single-dose vial were administered)

Note: *Check payer requirements and format for reporting NDC.*

FL 44: Enter the appropriate CPT/HCPCS codes and modifiers, eg:
- Drug: J3490 for VYVGART Hytrulo at launch
  - Modifier JZ indicates no drug was discarded
- Administration: 96372 for therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular

FL 46: Enter the appropriate number of billing units for each line item. When billing with miscellaneous codes, a billing unit of 1 is commonly reported per single-dose vial.

Note: *Payer-specific guidance may vary.*



FL 47: If VYVGART Hytrulo is acquired via specialty pharmacy, enter $0.00 or $0.01 on the claim line for the drug. This would indicate that the HCP who administered the medication did not incur any costs for the actual drug.

FL 66: Enter the appropriate diagnosis code(s) for the encounter.

Note: *Other diagnosis codes may apply based on medical record documentation.*

FL 80: Enter the drug-identifying information as required by the payer: eg, drug brand name, dose, amount administered and discarded (if applicable), route of administration, 11-digit NDC (with no dashes or other punctuation).

Note: *Payer requirements vary. Additional documentation can be submitted with the claim.*

Key: CMS, Centers for Medicare and Medicaid Services; CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; HCP, healthcare provider; NDC, National Drug Code.

References

1. VYVGART Hytrulo. Prescribing information. argenx; 2023. **2.** CMS. January 2023 alpha-numeric HCPCS file. Updated December 21, 2022. Accessed December 22, 2022. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update **3.** CMS. Medicare program: discarded drugs and biologicals – JW modifier and JZ modifier policy. Accessed January 20, 2023. https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf **4.** AMA. 2023 CPT Professional Edition. Current Procedural Terminology (CPT®) Copyright 2022 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association. Chicago, IL: AMA; 2022. **5.** CMS. 2023 ICD-10-CM tabular list of disease and injuries. Updated March 1, 2023. Accessed June 8, 2023. https://www.cms.gov/medicare/icd-10/2023-icd-10-cm **6.** ResDAC. Revenue center code. Updated February 2018. Accessed December 22, 2022. https://resdac.org/sites/datadocumentation.resdac.org/files/Revenue%20Center%20Code%20Table_2.txt **7.** CMS. Medicare claims processing manual: chapter 26 – completing and processing Form CMS-1500 data set. Updated May 27, 2022. Accessed December 22, 2022. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c26pdf.pdf **8.** CMS. Medicare claims processing manual: chapter 25 – completing and processing the Form CMS-1450 data set. Updated August 6, 2021. Accessed December 22, 2022. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c25.pdf

INDICATION

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

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Infection

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 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

Hypersensitivity reactions, including rash, angioedema, and dyspnea were observed in patients treated with VYVGART HYTRULO and efgartigimod alfa-fcab. Urticaria was also observed in patients treated with VYVGART HYTRULO. In clinical trials, hypersensitivity reactions were mild or moderate, occurred within 1 hour to 3 weeks of administration, and did not lead to treatment discontinuation. Monitor patients for at least 30 minutes after administration for clinical signs and symptoms of hypersensitivity reactions. If a hypersensitivity reaction occurs, institute appropriate supportive measures if needed.

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 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. 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.

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/access.

My VYVGART® Path