

NOW AVAILABLE | VYVGART HYTRULO®
PREFILLED SYRINGE FOR SELF-INJECTION

VYVGART Hytrulo®
(efgartigimod alfa and hyaluronidase-qvfc)
Subcutaneous Injection
180 mg/mL and 2000 U/mL | 200 mg/mL and 2000 U/mL

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

Overview of clinical data for 3 administration options

VYVGART for IV infusion and VYVGART Hytrulo for SC injection: the combined **#1 prescribed FDA-approved biologic treatments** for adults with anti-acetylcholine receptor (AChR) antibody positive gMG*

Patient portrayals

*Based on IQVIA LAAD from January 2023 to December 2024. Data is based on validated open claims of VYVGART for IV infusion, VYVGART Hytrulo for SC injection, oral products and other biologics that have been approved by the FDA for the treatment of adults with generalized myasthenia gravis. Patients who had more than one medical claim in this data set were counted only once, based on a pre-defined hierarchy.

gMG=generalized myasthenia gravis; IV=intravenous; LAAD=Longitudinal Access and Adjudication Data; SC=subcutaneous.

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.

Please see additional Important Safety Information throughout and full Prescribing Information for VYVGART Hytrulo and full Prescribing Information for VYVGART.



You don't know
how you will feel
from one day to
the next or what
the future holds.

—Real patient living with gMG^{1*}

^{*}This analysis was led by the International Myasthenia Gravis Patient Council: a group of people living with MG who serve as leading patient advocates across the globe. The International Myasthenia Gravis Patient Council reconvened in August 2020 to review insights from multiple data sources and generate statements that represented the lived experience of gMG.¹

[†]Data for this comparative analysis is based on 2 multinational, observational studies conducted between 2020 and 2021. One study was conducted among patients with MG (N=2,074) and the other collected data from the general population (N=9,000). Patients with MG were at least 18 years of age with mild to severe MG.²

[‡]Data collected from an argenx-sponsored, cross-sectional study of 150 people who had a self-reported diagnosis of gMG from an HCP between June 22-30, 2020. Eligible participants were US residents who were ≥18 years old. The survey explored the gMG diagnosis process, burden of disease, and burden of treatment. QOL and disease burden were measured with the WHO-5 Well-Being Index and the MG-QOL15r.³

gMG=generalized myasthenia gravis; HCP=healthcare professional; MG=myasthenia gravis; MG-QOL15r=revised 15-item Myasthenia Gravis Quality of Life questionnaire; QOL=quality of life.

71%

(N=1,299)

of MG patients **had problems doing their usual activities** vs 23% of the general population (N=9,000)^{2†}

63%

(N=150)

of patients have had **career or education interruptions due to gMG symptoms**^{3‡}

62%

(n=144)

of patients who were taking a gMG medication felt that **their symptoms were significant enough to want to try an additional treatment**^{3‡}

60%

(N=1,177)

of MG patients have **lost some personal independence** vs 16% of the general population (N=9,000)^{2†}

Are your patients struggling with symptom
management on traditional gMG therapies?

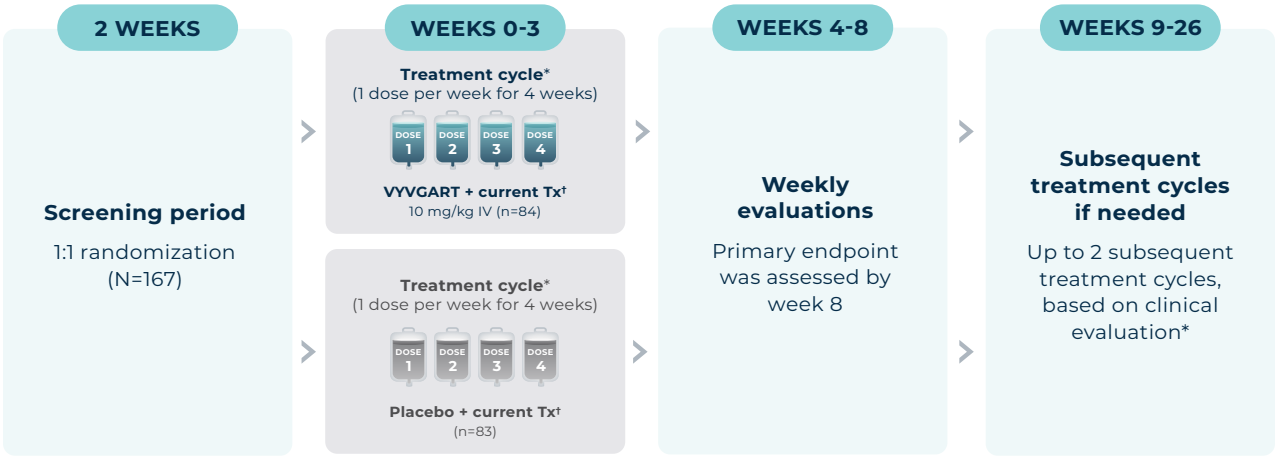
**Consider an add-on treatment
to their current gMG therapy.**

The ADAPT phase 3 clinical trial^{4,5}

A 26-week, multicenter, randomized, double-blind, placebo-controlled trial in 167 adult patients with gMG⁴

PRIMARY ENDPOINT

The percentage of anti-AChR antibody positive patients who were MG-ADL responders, defined as a ≥2-point reduction in the total MG-ADL score compared to the treatment cycle baseline for at least 4 consecutive weeks during the first treatment cycle (by week 8), with the first reduction occurring no later than 1 week after the last infusion of the cycle.⁴



The majority of patients (n=65 for **VYVGART**; n=64 for placebo) were positive for AChR antibodies.^{4†}

*All patients received an initial cycle, with subsequent cycles administered based on individual clinical evaluation when their MG-ADL score was at least 5 (with >50% MG-ADL nonocular) and if the patient was an MG-ADL responder, when they no longer had a clinically meaningful decrease (defined as having a ≥2-point improvement in total MG-ADL score) compared to baseline. The minimum time between treatment cycles, specified by study protocol, was 4 weeks from the last infusion. A maximum of 3 cycles was possible in the 26-week study.^{4,5}

†All patients received stable doses of their current gMG treatment.^{4,5}

AChR=acetylcholine receptor; gMG=generalized myasthenia gravis; IV=intravenous; MG-ADL=Myasthenia Gravis Activities of Daily Living; Tx=treatment.

