VYVGART Hytrulo®
(efgartigimod alfa and hyaluronidase-qvfc)

VYVGART®
(efgartigimod alfa-fcab)

BILLING AND CODING GUIDE FOR VYVGART Hytrulo AND VYVGART IN GENERALIZED MYASTHENIA GRAVIS

VYVGART Hytrulo® vial (180 mg/mL efgartigimod alfa and 2,000 U/mL hyaluronidase) for subcutaneous injection and VYVGART® (400 mg of efgartigimod alfa-fcab in 20 mL) for intraveneous infusion are each indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.[1,2]

Please see Important Safety Information for VYVGART Hytrulo in tab below and full Prescribing Information for VYVGART Hytrulo.

Please see Important Safety Information for VYVGART in tab below and full Prescribing Information for VYVGART.

This guide is provided as an educational resource for healthcare providers (HCPs) regarding billing and coding for VYVGART Hytrulo and VYVGART for gMG. This guide does not include all possible or required billing and coding options for VYVGART Hytrulo or 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 Hytrulo or 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 and is subject to change.

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

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VYVGART Hytrulo®
(efgartigimod alfa and hyaluronidase-qvfc)

Coding
for VYVGART Hytrulo in gMG

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[3]	J9334	Injection, efgartigimod alfa, 2 mg and hyaluronidase-qvfc	✓	✓
HCPCS modifier[3,4]	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[2]	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[5,a]	96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	✓	✓
ICD-10-CM diagnosis code[6]	G70.00	Myasthenia gravis without (acute) exacerbation	✓	✓
	G70.01	Myasthenia gravis with (acute) exacerbation	✓	✓
Revenue code[7]	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.

[a]CPT Copyright 2023 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association.
[b]340B-covered entities must report modifier TB starting with services on January 1, 2025.[8]
[c]Other revenue codes may apply.

Do not use HCPCS code J9334 to report use of VYVGART® (efgartigimod alfa-fcab). Click here for information on VYVGART.

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Sample CMS-1500 Claim Form

for VYVGART Hytrulo in the physician office[9]

Item Number 21

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

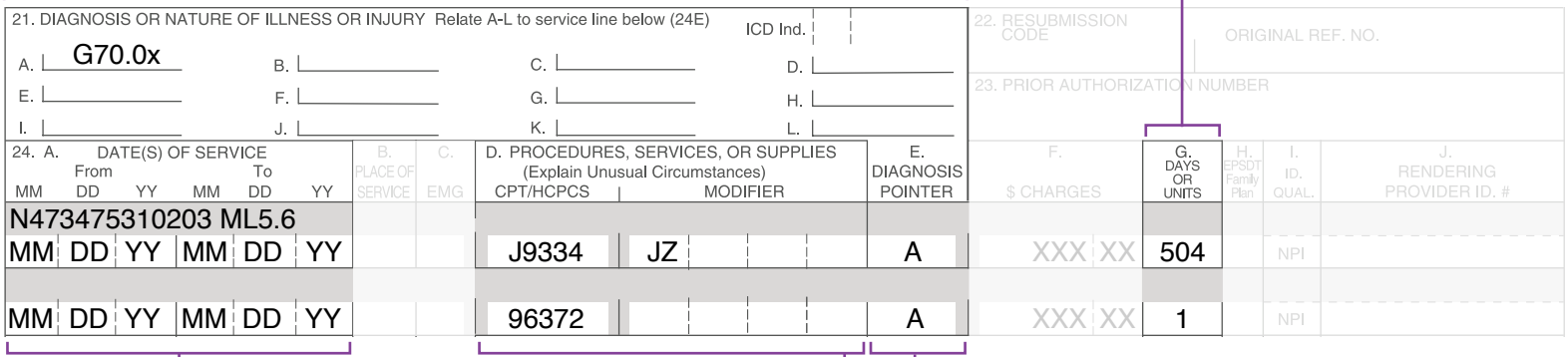
ICD-10-CM: G70.0x for myasthenia gravis

Note: *An "x" indicates that additional characters are required. Final code depends on medical record documentation.*

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. G70.0x | 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. 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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VYVGART Hytrulo®
(efgartigimod alfa and hyaluronidase-qvfc)

Sample CMS-1450 (UB-04) Claim Form

for VYVGART Hytrulo in the hospital outpatient department[10]

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:

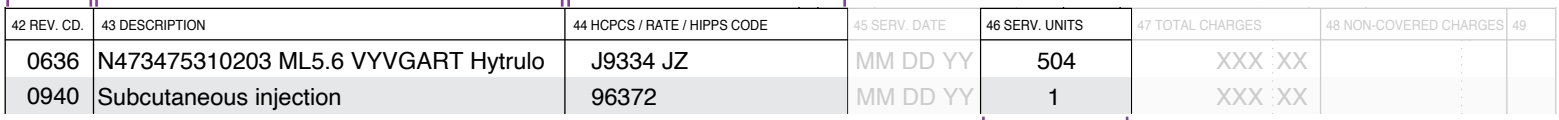
- N4 (in front of the NDC)
- 11-digit NDC (with no dashes or other punctuation)
- NDC unit of measure (ML, place 1 space after the NDC)
- NDC quantity (5.6 – signifying that the full contents of the single-dose vial were administered)

