

What is VYVGART® (efgartigimod alfa-fcab) for intravenous (IV) infusion and what is VYVGART® HYTRULO (efgartigimod alfa and hyaluronidase-qvfc) for subcutaneous injection? VYVGART and VYVGART HYTRULO are both prescription medicines, each used to treat a condition called generalized myasthenia gravis, which causes muscles to tire and weaken easily throughout the body, in adults who are positive for antibodies directed toward a protein called acetylcholine receptor (anti-AChR antibody positive).

SELECT IMPORTANT SAFETY INFORMATION

Do not use VYVGART if you have a serious allergy to efgartigimod alfa or any of the other ingredients in VYVGART. Do not use VYVGART HYTRULO if you have a serious allergy to efgartigimod alfa, hyaluronidase, or any of the other ingredients in VYVGART HYTRULO. VYVGART and VYVGART HYTRULO can cause serious allergic reactions and a decrease in blood pressure leading to fainting.

Please see full Important Safety Information throughout. Please see full Prescribing Information for VYVGART for IV infusion and VYVGART HYTRULO for subcutaneous injection.

Understand your insurance

VYVGART has **coverage** from both national and regional payers, with about 85% of insurance plans offering coverage for VYVGART intravenous (IV) infusion treatment. However, your insurance coverage for VYVGART depends on the terms and conditions listed in your insurance plan.

→ Coverage is your legal entitlement to payment or reimbursement for certain healthcare costs. Generally, this is specified under a contract with a health insurance company, a group health plan offered in connection with employment, or a government program like Medicare or Medicaid



Medicare

Medicare is a federal insurance program for adults aged 65 years or older. Younger individuals with certain types of disabilities or permanent kidney failure may also qualify.

Medicare may cover treatments for FDA-approved indications. This insurance program has 4 parts (A, B, C, and D), each providing a specific type of coverage.

- → Medicare Part A covers inpatient hospital stays, care in a skilled nursing facility, hospice care, and some home healthcare
- Medicare Part B helps cover doctors' and other healthcare providers' services, outpatient care, home healthcare, durable medical equipment, and many preventive services
- → Medicare Part C (Medicare Advantage) is a Medicare-approved plan from a private company that offers an alternative to Original Medicare for your health and drug coverage. These "bundled" plans include Part A, Part B, and usually Part D
- Medicare Part D helps cover the cost of prescription drugs
- Medicare Supplement Insurance (Medigap) is extra insurance you can buy from a private company that helps pay your share of costs in Original Medicare

Medicaid

Medicaid is a health insurance program that is administered by the government. Medicaid may provide coverage for families with low income, individuals who are pregnant, older adults, and people with disabilities. Each state has different eligibility rules.

Dual eligibility

People who are enrolled in both Medicare and full-benefit Medicaid and/or a Medicare Savings Program (MSP) have dual eligibility.

→ Medicare Savings Programs: MSPs assist with Medicare Parts A and B expenses for people with low incomes

Commercial insurance

Commercial insurance, also called private insurance, is provided and administered by a private insurance company. You may receive this insurance from your employer or purchase it from the Health Insurance Marketplace.

No health insurance

If you do not have insurance, you can purchase a health insurance plan from the Health Insurance Marketplace during Annual Enrollment or a qualifying life event. Reviewing a plan's summary of benefits and coverage (SBC) can be helpful when deciding which plan to choose.

→ An SBC is a short, plain-language summary about a health plan's benefits and coverage that you can use to review the benefits and cost of an insurance plan

We can help you understand your insurance coverage!

My VYVGART Path is a Patient Support Program that provides personalized support from committed Nurse Case Managers and Access Managers. The team at My VYVGART Path can help you navigate your insurance and understand your insurance plan.

- Access Managers can complete a benefits investigation and help you understand your insurance coverage, including possible out-of-pocket costs you may have for VYVGART Hytrulo or VYVGART
- Nurse Case Managers may be able to inform you about potential financial assistance programs, check your eligibility for the VYVGART Co-pay Program, and refer you to charitable donations that may help cover some of your out-of-pocket costs

To get started, ask your doctor to enroll you in My VYVGART Path

Navigating VYVGART Hytrulo or VYVGART cost and coverage

Your **out-of-pocket cost** for treatment may vary depending on your insurance plan. Different factors such as your insurer's **co-pay, co-insurance, deductible, site of care,** and **out-of-pocket maximum** requirements for medications may impact your treatment cost.

Where you receive treatment and whether your provider or specialty pharmacy is in **network** may also affect your out-of-pocket costs.