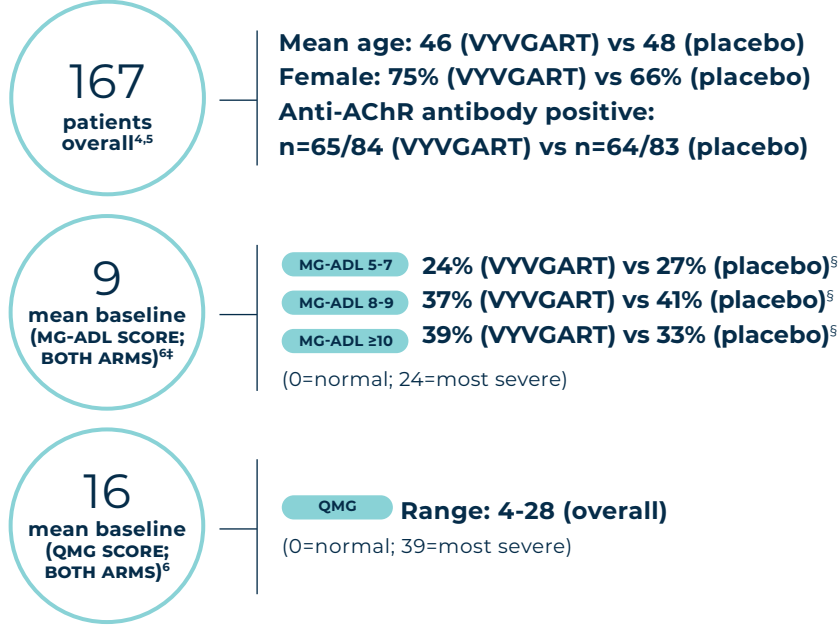
IMPORTANT SAFETY INFORMATION (cont'd)

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).

ADAPT represented a range of adult patients with gMG⁴⁻⁷



Patients should be advised to complete age-appropriate vaccines according to immunization guidelines prior to initiation of a new treatment cycle with VYVGART. Vaccination with live vaccines is not recommended during treatment with VYVGART. No specific vaccinations were required in the ADAPT clinical trial inclusion criteria.^{4,5}

⁴MG-ADL total score of ≥5 required at screening with >50% of the total score attributed to nonocular symptoms.⁵

⁵Sum of the percentages is over 100% due to rounding.

⁶Conditions shown represent the 5 most prevalent comorbidities reported by investigator at baseline in the ADAPT clinical trial (N=167).⁷

AChE=acetylcholinesterase; MGFA=Myasthenia Gravis Foundation of America; NSIST=nonsteroidal immunosuppressive therapy; QMG=Quantitative Myasthenia Gravis.

IMPORTANT SAFETY INFORMATION (cont'd)

Infections (cont'd)

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).

Please see additional Important Safety Information throughout and full Prescribing Information for **VYVGART Hytrulo** and full Prescribing Information for **VYVGART**.

VYVGART Hytrulo®
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VYVGART®
(efgartigimod alfa-fcab)

MGFA class at screening⁵:

- **40%** in the VYVGART arm had **mild** disease (MGFA class II) vs **37%** placebo
- **56%** in the VYVGART arm had **moderate** disease (MGFA class III) vs **59%** placebo
- **4%** in the VYVGART arm had **severe** disease (MGFA class IV) vs **4%** placebo

gMG treatments at study entry (in each arm)⁴:

- ~**60%** NSISTs
- >**70%** Steroids
- >**80%** AChE inhibitors

5 most prevalent comorbidities at baseline (overall population)^{7¶}:

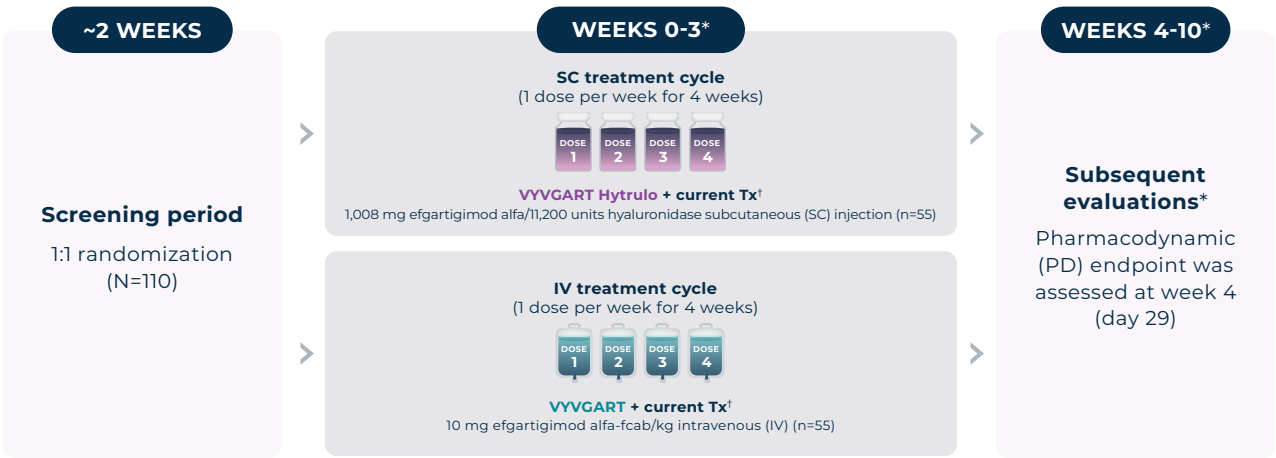
- **Hypertension: 28%**
- **Depression: 13%**
- **Diabetes Mellitus: 10%**
- **Osteoporosis: 9%**
- **Gastroesophageal Reflux Disease: 9%**

Patients who had active hepatitis B, were seropositive for hepatitis C, were seropositive for HIV with low CD4 count, had severe infections, or had evidence of any significant malignant disease were not eligible to participate in the ADAPT trial.⁵

A 10-week, phase 3, multicenter, randomized, open-label, parallel-group trial in 110 adult patients with gMG⁸

PD ENDPOINT

The pharmacological effect of **VYVGART Hytrulo** administered subcutaneously was compared to **VYVGART** administered intravenously in adult patients with gMG⁹



- Efficacy of **VYVGART Hytrulo** is based on this pharmacodynamic bridging study, which assessed the decrease in AChR-autoantibody levels⁹
- The majority of patients (n=91) were positive for AChR antibodies⁸
- In addition to pharmacodynamics, safety of **VYVGART Hytrulo** was also assessed⁹
- Eligible patients were able to enter the open-label extension ADAPT-SC+ trial⁸