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

67 DX	A	B	C	D	E	F	G	H	68
G70.0x									
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: G70.0x for myasthenia gravis

Note: *An "x" indicates that additional characters are required. Final code depends on medical record documentation.*

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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VYVGART®
(efgartigimod alfa-fcab)

Coding
for VYVGART in gMG

Coding | CMS-1500 Claim Form | CMS-1450 Claim Form

Dosing calculator

The following codes may be applicable when billing for VYVGART and its administration:

Code Type	Code	Description	Physician office	HOPD
HCPCS code[3]	J9332	Injection, efgartigimod alfa-fcab, 2 mg	✓	✓
HCPCS modifier[3,4]	JW	Drug amount discarded/not administered to any patient	✓	✓
	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]	73475-3041-05	400 mg of efgartigimod alfa-fcab in 20 mL (20 mg/mL)	✓	✓
CPT[5,a]	96365[c]	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour	✓	✓
	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[6]	G70.00	Myasthenia gravis without (acute) exacerbation	✓	✓
	G70.01	Myasthenia gravis with (acute) exacerbation		
Revenue code[7]	0636	Drugs requiring detailed coding	—	✓
	0260	IV therapy: General		
	0269	IV therapy: Other		
	0510[e]	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; IV, intravenous; NDC, National Drug Code.

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[b]340B-covered entities must report modifier TB starting with services on January 1, 2025.[8]

[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).

[e]Other revenue codes may apply.

Do not use HCPCS code J9332 to report use of VYVGART Hytrulo® (efgartigimod alfa and hyaluronidase-qvfc). Click here for information on VYVGART Hytrulo.

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VYVGART®
(efgartigimod alfa-fcab)

Sample CMS-1500 Claim Form

for VYVGART in the physician office[9]

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: G70.0x for myasthenia gravis

Note: *An "x" indicates that additional characters are required. Final code depends on medical record documentation.*

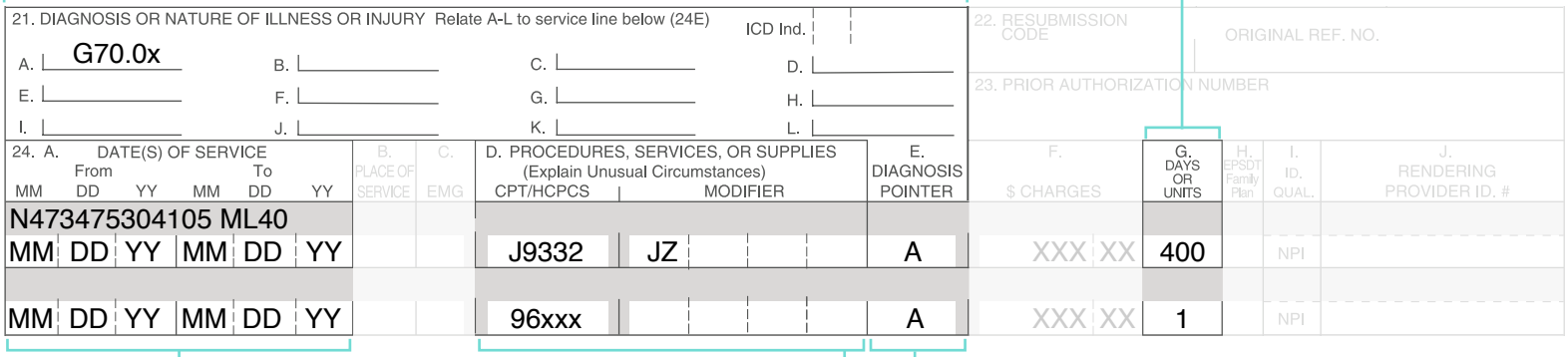
Item Number 24G

Enter the appropriate number of billing units for each line item. For example, an 80 kg patient is administered 800 mg (VYVGART 10 mg/kg). The dose requires two 400 mg single-dose vials.

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

- For J9332, 1 billing unit is equal to 2 mg of VYVGART
- For 96xxx, 1 unit represents up to a 90-minute IV infusion

Note: *An "x" indicates that additional characters are required. Final code depends on medical record documentation and payer requirements.*



21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.

