VYVGART®
(efgartigimod alfa-fcab)
Injection for Intravenous Use
400 mg/20 mL vial

VYVGART BILLING & CODING GUIDE

VYVGART® (efgartigimod alfa-fcab) is indicated for the treatment of generalized myasthenia gravis in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.[1] VYVGART is administered as an intravenous (IV) infusion that typically occurs in a physician's office or hospital outpatient clinic.

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. This guide does not include 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 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 (efgartigimod alfa-fcab, 2 mg).
Do not use this guide if a patient received VYVGART® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc).

Coding for VYVGART

The following codes may be applicable when billing for VYVGART:

Code Type	Code	Description	Place of Service
HCPCS code[2]	J9332	Injection, efgartigimod alfa-fcab, 2 mg	Physician office, HOPD
HCPCS Modifier[3]	JW	Drug amount discarded/not administered to any patient	Physician office, HOPD
	JZ	Zero drug amount discarded/not administered to any patient	Physician office, HOPD
	TB[a]	Drug or biological acquired with 340b drug pricing program discount, reported for informational purposes for select entities	HOPD
NDC[1]	73475-3041-05	400 mg of efgartigimod alfa-fcab in 20 mL (20 mg/mL)	Physician office, HOPD
CPT[4b]	96365[c]	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour	Physician office, HOPD
	96413[c,d]	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug [Used for IV infusion of certain complex/high-risk drugs]	
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
	0260	IV therapy: General	
	0269	IV therapy: Other	
	0510	Clinic: General	

[a]No later than January 1, 2024, 340B modifiers, "JG" or "TB" are required on Medicare claims for separately payable Part B drugs and biologicals for all 340B-covered entities, including hospital-based and non-hospital-based entities.
[b]CPT Copyright 2022 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association.
[c]Use of appropriate codes will be at the discretion of the payer.
[d]Highly complex drugs, including biologic agents or chemotherapy codes, require clinical documentation in the medical record of the complexity involved beyond what is required for therapeutic infusion codes (963XX codes).

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.

Do not use HCPCS code J3490 (unclassified drugs) to report use of VYVGART (efgartigimod alfa-fcab).

Sample CMS-1500 Form for patient weighing 80kg: For the physician office setting[7]

