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

Frequently Asked Questions

about treatment with VYVGART Hytrulo for adults with CIDP

Patient portrayal. Individual results may vary.

CIDP=chronic inflammatory demyelinating polyneuropathy.

INDICATION AND IMPORTANT SAFETY INFORMATION
INDICATION
VYVGART® HYTRULO (efgartigimod alfa and hyaluronidase-qvfc) is indicated for the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive.

VYVGART® HYTRULO (efgartigimod alfa and hyaluronidase-qvfc) is indicated for the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP).

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.

Please see additional Important Safety Information throughout and full Prescribing Information.

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CIDP=chronic inflammatory demyelinating polyneuropathy; FcRn=neonatal Fc receptor; IG=immunoglobulin; IVIG=intravenous immunoglobulin; PA=prior authorization.

Please see additional Important Safety Information throughout and full Prescribing Information.

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Mechanism of action

How does VYVGART Hytrulo work in CIDP?

VYVGART Hytrulo contains efgartigimod alfa, the first and only targeted IgG Fc-antibody fragment in CIDP. This is the first novel mechanism for CIDP treatment in 30+ years.[1-4]

Efgartigimod alfa targets FcRn, which plays a key role in recycling IgG antibodies. By binding to and blocking FcRn, VYVGART Hytrulo results in the reduction of circulating IgG.[1,2,5-7]

VYVGART Hytrulo is a coformulation of efgartigimod alfa and hyaluronidase. Hyaluronidase increases permeability of the subcutaneous tissue by depolymerizing hyaluronan. This effect is transient, and permeability of the subcutaneous tissue is restored within 24 to 48 hours.[1]

What role does FcRn play in CIDP?

FcRn binds IgG antibodies, including autoantibodies, preventing them from being destroyed in the lysosome. In doing so, FcRn helps maintain high levels of circulating IgG.[7]

What is the proposed pathophysiology of CIDP?

While the exact pathophysiology of CIDP is complex and not completely understood, IgG autoantibodies are thought to contribute to demyelination in CIDP in 2 ways.[5,8]

1. **Macrophage recruitment:** Macrophages may recognize and bind to the Fc portion of IgG bound to the myelin sheath and phagocytize myelin.[5,8,9]
2. **Complement activation:** Complement proteins may recognize and bind to IgG anchored on the myelin sheath, activating the complement pathway and ultimately recruiting more macrophages.[5,8,9]

CIDP=chronic inflammatory demyelinating polyneuropathy; Fc=fragment, crystallized; FcRn=neonatal Fc receptor; IG=immunoglobulin; IgG=immunoglobulin G.

Mechanism of action FAQs

How does VYVGART Hytrulo work in CIDP?

What role does FcRn play in CIDP?

What is the proposed pathophysiology of CIDP?

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IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Infection

VYVGART HYTRULO may increase the risk of infection. The most common infections observed in Study 1 in patients with gMG 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.

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Mechanism of action (cont'd)

Is VYVGART Hytrulo a plasma-derived IG product?

No. VYVGART Hytrulo is a novel treatment mechanism and not a plasma-derived IG product. It is a combination of efgartigimod alfa and hyaluronidase. It is the first and only targeted IgG Fc-antibody fragment, which is non–plasma-derived and is administered via a fast ~30-90–second injection.[1,7]

VYVGART Hytrulo does not require a pump; it is injected subcutaneously on the abdomen with a winged infusion set by a healthcare professional. VYVGART Hytrulo can be administered in an office, infusion center, or at home by a healthcare professional. Patients should be monitored for clinical signs and symptoms of hypersensitivity reactions for at least 30 minutes after administration.[1] Please see the Prescribing Information for full administration guidance.

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CIDP=chronic inflammatory demyelinating polyneuropathy; Fc=fragment, crystallized; FcRn=neonatal Fc receptor; IG=immunoglobulin; IgG=immunoglobulin G.

