

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

VYVGART<sup>®</sup> (efgartigimod alfa-fcab) is indicated for the treatment of generalized myasthenia gravis in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.<sup>1</sup>

**Please see Important Safety Information on the last page and see accompanying full Prescribing Information or visit [www.VYVGART.com/PI](http://www.VYVGART.com/PI).**

**This guide is provided as an educational resource for healthcare providers (HCPs) regarding billing and coding for VYVGART. This guide is not comprehensive of all possible or required billing and coding options for VYVGART 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 by argenx. It is the responsibility of the HCP to refer to, check, and comply with payer-specific policies regarding coding, coverage, and billing requirements prior to submitting claims.**

## Coding for VYVGART



The following codes may be relevant when filing claims for VYVGART. The drug-specific Healthcare Common Procedure Coding System (HCPCS) billing code can be reported on medical claims forms for reimbursement for VYVGART, effective July 1, 2022.

Code Type	Code	Description	Place of Service
HCPCS code <sup>2</sup>	J9332	Injection, efgartigimod alfa-fcab, 2 mg	Physician office, HOPD
HCPCS Modifier <sup>3</sup>	JW	Drug amount discarded/not administered to any patient	Physician office, HOPD
NDC <sup>1</sup>	73475-3041-05	400 mg of efgartigimod alfa-fcab in 20 mL (20 mg/mL)	Physician office, HOPD
CPT <sup>4b</sup>	96365 <sup>a</sup>	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour	Physician office, HOPD
	96413 <sup>a</sup>	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug [Used for IV infusion of certain complex/high-risk drugs] <sup>5</sup>	
ICD-10-CM diagnosis code <sup>6</sup>	G70.00	Myasthenia gravis without (acute) exacerbation	Physician office, HOPD
	G70.01	Myasthenia gravis with (acute) exacerbation	
Revenue code <sup>7</sup>	0636	Drugs requiring specific identification-detailed coding	HOPD
	0260	IV therapy: General classification	
	0269	IV therapy: Other IV therapy	
	0510	Clinic-general classification	

<sup>a</sup> Use of appropriate codes will be at the discretion of the payer.

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; IV – intravenous; NDC – National Drug Code.

<sup>b</sup> CPT Copyright 2022 American Medical Association. All rights reserved. CPT<sup>®</sup> is a registered trademark of the American Medical Association.

**Sample CMS-1500 Form for patient weighing 80kg: For the physician office setting<sup>8</sup>**

**Item 24G:** Enter the number of service units.

For example, an 80kg patient is administered 800mg (VYVGART 10 mg/kg). One single-use vial of VYVGART contains 400mg. Each service unit is billed per 2mg. The total billable units for one single-use vial of VYVGART is 200 [400mg / 2mg (Service Unit per J-Code assignment)].

Calculation of service units billed: Dose administered (800mg) / 2mg (Service Unit per J-Code assignment) = 400 units

**Note:** Payer requirements may vary.

CITY		STATE	
ZIP CODE		TELEPHONE (Include Area Code) ( )	
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)			
a. OTHER INSURED'S POLICY OR GROUP NUMBER		a. EMPLOYMENT? (Current or Previous) <input type="checkbox"/> YES <input type="checkbox"/> NO	
b. RESERVED FOR NUCC USE		b. AUTO ACCIDENT? <input type="checkbox"/> YES <input type="checkbox"/> NO	
c. RESERVED FOR NUCC USE		c. OTHER ACCIDENT? <input type="checkbox"/> YES <input type="checkbox"/> NO	
d. INSURANCE PLAN NAME OR PROGRAM NAME		10d. CLAIM CODES (Designated by NUCC)	
12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE. I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.  SIGNED _____ DATE _____		13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.  SIGNED _____ DATE _____	
14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.		15. OTHER DATE MM DD YY QUAL.	
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE		18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM MM DD YY TO MM DD YY	
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)		20. OUTSIDE LAB? \$ CHARGES <input type="checkbox"/> YES <input type="checkbox"/> NO	
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY. Relate A-L to service line below (24E) A. <u>G70.00</u> B. _____ C. _____ D. _____ E. _____ F. _____ G. _____ H. _____ I. _____ J. _____ K. _____ L. _____		22. RESUBMISSION CODE ORIGINAL REF. NO. 23. PRIOR AUTHORIZATION NUMBER	
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. EPSONI Family Plan	
I. ID. QUAL.		J. RENDERING PROVIDER ID. #	
25. FEDERAL TAX I.D. NUMBER		26. PATIENT'S ACCOUNT NO.	
27. ACCEPT ASSIGNMENT? (For govt. claims, see back) <input type="checkbox"/> YES <input type="checkbox"/> NO		28. TOTAL CHARGE \$	
29. AMOUNT PAID \$		30. Rsvd for NUCC Use	
31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof)		32. SERVICE FACILITY LOCATION INFORMATION	
33. BILLING PROVIDER INFO & PH # ( )			

**Item 21:** Enter the appropriate ICD-10-CM diagnosis code(s). See table on page 1 for more information.  
**Note:** Other diagnosis codes may apply.