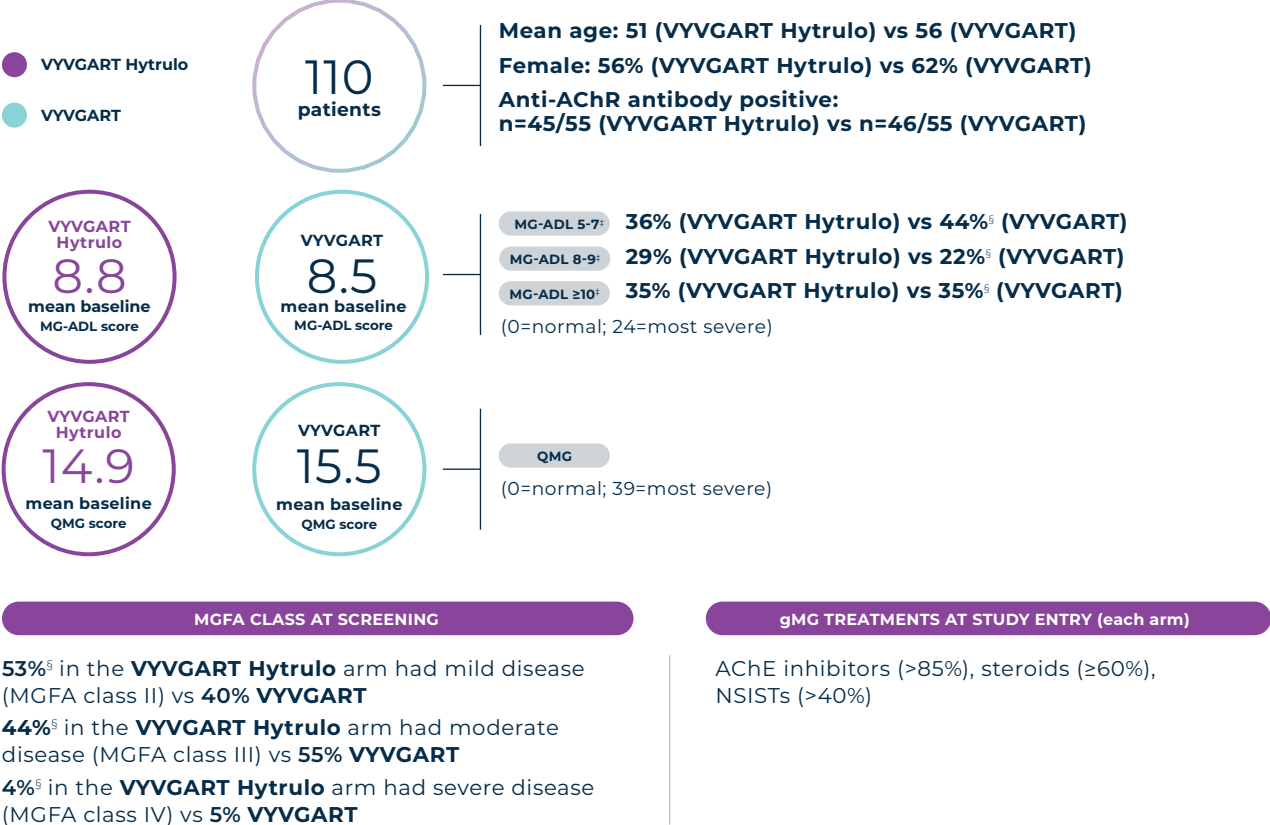
*Patients were evaluated weekly from weeks 1-8, and then at week 10.⁸

[†]All patients received stable doses of their current gMG treatment.⁸
AChR=acetylcholine receptor; gMG=generalized myasthenia gravis; Tx=treatment.

IMPORTANT SAFETY INFORMATION (cont'd)

Infections (cont'd)

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.



[‡]MG-ADL total score of ≥5 required at screening with >50% of the total score attributed to nonocular symptoms.⁸

[§]Sum of the percentages is over 100% due to rounding.⁸

AChE=acetylcholinesterase; MG-ADL=Myasthenia Gravis Activities of Daily Living; MGFA=Myasthenia Gravis Foundation of America; NSIST=nonsteroidal immunosuppressive therapy; QMG=Quantitative Myasthenia Gravis.

IMPORTANT SAFETY INFORMATION (cont'd)

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.

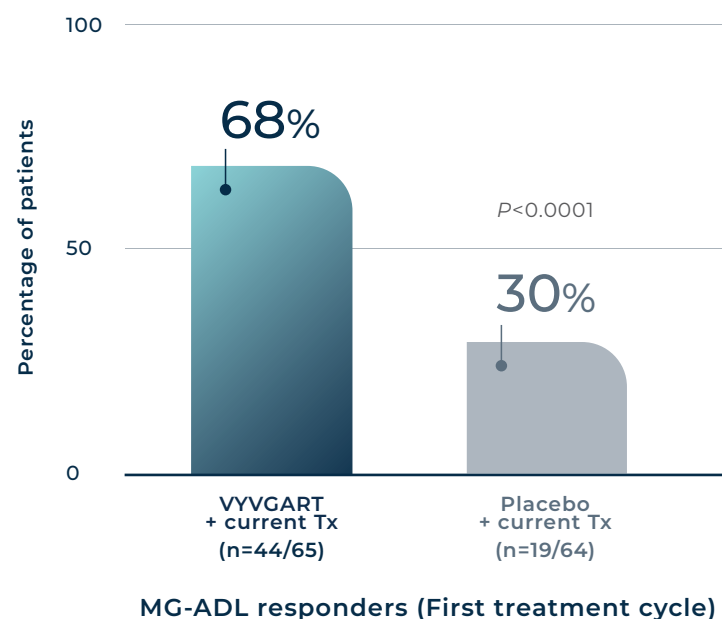
Please see additional Important Safety Information throughout and full Prescribing Information for VYVGART Hytrulo and full Prescribing Information for VYVGART.

VYVGART Hytrulo[®]
(efgartigimod alfa and hyaluronidase-qvfc)

VYVGART[®]
(efgartigimod alfa-fcab)

Significantly more patients had improvement in daily function that was sustained for ≥ 4 weeks^{4,5}

≥ 2 POINT REDUCTION in MG-ADL score from baseline for at least 4 consecutive weeks during the first treatment cycle⁴



The primary endpoint was the percentage of anti-AChR antibody positive patients who were **MG-ADL responders**, defined as a patient with a ≥ 2 -point reduction in the total MG-ADL score compared to the treatment cycle baseline for at least 4 consecutive weeks during the first treatment cycle (by week 8), with the first reduction occurring no later than 1 week after the last infusion of the cycle.⁴

AChR=acetylcholine receptor; MG-ADL=Myasthenia Gravis Activities of Daily Living; Tx=treatment.