A. G70.0x 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. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
N473475304105 ML40											
MM DD YY	MM DD YY			J9332	JZ	A	XXX XX	400		NPI	
MM DD YY	MM DD YY			96xxx		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 (40 – 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: J9332 for VYVGART

- Modifier JZ indicates no amount of drug was discarded

Administration: Enter the appropriate CPT code based on medical record documentation and payer requirements.

Item Number 24E

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

If VYVGART 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; IV, intravenous; NDC, National Drug Code.

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VYVGART®
(efgartigimod alfa-fcab)

Sample CMS-1450 (UB-04) Claim Form

For VYVGART in the hospital outpatient department[10]

Coding | CMS-1500 Claim Form | CMS-1450 Claim Form

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:

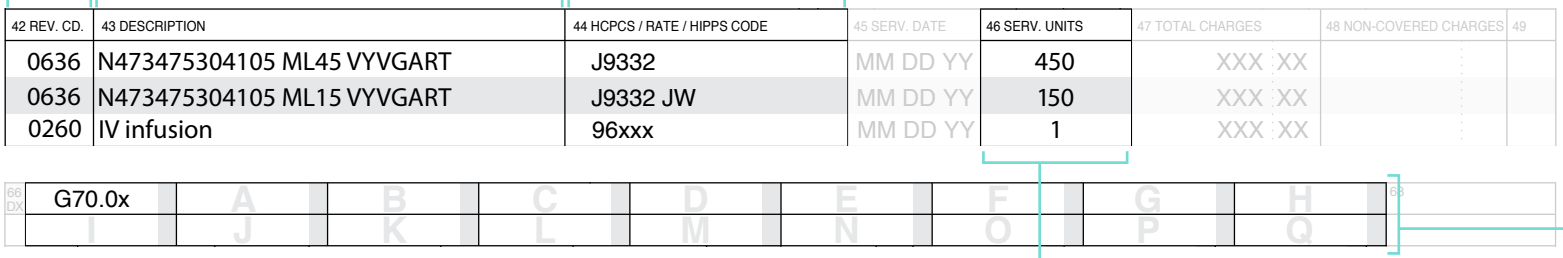
- N4 (in front of the NDC)
- 11-digit NDC (with no dashes or other punctuation)
- NDC unit of measure (ML, place 1 space after the NDC)
- List the NDC quantity for amounts administered (45) and discarded (15). Together, these amounts should total the full quantity (60) of the single-use vials

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

FL 44

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

- Drug: J9332 for VYVGART
  - Modifier JW indicates the amount of drug that was discarded
- Administration: Enter the appropriate CPT code based on medical record documentation and payer requirements.



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	N473475304105 ML45 VYVGART	J9332	MM DD YY	450	XXX XX		
0636	N473475304105 ML15 VYVGART	J9332 JW	MM DD YY	150	XXX XX		
0260	IV infusion	96xxx	MM DD YY	1	XXX XX		

66 DX	A	B	C	D	E	F	G	H	68
G70.0x									
I	J	K	L	M	N	O	P	Q	

FL 46

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

For example, a 90 kg 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.

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

- For J9332, 1 billing unit is equal to 2 mg of VYVGART
- For 96xxx, 1 unit represents up to a 90-minute IV infusion

Note: *An "x" indicates that additional characters are required. Final code depends on medical record documentation and payer requirements.*

FL 67 and 67A-67Q

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

ICD-10-CM: G70.0x for myasthenia gravis

Note: *An "x" indicates that additional characters are required. Final code depends on medical record documentation.*

If VYVGART 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; IV, intravenous; NDC, National Drug Code.

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VYVGART Hytrulo®
(efgartigimod alfa and hyaluronidase-qvfc)

VYVGART®
(efgartigimod alfa-fcab)

Important Safety Information

INDICATION

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

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

Infections

VYVGART and 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 the administration of VYVGART or VYVGART HYTRULO 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 treatment with VYVGART or 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 or VYVGART HYTRULO. The safety of immunization with live vaccines and the immune response to vaccination during treatment with VYVGART or VYVGART HYTRULO are unknown. Because VYVGART and VYVGART HYTRULO cause a reduction in immunoglobulin G (IgG) levels, vaccination with live vaccines is not recommended during treatment with VYVGART or VYVGART HYTRULO.

Hypersensitivity Reactions

In clinical trials, hypersensitivity reactions, including rash, angioedema, and dyspnea were observed in patients treated with VYVGART or VYVGART HYTRULO. 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 during and for 1 hour after VYVGART administration, or for at least 30 minutes after VYVGART HYTRULO 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 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.

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

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 and VYVGART HYTRULO are 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 or VYVGART HYTRULO in utero.

Lactation

There is no information regarding the presence of efgartigimod alfa-fcab from administration of VYVGART, or 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 or VYVGART HYTRULO, and any potential adverse effects on the breastfed infant from VYVGART or VYVGART HYTRULO or from the underlying maternal condition.

Please see the full Prescribing Information for VYVGART and 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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References

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