**Item 24D Line 1:** Enter the appropriate HCPCS code for VYVGART (J9332).  
**Item 24D Line 2:** Enter the appropriate CPT code for the administration of VYVGART. See table on page 1 for more information.  
**Note:** Other CPT codes may apply. Payer requirements may vary.

**Item 24E:** Enter the reference to the CPT and HCPCS codes associated with the diagnosis code (in Item 21).  
**Note:** Payer requirements may vary.

**Sample CMS-1500 Form for patient weighing 90kg: For the physician office setting<sup>8</sup>**

**Item 24G:** Enter the number of service units utilized and units discarded/unused.

For example, a 90kg patient is administered 900mg (VYVGART 10 mg/kg) and 300mg is wasted.

One single-use vial of VYVGART contains 400mg. Each service unit is billed per 2mg. The total billable units for one single-use vial of VYVGART is 200 [400mg / 2mg (Service Unit per J-Code assignment)]. A 90kg patient requires 3 vials.

Calculation of service units billed: Dose administered (900mg) / 2mg (Service Unit per J-Code assignment) = 450 units

Calculation of wastage units billed: Amount wasted (300mg) / 2mg (Service Unit per J-Code assignment) = 150 units

**Note:** Payer requirements may vary.

5. PATIENT'S ADDRESS (No., Street)		CITY		ZIP CODE		TELEPHONE (Include Area Code)					
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)											
a. OTHER INSURED'S POLICY OR GROUP NUMBER											
b. RESERVED FOR NUCC USE				b. AUTO ACCIDENT? PLACE (State)		b. OTHER CLAIM ID (Designated by NUCC)					
				<input type="checkbox"/> YES <input type="checkbox"/> NO							
c. RESERVED FOR NUCC USE				c. OTHER ACCIDENT?		g. INSURANCE PLAN NAME OR PROGRAM NAME					
				<input type="checkbox"/> YES <input type="checkbox"/> NO							
d. INSURANCE PLAN NAME OR PROGRAM NAME				10d. CLAIM CODES (Designated by NUCC)		d. IS THERE ANOTHER HEALTH BENEFIT PLAN?					
						<input type="checkbox"/> YES <input type="checkbox"/> NO <i>If yes, complete items 9, 9a, and 9d.</i>					
<b>READ BACK OF FORM BEFORE COMPLETING &amp; SIGNING THIS FORM.</b>											
12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.				13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.							
SIGNED _____				SIGNED _____							
DATE _____				DATE _____							
14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY				15. OTHER DATE MM DD YY		16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION FROM MM DD YY TO MM DD YY					
QUAL. _____				QUAL. _____		FROM MM DD YY TO MM DD YY					
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE				17a. _____		18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM MM DD YY TO MM DD YY					
				17b. NPI _____							
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)				20. OUTSIDE LAB? <input type="checkbox"/> YES <input type="checkbox"/> NO		\$ CHARGES _____					
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. <u>G70.00</u>				23. PRIOR AUTHORIZATION NUMBER _____							
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. #
1 MM DD YY MM DD YY				J9332		A		450		NPI	
2 MM DD YY MM DD YY				J9332 JW		A		150		NPI	
3 MM DD YY MM DD YY				96365		A		1		NPI	
4										NPI	
5										NPI	
6										NPI	
25. FEDERAL TAX I.D. NUMBER		SSN EIN		29. AMOUNT PAID		30. Rsvd for NUCC Use					
				\$							

**Item 21:** Enter the appropriate ICD-10-CM diagnosis code(s). See table on page 1 for more information.

**Note:** Other diagnosis codes may apply.

**Item 24D Line 1:** Enter the appropriate HCPCS code for VYVGART (J9332) to bill for service units utilized.

**Item 24D Line 2:** Enter the appropriate HCPCS code for VYVGART (J9332) with the JW modifier to bill for amount discarded/unused.

**Item 24D Line 3:** Enter the appropriate CPT code for the administration of VYVGART. See table on page 1 for more information.