IMPORTANT SAFETY INFORMATION (cont'd)

Immunization (cont'd)

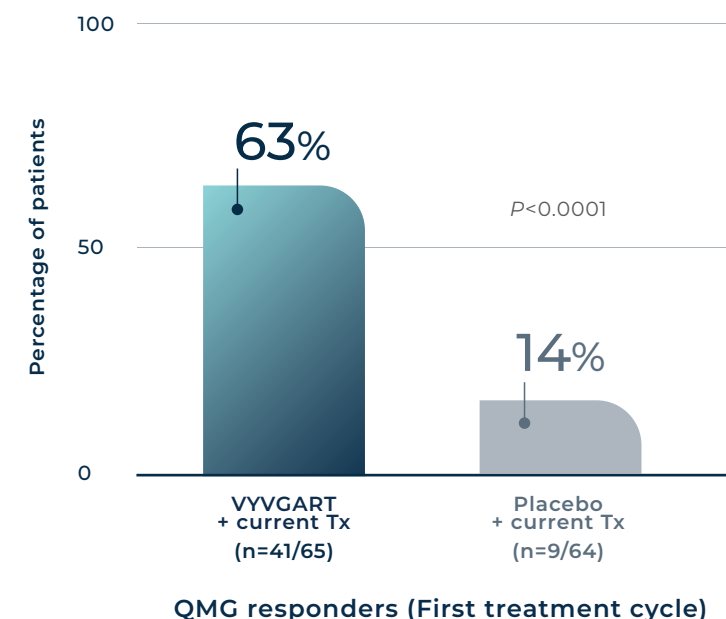
Because VYVGART and VYVGART HYTRULO cause a reduction in immunoglobulin G (IgG) levels, vaccination with live vaccines is not recommended during treatment with VYVGART or VYVGART HYTRULO.

Hypersensitivity Reactions

In clinical trials, hypersensitivity reactions, including rash, angioedema, and dyspnea were observed in patients treated with VYVGART or VYVGART HYTRULO.

Significantly more patients had reduction in muscle weakness sustained for ≥ 4 weeks^{4,5}

≥ 3 POINT REDUCTION in QMG score from baseline for at least 4 consecutive weeks during the first treatment cycle⁴



The secondary endpoint was the percentage of anti-AChR antibody positive patients who were **QMG responders**, defined as a patient with a ≥ 3 -point reduction in the total QMG score compared to the treatment cycle baseline for at least 4 consecutive weeks during the first treatment cycle (by week 8), with the first reduction occurring no later than 1 week after the last infusion of the cycle.⁴

QMG=Quantitative Myasthenia Gravis.

IMPORTANT SAFETY INFORMATION (cont'd)

Hypersensitivity Reactions (cont'd)

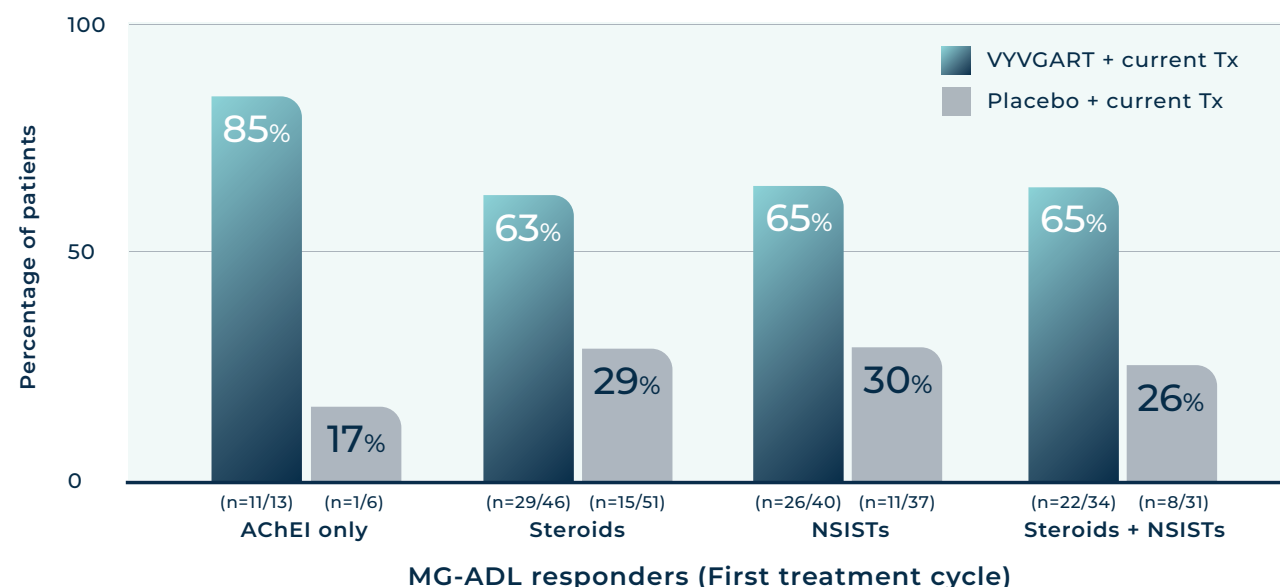
Urticaria was also observed in patients treated with VYVGART HYTRULO. Hypersensitivity reactions were mild or moderate, occurred within 1 hour to 3 weeks of administration. Anaphylaxis and hypotension leading to syncope have been reported in postmarketing experience with intravenous efgartigimod alfa-fcab.

Please see additional Important Safety Information throughout and full [Prescribing Information for VYVGART Hytrulo](#) and full [Prescribing Information for VYVGART](#).

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(efgartigimod alfa-fcab)

MG-ADL response data when adding VYVGART or placebo to current treatment^{11*†}



Limitations: a post-hoc analysis not controlled for multiplicity and not powered; therefore, data should be interpreted with caution and conclusions cannot be drawn. The analysis is based on limited sample size and follow-up per patient duration. Patients may have been taking different treatments for gMG simultaneously, therefore some patients may have been counted multiple times across subgroups.

*MG-ADL response was defined as a ≥ 2 -point reduction in the total MG-ADL score compared to the treatment cycle baseline for at least 4 consecutive weeks during the first treatment cycle (by week 8), with the first reduction occurring no later than 1 week after the last infusion of the cycle.¹¹

†Clinical trial data for anti-AChR antibody positive patients. Patients were treated with VYVGART + current treatment or placebo + current treatment. Patients were required to be on a stable dose of at least 1 treatment for gMG (ie, AChEIs, corticosteroids, or NSISTs) before screening and throughout the trial.^{4,11}

AChEI=acetylcholinesterase inhibitor; AChR=acetylcholine receptor; gMG=generalized myasthenia gravis; MG-ADL=Myasthenia Gravis Activities of Daily Living; NSIST=nonsteroidal immunosuppressive therapy; Tx=treatment.