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

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ADHERE clinical trial

DESIGN

What was the design of the ADHERE clinical trial?

ADHERE, the largest trial to date in adult patients with CIDP, was an event-driven, randomized withdrawal trial conducted in 2 stages. The initial open-label treatment period (up to 12 weeks; also referred to as stage A; N=322) identified responders who then proceeded to a double-blind, placebo-controlled, randomized withdrawal period (up to 48 weeks; also referred to as stage B; VYVGART Hytrulo n=111, placebo n=110) to assess time to first clinical deterioration (relapse).[1,10]

As ADHERE was an event-driven trial, patients who had clinical deterioration (relapse) ended their participation in the randomized withdrawal period (stage B). The study ended after 88 events of relapse.[1]

Why did ADHERE include an open-label initial treatment period (stage A) to identify responders?

The efficacy of VYVGART Hytrulo for the treatment of adults with CIDP was established in a 2-stage, prospective, multicenter study. It included an open-label period to identify VYVGART Hytrulo responders (stage A), who then entered a randomized, double-blind, placebo-controlled withdrawal period (stage B).[1]

The trial was consistent with FDA guidance on enrichment strategies for clinical trials to increase the efficiency of drug development. An example of an enrichment strategy is having an open-label, single-arm trial followed by randomization, in which only the responding patients are randomized into a placebo-controlled trial. The ADHERE clinical trial also incorporated elements from previous CIDP trials.[11-13]

CIDP=chronic inflammatory demyelinating polyneuropathy.

IMPORTANT SAFETY INFORMATION (cont'd)

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 in gMG. 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.

Please see additional Important Safety Information throughout and full Prescribing Information.

ADHERE clinical trial FAQs

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ADHERE clinical trial (cont'd)

When were patients eligible to enter the randomized withdrawal period (double blind, stage B)?

The ADHERE clinical trial included an initial treatment period (open label, stage A) to identify responders to VYVGART Hytrulo to move into the randomized withdrawal period (double blind, stage B).[1]

The initial treatment period lasted up to 12 weeks; 69% (n=221/322) of patients had improvement in functional ability or strength with VYVGART Hytrulo and were eligible to enter the randomized withdrawal period.[1]

Why was ADHERE an event-driven clinical trial?

ADHERE was designed as an event-driven trial to allow for an efficient gathering of enough data to evaluate treatment, while limiting the time participants spent on placebo. The randomized withdrawal period was designed to last up to 48 weeks, or until 88 events of clinical deterioration (relapse) occurred. If patients had clinical deterioration (relapse), then their participation in the randomized withdrawal period ended. The study stopped when 88 events of relapse occurred for the primary endpoint analysis. The primary endpoint was measured once 88 total deterioration (relapse) events occurred and was based on a 0.5 hazard ratio (50% reduction in the risk of relapse) for the time to first aINCAT deterioration.[1,11,14]

ENROLLMENT

Which patients were enrolled in the ADHERE clinical trial?

Participants enrolled in the study (N=322) were adults aged 18 years or older who had a documented diagnosis of definite or probable CIDP using the 2010 European Federation of Neurological Societies/Peripheral Nerve Society criteria for progressing or relapsing forms.[1]

ADHERE clinical trial FAQs

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aINCAT=adjusted Inflammatory Neuropathy Cause and Treatment; CIDP=chronic inflammatory demyelinating polyneuropathy.

IMPORTANT SAFETY INFORMATION (cont'd)

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.

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ADHERE clinical trial (cont'd)

Had patients received prior therapy for CIDP at study entry?

Upon study entry, participants included those who[1]:

- Were currently receiving standard-of-care therapy
- Had not received standard-of-care therapy for ≥6 months
- Had not received prior treatment for CIDP

EFFICACY

What was the primary endpoint of the ADHERE clinical trial?