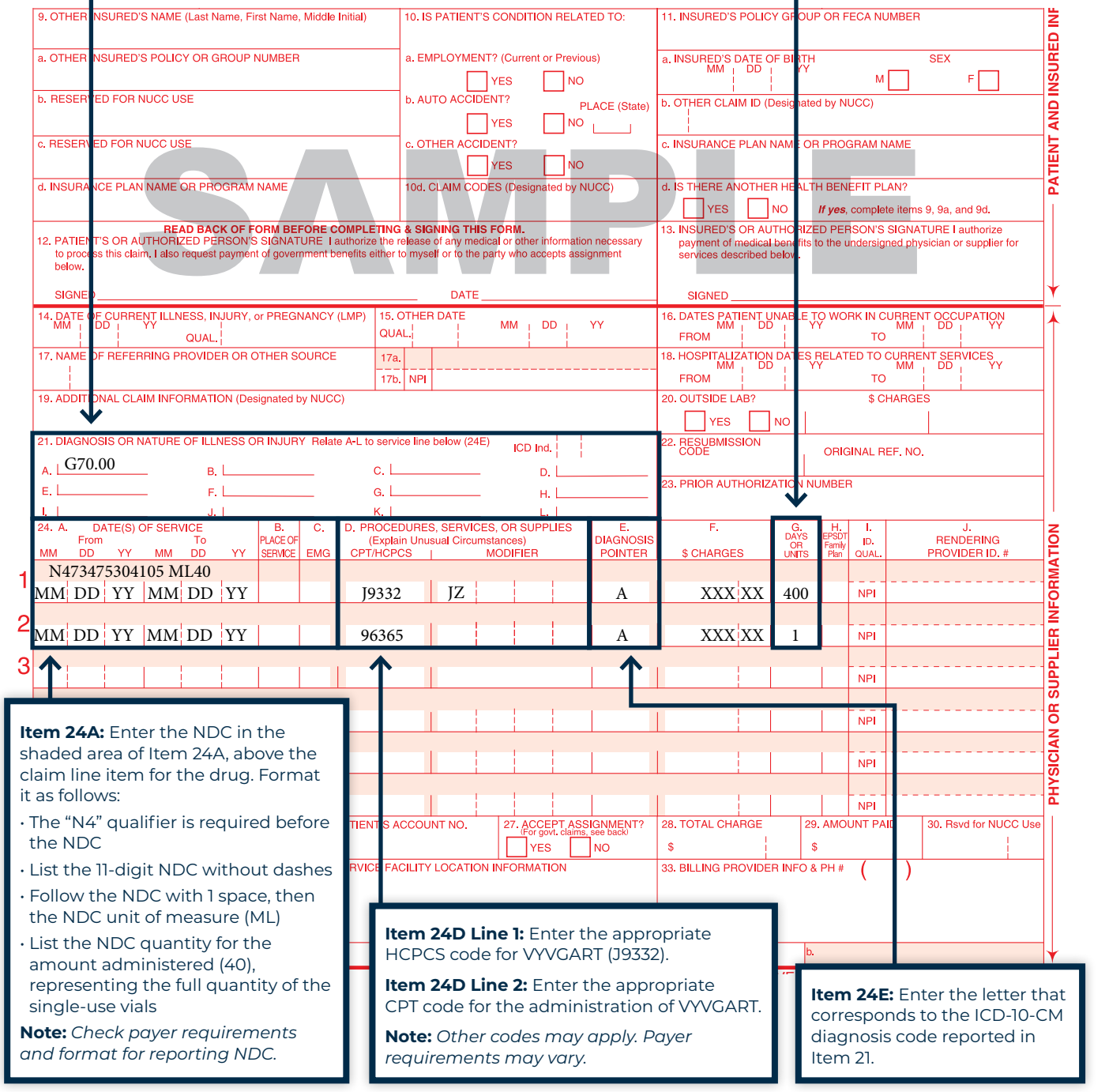
Item 21: Enter the appropriate ICD-10-CM diagnosis code(s).

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

Item 24G: Enter the number of billing units.

For example, a 80kg patient is administered 800 mg (VYVGART 10 mg/kg). The dose requires two 400 mg single-dose vials. For J9332, 1 billing unit is equal to 2 mg of VYVGART.

Calculation of billing units for amount administered: 800 mg / 2 mg = 400 billing units.



Item 24A: Enter the NDC in the shaded area of Item 24A, above the claim line item for the drug. Format it as follows:

- The "N4" qualifier is required before the NDC
- List the 11-digit NDC without dashes
- Follow the NDC with 1 space, then the NDC unit of measure (ML)
- List the NDC quantity for the amount administered (40), representing the full quantity of the single-use vials

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

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.

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

Item 24E: Enter the letter that corresponds to the ICD-10-CM diagnosis code reported in Item 21.

Sample CMS-1500 Form for patient weighing 90kg: For the physician office setting[7]

Item 21: Enter the appropriate ICD-10-CM diagnosis code(s).