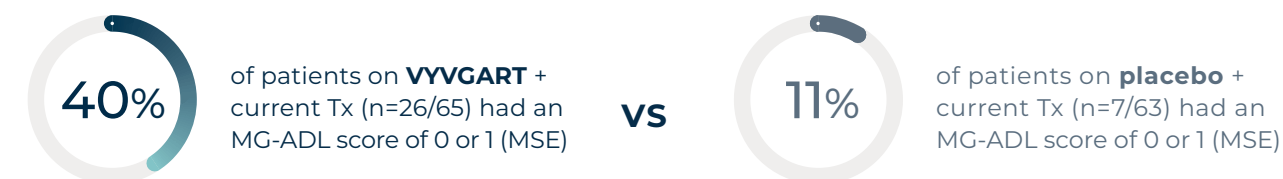
IMPORTANT SAFETY INFORMATION (cont'd)

Hypersensitivity Reactions (cont'd)

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.

MG-ADL data for Minimal Symptom Expression (MSE)^{5,12-14‡}

Observed during at least one visit in the first treatment cycle⁵:



Percentage of patients with observed MSE. MSE is characterized by an MG-ADL total score of 0 or 1 out of a maximum of 24. Patients were evaluated at any visit during the first treatment cycle.^{5,12,13§}

Limitations: a prespecified descriptive exploratory analysis not controlled for multiplicity and not powered; therefore, data should be interpreted with caution and conclusions cannot be drawn.

‡Clinical trial data for anti-AChR antibody positive patients. Patients were treated with VYVGART + current treatment or placebo + current treatment.⁵

§MSE evaluation occurred at any visit from week 1 through week 26.¹⁴

IMPORTANT SAFETY INFORMATION (cont'd)

Infusion-Related Reactions

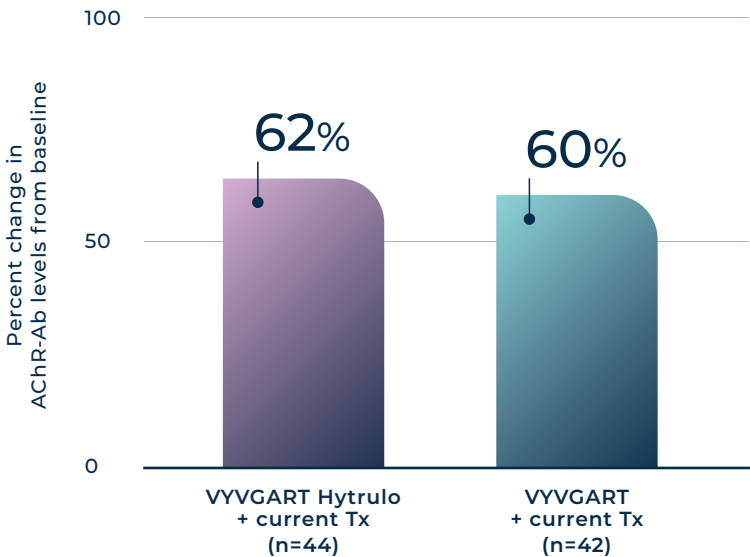
Infusion-related reactions have been reported with VYVGART in postmarketing experience. The most frequent symptoms and signs were hypertension, chills, shivering, and thoracic, abdominal, and back pain. Infusion-related reactions occurred during or within an hour of administration and led to infusion discontinuation.

Please see additional Important Safety Information throughout and full Prescribing Information for VYVGART Hytrulo and full Prescribing Information for VYVGART.

VYVGART Hytrulo®
(efgartigimod alfa and hyaluronidase-qvfc)

VYVGART®
(efgartigimod alfa-fcab)

Comparable pharmacodynamic effect for
VYVGART Hytrulo^{9,15*†}



PD effect of **VYVGART Hytrulo** and **VYVGART** in percent reduction from baseline in AChR-Ab levels at week 4 (day 29) in the anti-AChR antibody positive population.^{9‡}

The maximum mean reduction in AChR-Ab levels was observed at week 4.⁹

The decrease in total IgG levels followed a similar pattern.⁹

VYVGART Hytrulo[®]
(efgartigimod alfa and hyaluronidase-qvfc)

VYVGART[®]
(efgartigimod alfa-fcab)

*The 90% confidence interval for the geometric mean ratios of AChR-Ab reduction at day 29 and AUEC_{0-4w} (area under the effect-time curve from time 0 to 4 weeks post dose) were within the range of 80% to 125%, indicating no clinically significant difference between the two formulations.⁹

†Clinical trial data for anti-AChR antibody positive patients.⁹

‡Seven days after the fourth IV or SC administration.⁹

AChR=acetylcholine receptor; AChR-Ab=acetylcholine receptor antibody; IgG=immunoglobulin G; IV=intravenous; PD=pharmacodynamic; SC=subcutaneous; Tx=treatment.

IMPORTANT SAFETY INFORMATION (cont'd)

Infusion-Related Reactions (cont'd)

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.

Patient portrayals

IMPORTANT SAFETY INFORMATION (cont'd)

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.

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Demonstrated safety profile in the ADAPT clinical trial⁴

Adverse reactions in ≥5% of patients treated with VYVGART and more frequently than placebo in ADAPT

Adverse reaction	VYVGART (n=84)	Placebo (n=83)
Respiratory tract infection	33%	29%
Headache*	32%	29%
Urinary tract infection	10%	5%
Paraesthesia†	7%	5%
Myalgia	6%	1%

*Headache includes migraine and procedural headache.
†Paraesthesia includes oral hypoesthesia, hypoesthesia, and hyperesthesia.

A higher frequency of patients who received VYVGART compared to placebo were observed to have below normal levels of white blood cell counts (12% vs 5%), lymphocyte counts (28% vs 19%), and neutrophil counts (13% vs 6%).⁴

The majority of infections and hematologic abnormalities were mild to moderate in severity.

In clinical trials, hypersensitivity reactions, including rash, angioedema, and dyspnea were observed in VYVGART-treated patients. Hypersensitivity reactions were mild or moderate, occurred within one hour to three weeks of administration, and did not lead to treatment discontinuation.⁴

IMPORTANT SAFETY INFORMATION (cont'd)
Infusion/Injection-Related Reactions (cont'd)

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.

Postmarketing experience with VYVGART included reports of anaphylaxis and hypotension leading to syncope, as well as infusion-related reactions including hypertension, chills, shivering, and thoracic, abdominal, and back pain. These reactions occurred during or within an hour of administration and led to infusion discontinuation and in some cases to permanent treatment discontinuation.⁴

Pregnancy registry: There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to VYVGART during pregnancy. Healthcare providers and patients may call 1-855-272-6524 or go to <https://www.vyvgartpregnancy.com> to enroll in or to obtain information about the registry.⁴

IMPORTANT SAFETY INFORMATION (cont'd)
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.

Please see additional Important Safety Information throughout and full Prescribing Information for VYVGART Hytrulo and full Prescribing Information for VYVGART.