The primary endpoint for the randomized withdrawal period (double blind, stage B) was defined as time to first clinical deterioration (relapse), defined as a 1-point increase in aINCAT score at 2 consecutive visits or a >1-point increase in aINCAT score at 1 visit.[1]

The adjusted INCAT (aINCAT) disability score, which is identical to the INCAT disability score but excludes changes in the upper limb function from 0 (normal function) to 1 (minor symptoms), was used to assess the efficacy of VYVGART Hytrulo for the treatment of CIDP.[1]

How was clinical deterioration defined in the randomized withdrawal period (placebo controlled, stage B)?

Clinical deterioration (relapse) was defined as a 1-point increase in aINCAT score at 2 consecutive visits or a >1-point increase in aINCAT score at 1 visit compared to randomized withdrawal period (stage B) baseline.[1]

The INCAT disability scale assesses function in the arms and legs. Total disability scores range from 0 to 10, with 0 indicating no signs of disability and 10 indicating maximum disability.[1]

The adjusted INCAT (aINCAT) disability score, which is identical to the INCAT disability score but excludes changes in the upper limb function from 0 (normal function) to 1 (minor symptoms), was used to assess the efficacy of VYVGART Hytrulo for the treatment of CIDP.[1]

aINCAT=adjusted Inflammatory Neuropathy Cause and Treatment; CIDP=chronic inflammatory demyelinating polyneuropathy.

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS

Patients with gMG: 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 in patients with gMG, 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.

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ADHERE clinical trial FAQs

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ADHERE clinical trial (cont'd)

How was improvement assessed in the initial treatment period (open label, stage A) of the ADHERE clinical trial?

The initial treatment period (open label, stage A) was intended to identify responders. Evidence of improvement was defined as meeting 1 of the following at 2 consecutive visits[1]:

- A ≥1-point improvement on the aINCAT scale
- A ≥4-point improvement on the I-RODS scale
- An improvement of ≥8 kPa in grip strength

The INCAT disability scale assesses function in the arms and legs. Total disability scores range from 0 to 10, with 0 indicating no signs of disability and 10 indicating maximum disability.[1]

The adjusted INCAT (aINCAT) disability score, which is identical to the INCAT disability score but excludes changes in the upper limb function from 0 (normal function) to 1 (minor symptoms), was used to assess the efficacy of VYVGART Hytrulo for the treatment of CIDP.[1]

I-RODS focuses on the patient's ability to perform daily and social activities. Patients rate their ability to perform 24 activities on a scale from 0 to 2 based on difficulty, with 0 being impossible to perform and 2 being easily performed.[15]

Grip strength is measured to assess the maximum voluntary contractions in each hand.[16]

OPEN-LABEL EXTENSION PHASE

Which patients were eligible to enter the open-label extension phase?

The patients eligible to enter the open-label extension phase included those who[17]:

- Experienced clinical deterioration in the randomized withdrawal period (stage B)
- Completed the randomized withdrawal period without deterioration
- Were ongoing in the study at trial completion (either in the initial treatment period [stage A] or randomized withdrawal period [stage B])
- Were in the run-in period after finishing the early discontinuation visit

aINCAT=adjusted Inflammatory Neuropathy Cause and Treatment; CIDP=chronic inflammatory demyelinating polyneuropathy; I-RODS=Inflammatory Rasch-built Overall Disability Scale; kPa=kilopascals.

ADHERE clinical trial FAQs

What was the design of the ADHERE clinical trial?

Why did ADHERE include an open-label initial treatment period (stage A) to identify responders?

When were patients eligible to enter the randomized withdrawal period (double blind, stage B)?

Why was ADHERE an event-driven clinical trial?

Which patients were enrolled in the ADHERE clinical trial?

Had patients received prior therapy for CIDP at study entry?

What was the primary endpoint of the ADHERE clinical trial?

How was clinical deterioration defined in the randomized withdrawal period (placebo controlled, stage B)?

How was improvement assessed in the initial treatment period (open label, stage A) of the ADHERE clinical trial?