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

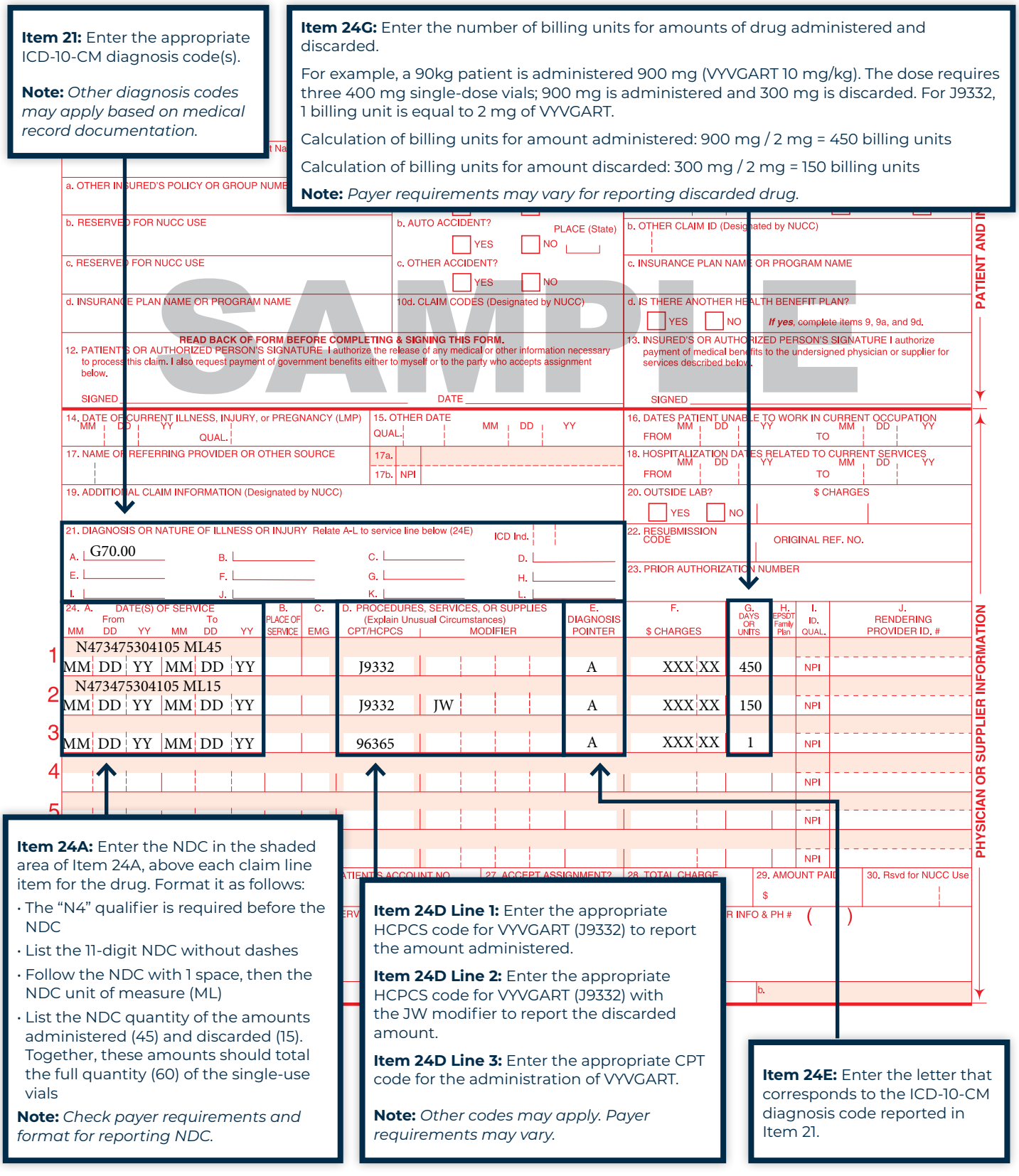
Item 24G: Enter the number of billing units for amounts of drug administered and discarded.

For example, a 90kg patient is administered 900 mg (VYVGART 10 mg/kg). The dose requires three 400 mg single-dose vials; 900 mg is administered and 300 mg is discarded. For J9332, 1 billing unit is equal to 2 mg of VYVGART.

Calculation of billing units for amount administered: 900 mg / 2 mg = 450 billing units

Calculation of billing units for amount discarded: 300 mg / 2 mg = 150 billing units

Note: *Payer requirements may vary for reporting discarded drug.*



Item 24A: Enter the NDC in the shaded area of Item 24A, above each claim line item for the drug. Format it as follows:

- The "N4" qualifier is required before the NDC
- List the 11-digit NDC without dashes
- Follow the NDC with 1 space, then the NDC unit of measure (ML)
- List the NDC quantity of the amounts administered (45) and discarded (15). Together, these amounts should total the full quantity (60) of the single-use vials

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

Item 24D Line 1: Enter the appropriate HCPCS code for VYVGART (J9332) to report the amount administered.