A consistent safety profile in the ADAPT-SC clinical trial^{4,9}

The overall safety profile of VYVGART Hytrulo, except for a higher rate of injection site reactions, was consistent with the proven safety profile of VYVGART^{4,9}

In the ADAPT clinical trial, the most common adverse reactions for **VYVGART**-treated patients were respiratory tract infection, headache, and urinary tract infection.⁹

In ADAPT-SC, injection site reactions occurred in 38% of patients receiving **VYVGART Hytrulo**. These were injection site rash, erythema, pruritus, bruising, pain, and urticaria.⁹

In ADAPT-SC and its open-label extension (n=168)⁹:

- 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 of injection site reactions decreased with each subsequent cycle
 - From 34.6% (n=62/179) in cycle 1 to 10.3% (n=7/68) in cycle 9^{16*}

^{*}Interim data cut-off date of December 2022. The ADAPT-SC+ Open-label Extension study is still ongoing.

IMPORTANT SAFETY INFORMATION (cont'd)

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.

In clinical trials, hypersensitivity reactions, including rash, angioedema, and dyspnea were observed in patients treated with **VYVGART Hytrulo** or **VYVGART**. Urticaria was also observed in patients treated with **VYVGART Hytrulo**. Hypersensitivity reactions were mild or moderate and occurred within one hour to three weeks of administration.^{4,9}

VYVGART Hytrulo can cause anaphylaxis and hypotension leading to syncope, as well as infusion/injection-related reactions including hypertension, chills, shivering, and thoracic, abdominal, and back pain. These reactions occurred during or within an hour of administration with **VYVGART** and led to infusion discontinuation and in some cases to permanent treatment discontinuation. If a hypersensitivity reaction occurs with **VYVGART Hytrulo**, the healthcare professional should institute appropriate measures if needed or the patient should seek medical attention. If a severe infusion/injection-related reaction occurs with **VYVGART Hytrulo**, initiate appropriate therapy.^{4,9}

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to **VYVGART Hytrulo** or **VYVGART** during pregnancy. Healthcare providers and patients may call 1-855-272-6524 or go to <https://www.vyvgartpregnancy.com> to enroll in or obtain information about the registry.^{4,9}

IMPORTANT SAFETY INFORMATION (cont'd)

Lactation (cont'd)

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).

Please see additional Important Safety Information throughout and full Prescribing Information for VYVGART Hytrulo and full Prescribing Information for VYVGART.

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VYVGART[®]
(efgartigimod alfa-fcab)

VYVGART Hytrulo and VYVGART:
3 administration options to use at home, in office,
or at an infusion center^{4,9}

1 TREATMENT CYCLE = 1 DOSE PER WEEK FOR 4 WEEKS

Recommended dose and dose schedule from Prescribing Information:




Not actual size.

VYVGART Hytrulo
Single-dose prefilled syringe

Administered by a patient or caregiver*

~20-30-SECOND SC SELF-INJECTION†
(1,000 mg efgartigimod alfa/10,000 units hyaluronidase, fixed dose)

The recommended dose of **VYVGART Hytrulo** prefilled syringe is 1,000 mg/10,000 units (1,000 mg efgartigimod alfa/10,000 units hyaluronidase), given in treatment cycles of once-weekly SC injections for 4 weeks.



Not actual size.

VYVGART Hytrulo
Single-dose vial

HCP administered

~30-90-SECOND SC INJECTION†
(1,008 mg efgartigimod alfa/11,200 units hyaluronidase, fixed dose)

The recommended dose of **VYVGART Hytrulo** vial is 1,008 mg/11,200 units (1,008 mg efgartigimod alfa/11,200 units hyaluronidase), given in treatment cycles of once-weekly SC injections for 4 weeks.



Not actual size.

VYVGART
Single-dose vial

HCP administered

1-HOUR IV INFUSION‡
(10 mg efgartigimod alfa-fcab/kg, weight based)§

The recommended dose of **VYVGART** (efgartigimod alfa-fcab) is 10 mg/kg, given in treatment cycles of once-weekly, 1-hour IV infusions for 4 weeks.

For each option, administer **subsequent treatment cycles** based on clinical evaluation^{4,9}

The safety of initiating subsequent cycles sooner than 4 weeks from the last injection or infusion of the previous treatment cycle has not been established^{4,9}

*After proper instruction on SC injection technique, a patient or caregiver may inject VYVGART Hytrulo prefilled syringe. See Prescribing Information.⁹
†Refers to actual subcutaneous injection time. 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.⁹
HCP=healthcare professional; SC=subcutaneous.

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.

‡Refers to actual intravenous infusion time. Monitor patients during and for 1 hour thereafter for clinical signs and symptoms of hypersensitivity reactions. If a hypersensitivity reaction occurs during administration, discontinue administration of VYVGART and institute appropriate supportive measures.⁴
§In patients weighing 265 lb (120 kg) or more, the recommended dose of VYVGART is 1,200 mg (3 vials) per infusion.⁴
IV=intravenous.

IMPORTANT SAFETY INFORMATION (cont'd)
CONTRAINDICATIONS (cont'd)

VYVGART HYTRULO is also contraindicated in patients with serious hypersensitivity to hyaluronidase. Reactions have included anaphylaxis and hypotension leading to syncope.

Please see additional Important Safety Information throughout and full Prescribing Information for VYVGART Hytrulo and full Prescribing Information for VYVGART.





Patient portrayal

Now available for your adult patients with anti-AChR antibody positive gMG
Open up their world to **VYVGART Hytrulo**
prefilled syringe for self-injection⁹

A new way to administer **VYVGART Hytrulo** that can fit into their lives, including at home⁹



Fast, ~20–30–second self-injection

Refers to actual subcutaneous injection time of **VYVGART Hytrulo**. Monitor for clinical signs and symptoms of hypersensitivity reactions for at least 30 minutes after administration. If a hypersensitivity reaction occurs, the patient should seek medical attention.⁹



100% of patients with gMG and caregivers successfully used the prefilled syringe and interacted with the associated labeling, packaging, and instructional materials across 2 human factors studies (15 patients and 15 caregivers of gMG patients). All participants were able to follow the Instructions for Use and prepare and administer the dose into the simulated injection pad unaided.^{17*}

Patients and/or caregivers will receive in-person injection training until ready to inject[†]

*Human factors studies evaluated participants' ability to follow injection instructions and successfully prepare the product in a simulated-use environment. During the unaided injection, 2 use errors and one close call occurred. The use errors were participants not putting the product back into the original packaging before putting into the refrigerator, and the close call was a participant removing the needle cap at the incorrect time. Performance of critical tasks did not result in any patterns of use errors, close calls, or difficulties that would lead to patient harm (including compromised medical care). Findings were based on performance, observed behaviors, subjective feedback, and human factors analyses, and therefore were not traditionally statistically analyzed.¹⁷

[†]After proper instruction on subcutaneous injection technique, a patient or caregiver may inject **VYVGART Hytrulo** prefilled syringe. See Prescribing Information.⁹

AChR=acetylcholine receptor; gMG=generalized myasthenia gravis.