Which patients were eligible to enter the open-label extension phase?

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IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS (cont'd)

Patients with CIDP: In Study 3 stage B, the overall safety profile observed in patients with CIDP treated with VYVGART HYTRULO was consistent with the known safety profile of VYVGART HYTRULO and of efgartigimod alfa-fcab administered intravenously. In Study 3, injection site reactions occurred in 15% of patients treated with VYVGART HYTRULO compared to 6% of patients who received placebo. The most common of these injection site reactions were injection site bruising and injection site erythema. All injection site reactions were mild to moderate in severity. Most injection site reactions occurred during the first 3 months of treatment.

Please see additional Important Safety Information throughout and full Prescribing Information.

Safety

What are the most common adverse reactions for VYVGART Hytrulo?

The overall safety profile observed in patients with CIDP treated with VYVGART Hytrulo was consistent with the known safety profile of VYVGART Hytrulo and IV efgartigimod alfa-fcab.[1]

In Study 1, adverse reactions reported in ≥5% of patients treated with efgartigimod alfa-fcab IV (n=84) and more frequently than in patients who received placebo (n=83) were respiratory tract infection (33% vs 29%), headache (32% vs 29%; includes migraine and procedural headache), urinary tract infection (10% vs 5%), paraesthesia (7% vs 5%; includes oral hypoesthesia, hypoesthesia, and hyperesthesia), and myalgia (6% vs 1%).[1]

In Study 2, injection site reactions occurred in 38% of patients with gMG receiving VYVGART Hytrulo. These were injection site rash, erythema, pruritus, bruising, pain, and urticaria. In Study 2 and its open-label extension (n=168), 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.[1]

In the ADHERE study (Study 3), injection site reactions occurred in 15% of patients treated with VYVGART Hytrulo vs 6% with placebo. The most common of these injection site reactions were injection site bruising and injection site erythema. All injection site reactions were mild to moderate in severity. Most injection site reactions occurred during the first 3 months of treatment.[1]

Safety FAQ

What are the most common adverse reactions for VYVGART Hytrulo?

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CIDP=chronic inflammatory demyelinating polyneuropathy; gMG=generalized myasthenia gravis; IV=intravenous.

IMPORTANT SAFETY INFORMATION (cont'd)

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. Risk and benefits should be considered prior to administering live vaccines to infants exposed to VYVGART HYTRULO in utero.

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Dosing and administration

What is the dosing schedule for CIDP with VYVGART Hytrulo, and how was it evaluated?

The recommended dosage of VYVGART Hytrulo is 1,008 mg/11,200 units (1,008 mg efgartigimod alfa and 11,200 units hyaluronidase) administered subcutaneously as once-weekly injections over approximately 30 to 90 seconds. Allow additional time for appropriate storage, preparation, and setup. Patients should be monitored for clinical signs and symptoms of hypersensitivity reactions for at least 30 minutes after administration.[1] Please see the Prescribing Information for full administration guidance.

If a scheduled injection is missed, VYVGART Hytrulo may be administered up to 3 days after the scheduled time point. Thereafter, resume the original dosing schedule.[1]

The efficacy and safety of weekly dosing of VYVGART Hytrulo in adults with CIDP was evaluated in the ADHERE trial. The trial was designed in consultation with CIDP experts to determine the appropriate dose given the disease pathology and prior studies with efgartigimod alfa IV and VYVGART Hytrulo.[14,18] For further information, please contact our Medical Affairs team by filling out a medical information request form.

Does VYVGART Hytrulo require an infusion pump?

No, VYVGART Hytrulo does not require an injection pump. VYVGART Hytrulo is injected subcutaneously through an injection site on the abdomen with a winged infusion set by a healthcare professional.[1] Please see the Prescribing Information for full administration guidance.

How long does it take to inject VYVGART Hytrulo?

