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

VYVGART Hytrulo 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 and is subject to change.

Do not use this guide if a patient received intravenously administered VYVGART (Injection, efgartigimod alfa-fcab, 2 mg). Instead, please see the VYVGART Billing and Coding Guide for guidance.

Coding for VYVGART Hytrulo

VYVGART Hytrulo has been assigned a drug-specific Healthcare Common Procedure Coding System (HCPCS) billing code that can be reported on 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]	JW[b]	Drug amount discarded/not administered to any patient	✓	✓
	JZ	Zero drug amount discarded/not administered to any patient	✓	✓
	JG	Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes		✓[c]
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]	G70.00	Myasthenia gravis without (acute) exacerbation	✓	✓
	G70.01	Myasthenia gravis with (acute) exacerbation		
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]The flat dosing for VYVGART Hytrulo means the need to report amounts of discarded drug using the -JW modifier should be infrequent.
[c]Medicare only for facilities paid under the Outpatient Prospective Payment System (OPPS).

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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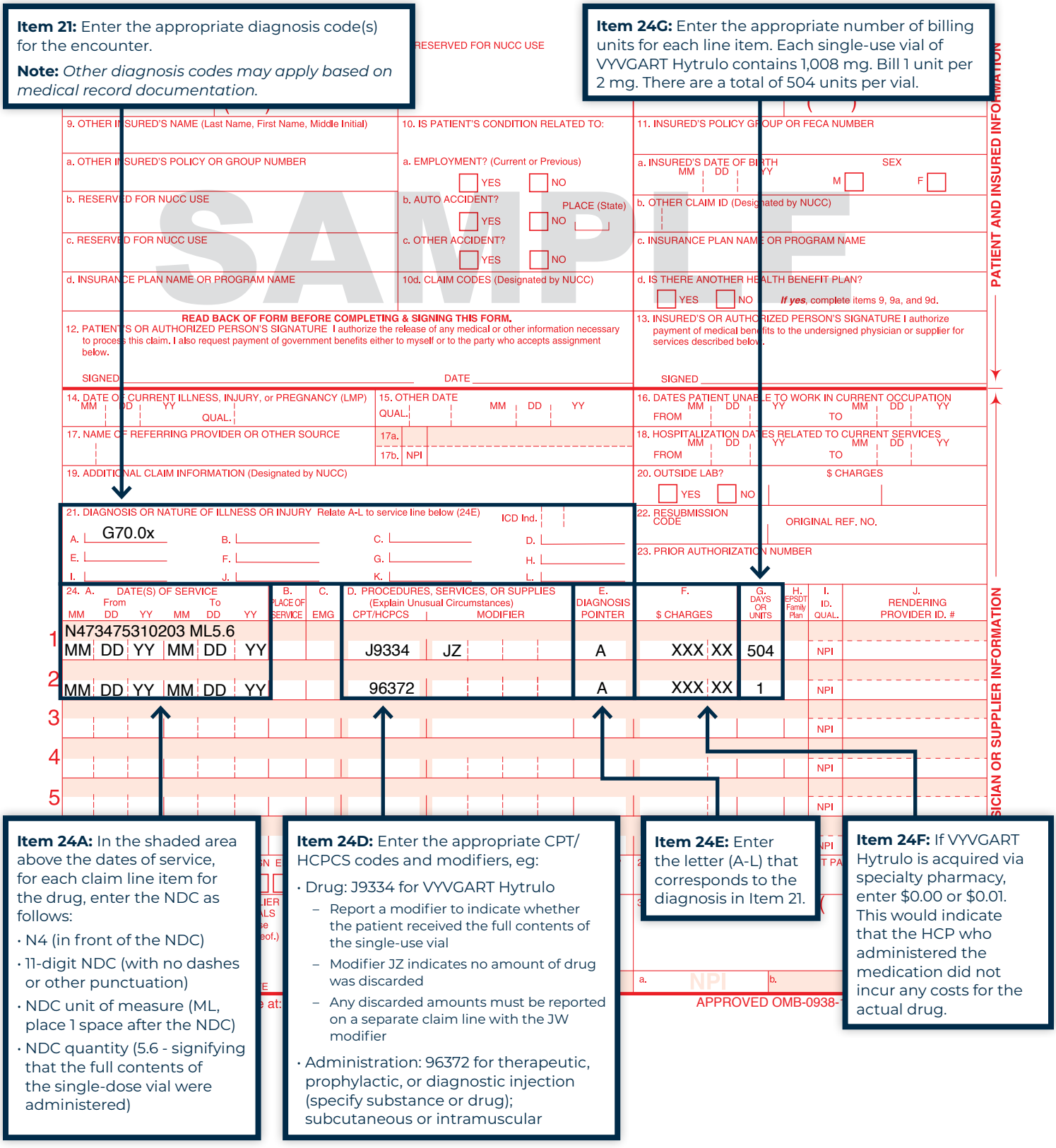
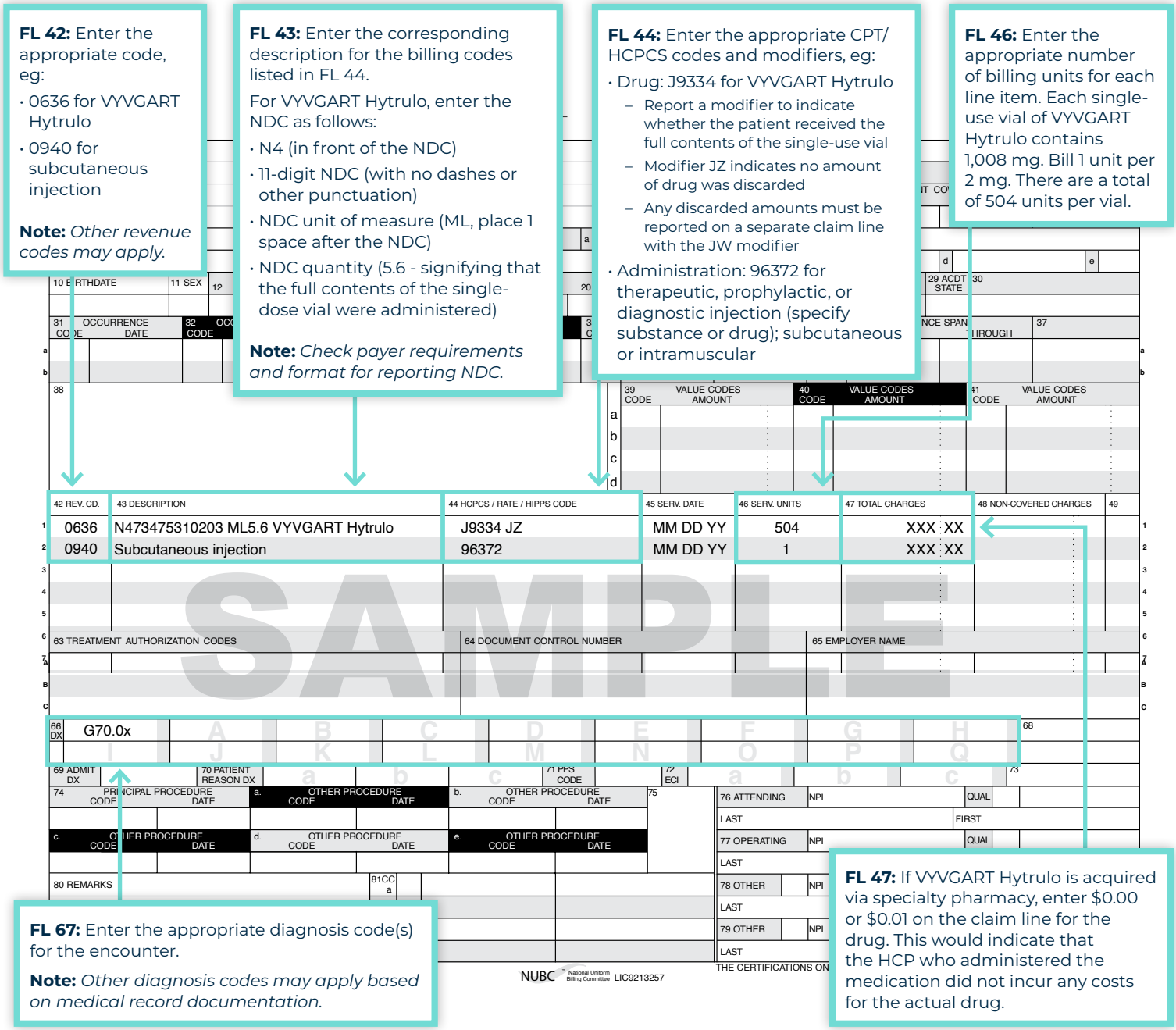
Sample CMS-1500 Form: For the physician office setting[7]



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

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



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

References

1. VYVGART Hytrulo. Prescribing information. argenx; 2023. **2.** CMS. January 2024 alpha-numeric HCPCS file. Updated November 6, 2023. Accessed November 9, 2023. 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 October 25, 2023. https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf **4.** AMA. 2024 CPT Professional Edition. Current Procedural Terminology (CPT®) Copyright 2023 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association. AMA; 2023. **5.** CMS. 2024 ICD-10-CM tabular list of disease and injuries. Updated June 29, 2023. Accessed October 25, 2023. https://www.cms.gov/medicare/coding-billing/icd-10-codes/2024-icd-10-cm **6.** ResDAC. Revenue center code. Updated February 2018. Accessed October 25, 2023. 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 October 25, 2023. 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 October 25, 2023. 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

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 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. 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

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. 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.

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