IMPORTANT SAFETY INFORMATION (cont'd)

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).

An example approach to dosing with **VYVGART Hytrulo** and **VYVGART**

Based on the most commonly observed schedule from a post-hoc analysis of **ADAPT-SC+** and **ADAPT+**^{18‡§}

CYCLES 1-3

CYCLES 4+



For **cycles 1-3**, this example approach shows **4 weeks on** and **4 weeks off** therapy for **3 cycles**.

For subsequent cycles, **continue** evaluating the appropriate time off therapy based on clinical evaluation.

Limitations: The distribution of average cycle duration in **ADAPT-SC+ and **ADAPT+** were post-hoc descriptive analyses not controlled for multiplicity and not powered; therefore, data should be interpreted with caution and conclusions cannot be drawn.**

[‡]**ADAPT-SC+** and **ADAPT+** were single-arm, open-label studies evaluating the long-term safety and tolerability of **VYVGART Hytrulo** and **VYVGART**.^{19,20}

[§]Analysis included all complete cycles, defined as cycles not interrupted by the cut-off/final study date of December 1, 2022 or a single incomplete cycle of at least 28 days.¹⁸

[¶]Four weeks off starts after the last injection or infusion of the most recent cycle.¹⁸

¹A cycle consists of 4 once-weekly doses over 22 days.¹⁸

IMPORTANT SAFETY INFORMATION (cont'd)

Infections (cont'd)

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.

Please see additional Important Safety Information throughout and full Prescribing Information for **VYVGART Hytrulo and full Prescribing Information for **VYVGART**.**

VYVGART Hytrulo
(efgartigimod alfa and hyaluronidase-qvfc)

VYVGART
(efgartigimod alfa-fcab)

Considerations for starting treatment



MG-ADL assessments

Share the MG-ADL scale and work with patients to get their baseline score



Patient counseling information

Discuss the risk of infections, hypersensitivity reactions, and infusion/injection-related reactions associated with their treatment*



Sites of care

Review options for administration to understand patient needs and preferences



Access to multiple treatment cycles

Initial authorization may allow for multiple treatment cycles for the majority of patients



No treatment-specific vaccinations required to begin treatment^{4,9}

HCPs should evaluate the need to administer age-appropriate vaccines according to immunization guidelines before initiation of a new treatment cycle with **VYVGART Hytrulo** or **VYVGART**[†]



No REMS required

VYVGART Hytrulo and **VYVGART** do not require any specific training or certification prior to starting treatment at this time



No routine lab monitoring required

No routine lab monitoring requirements for patients during treatment with **VYVGART Hytrulo** or **VYVGART**. Continue to evaluate response and monitor patients for possible side effects[‡]



No Boxed Warning

Please see the full Prescribing Information for **VYVGART Hytrulo** and **VYVGART** before starting patients on treatment

[†]In accordance with the recommendations found in Section 2.1 of the Prescribing Information.
[‡]Patients in the ADAPT-SC and ADAPT clinical trials were required to have IgG levels of at least 6 g/L at study entry. Please also see the Warnings and Precautions found in Section 5 of the Prescribing Information.^{4,9}
HCP=healthcare professional; IgG=immunoglobulin G; REMS=Risk Evaluation and Mitigation Strategy.

IMPORTANT SAFETY INFORMATION (cont'd) 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.

Please see additional Important Safety Information throughout and full Prescribing Information for VYVGART Hytrulo and full Prescribing Information for VYVGART.

VYVGART Hytrulo[®]
(efgartigimod alfa and hyaluronidase-qvfc)

VYVGART[®]
(efgartigimod alfa-fcab)

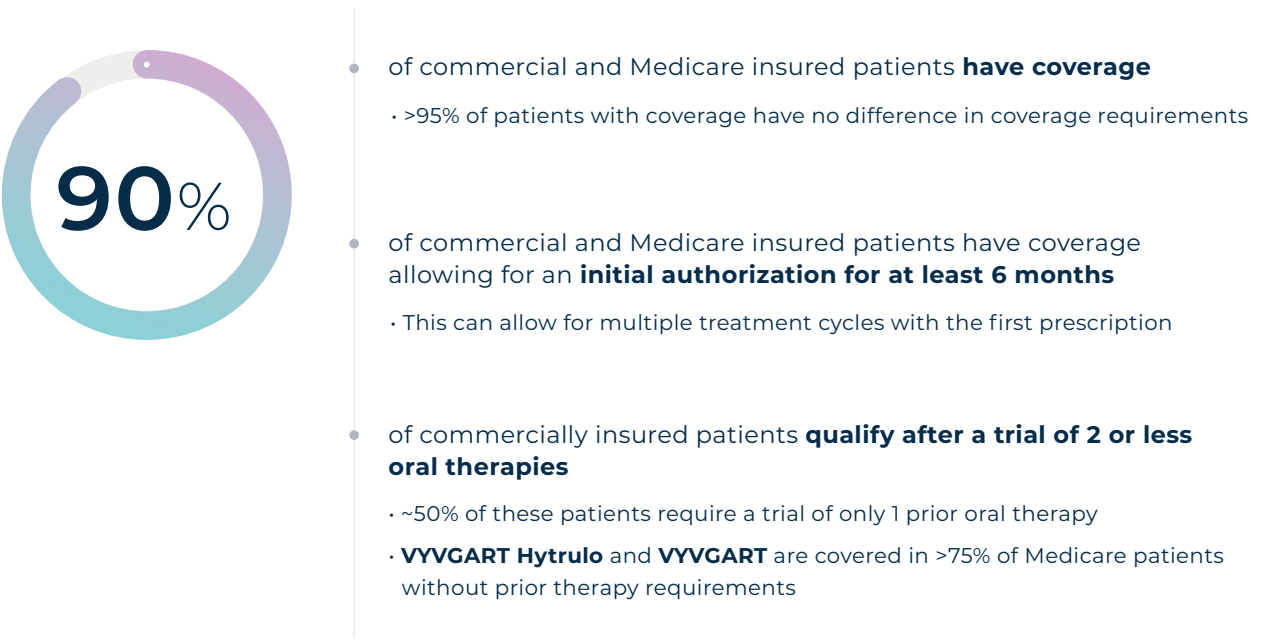
*Please also see the patient counseling information in Section 17 of the Prescribing Information.
MG-ADL=Myasthenia Gravis Activities of Daily Living.

IMPORTANT SAFETY INFORMATION (cont'd)

Infections (cont'd)

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.