- Out-of-pocket cost is your expenses for medical care that aren't reimbursed by insurance. Out-of-pocket costs include deductibles, co-insurance, and co-payments for covered services plus all costs for services that aren't covered
- A **co-pay**, also called co-payment, is a fixed amount you pay for a covered healthcare service and/or prescription medication after you've paid your deductible
- Co-insurance is the percentage of costs of a covered healthcare service you pay after you've paid your deductible
- → A deductible is the amount you pay for covered healthcare services before your insurance plan starts to pay
- Site of care is the physical location of your treatment. Examples of a site of care include hospital inpatient, hospital outpatient, physician office, ambulatory infusion site, and home-based setting
- An out-of-pocket maximum is the most you have to pay for covered services in a plan year. After you spend this amount on deductibles, co-payments, and co-insurance for in-network care and services, your health plan pays 100% of the costs of covered benefits
- A **network** is the facilities, providers, and suppliers your health insurer or plan has contracted with to provide healthcare services

What is an explanation of benefits?

After starting VYVGART Hytrulo or VYVGART, your insurance provider may mail you an explanation of benefits (EOB). An EOB is a statement that explains how much of the treatment costs your insurance will cover and what your potential out-of-pocket cost may be.

An EOB is often sent to you after your provider or specialty pharmacy submits a claim to insurance for the treatment you've received. It's important to remember that an EOB is not your treatment bill

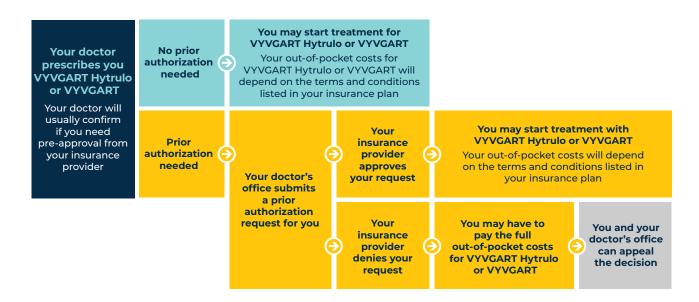
Do you need prior authorization for VYVGART Hytrulo or VYVGART?

Many insurance plans require prior authorization for VYVGART Hytrulo or VYVGART. Prior authorization, also called a pre-authorization or pre-approval, is a process insurance providers use to determine whether they will provide insurance coverage for specific healthcare services, prescriptions, or equipment.



Each insurance company's timeline for the prior authorization process may vary. You can reach out to the team at My VYVGART Path to receive more information and updates about the insurance process.

Overview of the prior authorization process



Explore potential financial assistance programs

If you have financial concerns or gaps in your insurance coverage, My VYVGART Path may be able to provide you with personalized support, resources, and information.

Once your doctor enrolls you in My VYVGART Path, the team will complete a benefits investigation to help provide you with personalized information about your insurance coverage, potential financial assistance programs, and possible out-of-pocket costs.

- → If you have commercial or private insurance, you may be eligible for assistance through the VYVGART Co-pay Program. 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
- If you do not have health insurance, you may be eligible for financial assistance through the My VYVGART Path Patient Support Program



Frequently asked questions

What is a prior authorization?

Prior authorization is a pre-approval your insurance provider may require before you can receive coverage for certain healthcare services or medications.

- Why is it taking so long to receive a decision from my insurance provider?
 - Medications that are recently FDA-approved may have longer timeframes for insurance pre-approval decisions. Other factors, such as missing information, an incomplete application, or a delayed submission can impact how long it takes to receive a decision. If you're enrolled in My VYVGART Path, the team can provide updates on the prior authorization process and support your doctor's office with the insurance process.
- What if I don't have health insurance or I cannot afford VYVGART Hytrulo or VYVGART?
 If you do not have health insurance coverage, you may be eligible for financial assistance

through My VYVGART Path, a Patient Support Program. Ask your doctor to enroll you in the Patient Support Program. Once you're enrolled, Nurse Case Managers can share information about potential financial assistance programs you may be eligible for.

Charitable foundations may be able to provide financial assistance for specific conditions and costs associated with treatment. However, funding from foundations may not be guaranteed and may differ from year to year. Nurse Case Managers may be able to refer you to charitable foundations that may be able to help with your out-of-pocket costs.

→ What if my insurance denies coverage for VYVGART Hytrulo or VYVGART?

You may still be able to receive treatment, but your out-of-pocket costs may be high if you do not obtain insurance coverage. If you're denied coverage for VYVGART Hytrulo or VYVGART, the team at My VYVGART Path may be able to assist your healthcare provider with the appeal process. If the appeal process is exhausted, a Nurse Case Manager from My VYVGART Path may be able to provide information on potential financial assistance programs.

→ How will I know what my out-of-pocket costs will be?