VYVGART Hytrulo is injected subcutaneously in ~30-90 seconds. Allow for appropriate storage, preparation, and setup time before use. Patients should be monitored for clinical signs and symptoms of hypersensitivity reactions for at least 30 minutes after administration.[1]

Dosing and administration FAQs

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CIDP=chronic inflammatory demyelinating polyneuropathy; IV=intravenous.

IMPORTANT SAFETY INFORMATION (cont'd)

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.

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Dosing and administration (cont'd)

Where can patients have VYVGART Hytrulo administered?

VYVGART Hytrulo offers flexibility in meeting patients' needs with subcutaneous administration in a healthcare professional's office, infusion center, or at home with assistance from a nurse. Home injections may be available for patients with insurance coverage for this service. Please contact the patient's insurance provider directly.

What is the volume of a subcutaneous injection of VYVGART Hytrulo? Does it require multiple injections?

VYVGART Hytrulo is delivered subcutaneously as a single 5.6 mL injection and includes 1,008 mg efgartigimod alfa and 11,200 units hyaluronidase (180 mg/2,000 units per mL). It is administered as once-weekly subcutaneous injections. An injection typically takes approximately 30 to 90 seconds. Allow for appropriate storage, preparation, and setup time before use. Patients should be monitored for clinical signs and symptoms of hypersensitivity reactions for at least 30 minutes after administration.[1] Please see the Prescribing Information for full administration guidance.

What are the missed dose instructions?

If a scheduled injection is missed, VYVGART HYTRULO may be administered up to 3 days after the scheduled time point. Thereafter, resume the original dosing schedule.[1]

How is VYVGART Hytrulo stored?

VYVGART Hytrulo vials should be stored under refrigeration at 2 °C to 8 °C (36 °F to 46 °F) in the original carton to protect them from light until the time of use. Do not freeze and do not shake the vials.[1]

If needed, unopened vials may be stored in the original carton for up to 3 days at room temperature at 20 °C to 25 °C (68 °F to 77 °F) for a single period before administering or returning to refrigeration. Do not store the vial at room temperature more than one time. Record the dates the carton is removed from and returned to the refrigerator on the carton.[1]

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CIDP=chronic inflammatory demyelinating polyneuropathy.

IMPORTANT SAFETY INFORMATION (cont'd)

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.

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Initiating therapy

Is the approved indication limited to induction or maintenance therapy?

No. VYVGART Hytrulo is approved for the treatment of adults with CIDP. The ADHERE trial enrolled patients treated with standard-of-care therapy as well as those off treatment for ≥6 months, including patients who were treatment naive.[1]

Can VYVGART Hytrulo be used in combination with IVIG?

VYVGART Hytrulo has not been studied in combination with any other treatments for CIDP.[1]

How do I switch my patients who are currently on IVIG to VYVGART Hytrulo?

ADHERE did not evaluate how to switch patients from another therapy to VYVGART Hytrulo, so we do not have data for switching treatments. HCPs should use their clinical judgment when switching adult patients with CIDP to VYVGART Hytrulo. For further information, please contact our Medical Affairs team by filling out a medical information request form.

Are there any contraindications to treatment with VYVGART Hytrulo?

Yes. 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.[1]

Are there monitoring or laboratory tests required during treatment with VYVGART Hytrulo?

There are no recommended routine lab monitoring requirements for patients during treatment with VYVGART Hytrulo. Continue to evaluate patient response and monitor patients for possible side effects using your clinical judgment.

CIDP=chronic inflammatory demyelinating polyneuropathy; HCP=healthcare professional; IVIG=intravenous immunoglobulin.

< DOSING ACCESS >

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Infection

VYVGART HYTRULO may increase the risk of infection. The most common infections observed in Study 1 in patients with gMG 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.

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Access

Is there a co-pay program for eligible patients?

Eligible commercially insured patients may pay as little as $0 for VYVGART Hytrulo 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.

How can my office clinicians receive training if I want to inject in the office?