For VYVGART Hytrulo vial and VYVGART*



argenx has a network of national distributors, specialty pharmacies, and infusion partners, making it easier for appropriate patients to access **VYVGART Hytrulo**, including the prefilled syringe, or **VYVGART**

*Based on published policies for VYVGART Hytrulo vial and VYVGART from Policy Reporter as of August 2024.

IMPORTANT SAFETY INFORMATION (cont'd)

Immunization (cont'd)
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.

Order VYVGART Hytrulo prefilled syringe through a network of specialty pharmacies. My VYVGART® Path can help.

Billing and coding insights

When submitting reimbursement for

VYVGART Hytrulo®
(efgartigimod alfa and hyaluronidase-qvfc)

use **HCPCS J-Code J9334**
(injection, efgartigimod alfa, 2 mg and hyaluronidase-qvfc)

VYVGART®
(efgartigimod alfa-fcab)

use **HCPCS J-Code J9332**
(injection, efgartigimod alfa-fcab, 2 mg)

Go to

VYVGARTHCP.com/gmg/resources to download the **Billing and Coding Guide** or **Acquisition Guide** for **VYVGART Hytrulo** or **VYVGART**

The VYVGART Hytrulo prefilled syringe was recently approved by the FDA.

While payer policies are still being developed, please enroll your patient in My VYVGART Path, argenx's patient support program, to initiate a benefits verification and determine your patient's specific coverage. If needed, your argenx Field Reimbursement Manager can provide education on the formulary exception process.

HCPCS=Healthcare Common Procedure Coding System.

IMPORTANT SAFETY INFORMATION (cont'd)

Hypersensitivity Reactions (cont'd)
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.

Please see additional Important Safety Information throughout and full Prescribing Information for VYVGART Hytrulo and full Prescribing Information for VYVGART.

VYVGART Hytrulo®
(efgartigimod alfa and hyaluronidase-qvfc)

VYVGART®
(efgartigimod alfa-fcab)



Eligible commercially insured patients may pay as little as \$0 for their co-pay through the VYVGART Co-pay Program*

Field Reimbursement Managers are available to educate your practice about acquiring **VYVGART Hytrulo** or **VYVGART**, including insurance approvals, reimbursements, and co-pay assistance.



Personalized support during the treatment journey

Access Managers and Nurse Case Managers at My VYVGART® Path offer help with patient-specific benefit verifications, screening for potential financial assistance programs for eligible patients, and help with the denial and appeal process.

*Eligible commercially insured patients may pay as little as \$0 for VYVGART Hytrulo or VYVGART and may receive a maximum benefit of \$25,000 per calendar year for their eligible out-of-pocket costs for the drug and drug administration. Persons residing in MA and RI are not eligible for financial assistance related to administration costs. Please see full Terms and Conditions.

IMPORTANT SAFETY INFORMATION (cont'd)

Hypersensitivity Reactions (cont'd)

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.



Enroll online at
[MyPathEnroll.com](https://www.mypathenroll.com)



Download and complete the enrollment form, then fax it to 1-833-698-7284

IMPORTANT SAFETY INFORMATION (cont'd)

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.

Please see additional Important Safety Information throughout and full Prescribing Information for VYVGART Hytrulo and full Prescribing Information for VYVGART.

VYVGART Hytrulo®
(efgartigimod alfa and hyaluronidase-qvfc)

VYVGART®
(efgartigimod alfa-fcab)

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).

Dosage Forms and Strengths: VYVGART Hytrulo is available as a single-dose subcutaneous injection containing: 200 mg/mL of efgartigimod alfa and 2,000 U/mL of hyaluronidase per prefilled syringe, or 180 mg/mL of efgartigimod alfa and 2,000 U/mL of hyaluronidase per vial.

VYVGART is available as a single-dose injection for intravenous use containing 400 mg/20 mL of efgartigimod alfa-fcab per vial.



VYVGART Hytrulo®
(efgartigimod alfa and hyaluronidase-qvfc)

VYVGART®
(efgartigimod alfa-fcab)



**SIGNIFICANT RESPONSE
DURING THE FIRST
TREATMENT CYCLE^{4,5,9*}**



**DEMONSTRATED
SAFETY^{4,9}**



**3 OPTIONS FOR ADMINISTRATION^{4,9}
INCLUDING VYVGART HYTRULO
PREFILLED SYRINGE FOR SELF-INJECTION**

*By week 8.⁴

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.

Please see additional Important Safety Information throughout and full Prescribing Information for VYVGART Hytrulo and full Prescribing Information for VYVGART.

References: **1.** Law N et al. *Neurol Ther*. 2021;10:1103-1125. doi:10.1007/s40120-021-00285-w **2.** Dewilde S et al. *Adv Ther*. 2023;41:271-291. doi:10.1007/s12325-023-02704-w **3.** Muley S et al. Poster presented at: Carrell-Krusen Neuromuscular Symposium; February 18-19, 2021. Virtual. **4.** VYVGART. Prescribing information. argenx US Inc; 2024. **5.** Howard JF Jr et al. *Lancet Neurol*. 2021;20(7):526-536. doi:10.1016/S1474-4422(21)00159-9 **6.** Data on file. REF-00690. argenx US Inc. November 2021. **7.** Data on file. REF-00692. argenx US Inc. November 2021. **8.** Howard JF Jr et al. *Neurotherapeutics*. 2024;21(5):1-12. doi:10.1016/j.neurot.2024.e00378 **9.** VYVGART Hytrulo. Prescribing information. argenx US Inc; 2025. **10.** Data on file. REF-01893. argenx US Inc. June 2023. **11.** Karam C et al. Presented at: Myasthenia Gravis Foundation of America (MGFA) National Conference; April 11-13, 2021. Canada. Virtual. **12.** Uzawa A et al. *Acta Neurol Belg*. 2023;123(3):979-982. doi:10.1007/s13760-022-02162-1 **13.** Wolfe GI et al. *Neurology*. 1999;52(7):1487-1489. doi:10.1212/wnl.52.7.1487 **14.** Data on file. REF-00724. argenx US Inc. December 2021. **15.** Data on file. REF-01900. argenx US Inc. June 2023. **16.** Howard JF Jr et al. Poster presented at: American Academy of Neurology (AAN) Annual Meeting; April 13-18, 2024. Denver, CO. **17.** Data on file. REF-03778. argenx US Inc. January 2025. **18.** Data on file. REF-02349. argenx US Inc. November 2023. **19.** ClinicalTrials.gov. NCT03770403. Accessed March 3, 2025. <https://clinicaltrials.gov/ct2/show/NCT03770403> **20.** ClinicalTrials.gov. NCT04818671. Accessed March 3, 2025. <https://clinicaltrials.gov/ct2/show/NCT04818671>



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