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

Item 24D Line 3: Enter the appropriate CPT code for the administration of VYVGART.

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

Item 24E: Enter the letter that corresponds to the ICD-10-CM diagnosis code reported in Item 21.

Sample CMS-1450 (or UB-04) Form for patient weighing 90kg: For the hospital outpatient department[8]

FL 42: Enter the appropriate revenue code, eg:
- 0636 for VYVGART
- 0260 for IV infusion

Note: *Other revenue codes may apply.*

FL 43: Enter the corresponding descriptions for the codes listed in FL 44. For the HCPCS code descriptor, enter the NDC number in FL 43:
- The "N4" qualifier is required before the NDC
- List the 11-digit NDC without dashes
- Follow the NDC with 1 space, then the NDC unit of measure (ML)
- List the NDC quantity for amounts administered (45) and discarded (15). Together, these amounts should total the full quantity (60) of the single-use vials

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

FL 46: Enter the number of billing units for amounts of drug administered and discarded.

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

The dose requires three 400 mg single-dose vials; 900 mg is administered and 300 mg is discarded.

For J9332, 1 billing unit is equal to 2 mg of VYVGART.

Calculation of billing units for amount administered: 900 mg / 2 mg = 450 billing units

Calculation of billing units for amount discarded: 300 mg / 2 mg = 150 billing units

Note: *Payer requirements may vary for reporting discarded drug.*

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	N473475304104 ML45 VYVGART	J9332	MM DD YY	450	XXX XX		
0636	N473475304104 ML15 VYVGART	J9332 JW	MM DD YY	150	XXX XX		
0260	IV infusion	96365	MM DD YY	1	XXX XX		

63 TREATMENT AUTHORIZATION CODES	64 DOCUMENT CONTROL NUMBER	65 EMPLOYER NAME

66 DX: G70.00

FL 66: Enter the appropriate ICD-10-CM diagnosis code(s).

Note: *Other diagnosis codes may apply.*

FL 44 Line 1: Enter the appropriate HCPCS code for VYVGART (J9332) to report the amount of drug administered to the patient.

FL 44 Line 2: Enter the appropriate HCPCS code for VYVGART (J9332) with the JW modifier to report any discarded amount of drug not administered to the patient.

FL 44 Line 3: Enter the appropriate CPT code for the administration of VYVGART.

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

References
1. VYVGART prescribing information. argenx; 2023. **2.** CMS. January 2023 alpha-numeric HCPCS file. 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. Accessed December 22, 2022. https://www.cms.gov/medicare/icd-10/2023-icd-10-cm **6.** ResDAC. Revenue center code. 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. 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 Form CMS-1450 data set. Accessed December 22, 2022. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c25.pdf

VYVGART®
(efgartigimod alfa-fcab)
Injection for Intravenous Use
400 mg/20 mL vial

INDICATION

VYVGART® (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

CONTRAINDICATIONS

VYVGART is contraindicated in patients with serious hypersensitivity to efgartigimod alfa products or to any of the excipients of VYVGART. Reactions have included anaphylaxis and hypotension leading to syncope.

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 infections (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 has 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

In clinical trials, hypersensitivity reactions, including rash, angioedema, and dyspnea were observed in VYVGART-treated patients. Hypersensitivity reactions were mild or moderate, occurred within 1 hour to 3 weeks of administration, and did not lead to treatment discontinuation. Anaphylaxis and hypotension leading to syncope have been reported in postmarketing experience with VYVGART. 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 patients during administration and for 1 hour thereafter for clinical signs and symptoms of hypersensitivity reactions. 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 VYVGART 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 during administration, discontinue VYVGART infusion and initiate appropriate therapy. Consider the risks and benefits of readministering VYVGART 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

In Study 1, the most common (≥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 efgartigimod alfa-fcab 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 and any potential adverse effects on the breastfed infant from VYVGART 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**, 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.

My VYVGART® Path

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