Reach out to your office's Field Clinical Educator (FCE) for any training needs. The FCEs are a team of nurses and experts who can provide the HCP, care team, and even patients with treatment education and support. Once a prescription is written for VYVGART Hytrulo, an FCE will engage with the care team and ensure all training needs are met. If your office has prescribed VYVGART Hytrulo and is not already working with an FCE, please reach out to your Territory Business Manager (TBM).

If training with an FCE is not available, the HCP office can request administration training and support from an argenx-contracted nursing network, Naven Health, at 1-877-330-7766 ext 171.

Whom do I contact for assistance with PAs and appeals for my patient?

argenx has multiple points of contact to provide information to the HCP/office about PAs and appeals.

- The My VYVGART® Path patient support program can provide information to the HCP/office with insurance coverage/verification for patients enrolled in the program. All patients are eligible to enroll in My VYVGART Path
- The argenx Field Reimbursement Managers (FRMs) can help the HCP/office understand payer policy criteria, navigate the PA and appeals process, and address specialty pharmacy network issues
- In addition, CoverMyMeds can be accessed to assist the HCP/office with the PA process

HCP=healthcare professional; PA=prior authorization.

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

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Access (cont'd)

Is VYVGART Hytrulo covered by insurance?

- Many commercial health insurance plans, Medicare, and Medicaid will cover VYVGART Hytrulo after completing their P&T review process
    - Some plans may take 3-6 months to review an established clinical policy for VYVGART Hytrulo in CIDP; however, coverage can still be obtained through the medical/formulary exception process
- Most commercial health plans and some Medicare plans may require PA
- Coverage for VYVGART Hytrulo will depend on the patient's insurance plan and benefits design
- My VYVGART® Path works closely with the HCP/office and insurance plan to determine the coverage requirements

Who can help with access support?

argenx has a committed field team designed to provide comprehensive support for HCPs and their offices to facilitate patient access to argenx products.

Our dedicated and experienced team of Field Reimbursement Managers (FRMs) can provide:

- Access and reimbursement education
- Case-specific support (limited to patients enrolled in My VYVGART Path)
- Patient support

CIDP=chronic inflammatory demyelinating polyneuropathy; HCP=healthcare professional; PA=prior authorization.

< INITIATING THERAPY

IMPORTANT SAFETY INFORMATION (cont'd)

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 in gMG. 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.

Please see additional Important Safety Information throughout and full Prescribing Information.

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

INDICATION AND IMPORTANT SAFETY INFORMATION
INDICATION
VYVGART® HYTRULO (efgartigimod alfa and hyaluronidase-qvfc) is indicated for the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive.

VYVGART® HYTRULO (efgartigimod alfa and hyaluronidase-qvfc) is indicated for the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP).

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 in patients with gMG 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
Evaluate the need to administer age-appropriate vaccines according to immunization guidelines before initiation of a new treatment cycle with VYVGART HYTRULO. The safety of immunization with live vaccines and the immune response to vaccination during treatment with VYVGART HYTRULO are unknown. Because VYVGART HYTRULO causes a reduction in immunoglobulin G (IgG) levels, vaccination with live vaccines is not recommended during treatment with VYVGART HYTRULO.

Hypersensitivity Reactions
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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.

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IMPORTANT SAFETY INFORMATION (cont'd)
ADVERSE REACTIONS
Patients with gMG: 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 in patients with gMG, 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.

Patients with CIDP: In Study 3 stage B, the overall safety profile observed in patients with CIDP treated with VYVGART HYTRULO was consistent with the known safety profile of VYVGART HYTRULO and of efgartigimod alfa-fcab administered intravenously. In Study 3, injection site reactions occurred in 15% of patients treated with VYVGART HYTRULO compared to 6% of patients who received placebo. The most common of these injection site reactions were injection site bruising and injection site erythema. All injection site reactions were mild to moderate in severity. Most injection site reactions occurred during the first 3 months of treatment.

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. Risk and benefits should be considered prior to administering live 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).

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