**Note:** Other CPT codes may apply. Payer requirements may vary.

**Item 24E:** Enter the reference to the CPT and HCPCS codes associated with the diagnosis code (in Item 21).

**Note:** Payer requirements may vary.

**Sample CMS-1450 (or UB-04) Form for patient weighing 90kg: For the hospital outpatient department<sup>9</sup>**

**FL 42 and 43:** Enter the revenue codes and descriptions for VYVGART and its administration. See table on page 1 for more information.

**Note:** Other revenue codes may apply.

**FL 46:** Enter the number of service units utilized and units discarded/unused.

For example, a 90kg patient is administered 900mg (VYVGART 10 mg/kg) and 300mg is wasted.

One single-use vial of VYVGART contains 400mg. Each service unit is billed per 2mg. The total billable units for one single-use vial of VYVGART is 200 [400mg / 2mg (Service Unit per J-Code assignment)]. A 90kg patient requires 3 vials.

Calculation of service units billed: Dose administered (900mg) / 2mg (Service Unit per J-Code assignment) = 450 units

Calculation of wastage units billed: Amount wasted (300mg) / 2mg (Service Unit per J-Code assignment) = 150 units

**Note:** Payer requirements may vary.

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	Injection, efgartigimod alfa-fcab, 2 mg	J9332	MM DD YY	450			
0636	Injection, efgartigimod alfa-fcab, 2 mg	J9332 JW	MM DD YY	150			
0260	IV infusion	96365	MM DD YY	1			

  

63 TREATMENT AUTHORIZATION CODES	64 DOCUMENT CONTROL NUMBER	65 EMPLOYER NAME

  

66 DR. CODE	68
G70.00	

  

69 ADMIT DX	70 PATIENT REASON DX	71 PPS CODE	72 ECI	73

  

74 PRINCIPAL PROCEDURE CODE	75 OTHER PROCEDURE CODE	76 ATTENDING NPI	77 OPERATING NPI	78 OTHER NPI

  

80 REMARKS	81CC a	81CC b

Enter the appropriate ICD-10-CM diagnosis code(s). See table on page 1 for more information.

**Note:** Other diagnosis codes may apply.

**FL 44 Line 1:** Enter the appropriate HCPCS code for VYVGART (J9332) to bill for service units utilized.

**FL 44 Line 2:** Enter the appropriate HCPCS code for VYVGART (J9332) with the JW modifier to bill for amount discarded/unused.

**FL 44 Line 3:** Enter the appropriate CPT code for the administration of VYVGART. See table on page 1 for more information.

**Note:** Other CPT codes may apply.

**References**

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3. Centers for Medicare & Medicaid Services (CMS). JW Modifier: Drug/Biological Amount Discarded/Not Administered To Any Patient Frequently Asked Questions. Accessed May 16, 2022. <https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf>
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9. CMS. CMS 1450. Medicare uniform instructional provider bill and supporting regulations 42 CFR 424.5. Accessed May 3, 2022. <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-1450>



## Additional Resources

If you have additional questions about **VYVGART**, 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](http://VYVGARTHCP.com).



## Indication

VYVGART<sup>®</sup> (efgartigimod alfa-fcab) 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 may increase the risk of infection. The most common infections observed in Study 1 were urinary tract infection (10% for VYVGART vs 5% for placebo) and respiratory tract infection (33% for VYVGART vs 29% for placebo). Patients on VYVGART 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 administration in patients with an active infection until the infection is resolved; monitor for clinical signs and symptoms of infections. If serious infection occurs, administer appropriate treatment and consider withholding VYVGART until the infection has resolved.

#### Immunization

Immunization with vaccines during VYVGART 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 causes a reduction in immunoglobulin G (IgG) levels, vaccination with live-attenuated or live vaccines is not recommended during VYVGART treatment. Evaluate the need to administer age-appropriate vaccines according to immunization guidelines before initiation of a new treatment cycle with VYVGART.

#### Hypersensitivity Reactions

Hypersensitivity reactions, including rash, angioedema, and dyspnea, were observed with VYVGART. 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 during administration and for 1 hour thereafter for clinical signs and symptoms of hypersensitivity reactions. If a hypersensitivity reaction occurs during administration, discontinue VYVGART infusion and institute appropriate supportive measures if needed.

#### Adverse Reactions

The most common ( $\geq 10\%$ ) adverse reactions with VYVGART were respiratory tract infection, headache, and urinary tract infection.

### USE IN SPECIFIC POPULATIONS

#### Pregnancy

As VYVGART 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 in utero.

#### Lactation

There is no information regarding the presence of VYVGART 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 and any potential adverse effects on the breastfed infant from VYVGART or from the underlying maternal condition.

### Please see full Prescribing Information in pocket.

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).