Your out-of-pocket costs for VYVGART Hytrulo or VYVGART may vary depending on your insurance plan. Many different factors may impact your treatment cost. You can contact your doctor's office, specialty pharmacy, site of care, or your insurance provider's customer service to learn more about potential out-of-pocket costs you may have. You can also review your plan's EOB to see a description of what costs your insurance plan may cover.

If you're enrolled in My VYVGART Path, you can reach out to the team to complete a benefits investigation. The team can review your coverage and inform you about potential out-of-pocket costs you may have for VYVGART Hytrulo or VYVGART.

→ Will I receive a bill from my site of care?

You may get a bill from your site of care. A site of care is the physical location where you receive an infusion or injection. Examples of site of care locations include an infusion center, your physician's office, or an ambulatory infusion site. Your bill may also include costs for infusions you received at home. Contact your site of care's billing department if you have any questions about your treatment bill.

Glossary

Benefits investigation

A benefits investigation is a review process with the aim of assessing a patient's medical or pharmacy insurance benefits.

Claim

A claim is a request for payment that you or your healthcare provider submits to your health insurer for covered healthcare services and treatments.

Commercial insurance

Commercial insurance, also called private insurance, is provided and administered by a private insurance provider. You may receive this insurance from your employer or purchase it from the Health Insurance Marketplace.

My VYVGART Path

My VYVGART Path is a Patient Support Program that provides personalized support from a Nurse Case Manager and committed support team.

> Network (in-network and out-of-network provider)

A network is made up of the healthcare providers, facilities, and suppliers that your health insurer or plan contracts with to provide healthcare services.

Prior authorization

Most insurance companies need to pre-approve specific healthcare services, prescriptions, or equipment before you can receive it. This process for getting approval is called a prior authorization (pre-authorization).

Specialty medication

A specialty medication is a prescription that requires special handling, special administration, or is a high-cost treatment.

Summary of benefits and coverage

Summary of benefits and coverage is a short, plain-language summary about a health plan's benefits and coverage. You can use it to compare the benefits and costs of different insurance plans.

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VYVGART and VYVGART HYTRULO may cause serious side effects, including:

- Infection. VYVGART and VYVGART HYTRULO may increase the risk of infection. The most common infections for efgartigimod alfafcab-treated patients were urinary tract and respiratory tract infections. Signs or symptoms of an infection may include fever, chills, frequent and/or painful urination, cough, pain and blockage of nasal passages/sinus, wheezing, shortness of breath, fatigue, sore throat, excess phlegm, nasal discharge, back pain, and/or chest pain.
- Allergic Reactions (hypersensitivity reactions).
 VYVGART and VYVGART HYTRULO can cause
 allergic reactions such as rashes, swelling
 under the skin, and shortness of breath. Hives
 were also observed in patients treated with
 VYVGART HYTRULO. Serious allergic reactions,
 such as trouble breathing and decrease in
 blood pressure leading to fainting have been
 reported with efgartigimod alfa-fcab.
- Infusion-Related Reactions. VYVGART and VYVGART HYTRULO can cause infusion-related reactions. The most frequent symptoms and signs reported with efgartigimod alfa-fcab were high blood pressure, chills, shivering, and chest, abdominal, and back pain.

Tell your doctor if you have signs or symptoms of an infection, allergic reaction, or infusion-related reaction. These can happen while you are receiving your VYVGART or VYVGART HYTRULO treatment or afterward. Your doctor may need to pause or stop your treatment. Contact your doctor immediately if you have signs or symptoms of a serious allergic reaction.

Before taking VYVGART or VYVGART HYTRULO, tell your doctor if you:

- take any medicines, including prescription and non-prescription medicines, supplements, or herbal medicines,
- have received or are scheduled to receive a vaccine (immunization), or
- have any allergies or medical conditions, including if you are pregnant or planning to become pregnant, or are breastfeeding.

What are the common side effects of VYVGART and VYVGART HYTRULO?

The most common side effects in efgartigimodalfa-fcab-treated patients were respiratory tract infection, headache, and urinary tract infection. Additional common side effects with VYVGART HYTRULO are injection site reactions, including rash, redness of the skin, itching sensation, bruising, pain, and hives.

These are not all the possible side effects of VYVGART and VYVGART HYTRULO. Call your doctor for medical advice about side effects. You may report side effects to the US Food and Drug Administration at 1-800-FDA-1088.

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Please see the full Prescribing Information for <u>VYVGART</u> and the full Prescribing Information for <u>VYVGART HYTRULO</u>, and talk to your doctor.



(efgartigimod alfa and hyaluronidase-qvfc)

Subcutaneous Injection 180 mg/mL and 2000 U/mL vial



400 mg/20 mL vial

