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

SUBMITTING A CLAIMS APPEAL FOR VYVGART Hytrulo

FOR CHRONIC INFLAMMATORY DEMYELINATING POLYNEUROPATHY

This information is current as of the date of publication but is subject to change.

Every payer manages access to VYVGART® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) differently, and some payers may deny coverage. This claims appeal guide provides considerations when appealing a denied or underpaid VYVGART Hytrulo claim. A claims appeal is a request to your patient's health plan to reconsider its decision to deny coverage for VYVGART Hytrulo. This resource provides information that may be helpful when **navigating the claims appeal process and drafting a letter of claims appeal for adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP).**

As payer-specific requirements for appealing a claim may vary, policies and processes should be reviewed to ensure all requirements are met. Detailed information regarding the denial or underpayment can be found in the Explanation of Benefits or Remittance Advice.

The information provided in this guide is intended for informational purposes only. The healthcare provider is solely responsible for the completion and submission of coverage- or reimbursement-related documentation. The use of this information does not guarantee coverage or reimbursement for VYVGART Hytrulo.

TIPS FOR NAVIGATING THE CLAIMS APPEAL PROCESS

Before you can resubmit the claim, you must determine why the claim was denied and correct the errors.

Some common denial reasons are:

Denial reason	Example
Incorrect coding	• Incorrect ICD-10-CM, HCPCS, CPT, or modifier for CIDP, VYVGART Hytrulo and/or its administration • Incorrect units billed, reporting of drug waste, or units discarded (when applicable)
Missing/incomplete/ invalid claims data	• Reopening a Medicare claim[1]

Key: CIDP, chronic inflammatory demyelinating polyneuropathy; CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification.

Many of these issues may be resolved by comparing the patient's medical record with information submitted on a claim and correcting the claim accordingly. Some clerical issues may be corrected via phone or provider portal without having to submit a formal appeal via the Medicare reopening process or similar steps under other payers.

Reopening a Medicare case[1]

Used for correction of minor clerical errors and omissions to change a determination/decision that results in over/underpayment
Request a reopening within 1 year (up to 4 years for good cause)
May avoid the formal appeal process

Details about the Medicare appeal process can be found in the Medicare Claims Processing Manual Chapter 29.[2,3] Individual payer policies may vary; check payer requirements for appeals.

References

1. CMS. Medicare Claims Processing Manual Chapter 34: reopening and revision of claim determinations and decisions: sections 10.4-10.5. Updated January 25, 2019. Accessed February 19, 2024. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c34.pdf **2.** CMS. Medicare Claims Processing Manual Chapter 29: appeals of claims decisions: sections 310-345. Updated December 20, 2023. Accessed February 19, 2024. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c29pdf.pdf **3.** CMS. Original Medicare (Parts A & B - fee-for-service). 2022. Accessed February 19, 2024. https://www.cms.gov/Medicare/Appeals-and-Grievances/OrgMedFFSAppeals/Downloads/Flowchart-FFS-Appeals-Process.pdf

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Be detailed and thorough. Recommended information for a Letter of Claims Appeal typically includes:

☐ **Patient information:**
- Full name
- Date of birth
- Date of denial
- Case ID number (if available)
- Insurance ID/group number
- Copies of relevant medical records

☐ **The patient's diagnosis and the indication for the intended use of VYVGART Hytrulo[4]**
- G61.81, Chronic inflammatory demyelinating polyneuritis

☐ **The severity of the patient's condition:**
- Hospitalizations, emergency room or urgent care visits
- Patient condition severity at baseline, 3-month follow-up, and 6-month follow-up, or longer
- Documentation of strength or weakness using a clinical measurement tool (eg, Inflammatory Neuropathy Cause and Treatment (INCAT), Medical Research Council (MRC) muscle strength, 6-minute walk test (6-MWT), Rankin, Modified Rankin, etc)

☐ **A summary of the patient's previous treatments, the duration of each, and the rationale for discontinuation (eg, corticosteroids, immunoglobulins, etc)**

☐ **The clinical rationale for treatment, including trial data supporting the Food and Drug Administration (FDA) approval, administration, and dosing information**

☐ **Acknowledgment of the health plan's policy, why you disagree with the denial, and a summary of your patient-specific recommendation**

☐ **Additional enclosures, including:**
- Prescribing information
- Clinical notes/medical records
- FDA approval letter
- Diagnostic test results including electro-diagnostic test results (electromyography (EMG) or nerve conduction studies)
- Relevant peer-reviewed articles

If a claim is denied, the health plan is required to notify you and your patient in writing and provide an explanation of the denied claim.[5]

Familiarize yourself with the plan's specific guidelines, but generally, you must file for an appeal within 180 days of receiving notice that your claim was denied.[1] Exact timelines may vary, please refer to the denial letter to determine appeal timelines specific to the patient's health plan.


Confirm the submission deadline


Submit an appeal within the specified deadline


Submit the appeal in the required format


Attach any supporting documentation from the medical record

Key: FDA, Food and Drug Administration.

References (cont.)

4. CMS. 2024 ICD-10-CM tabular list of disease and injuries. Updated February 1, 2024. Accessed February 23, 2024. https://www.cms.gov/medicare/coding-billing/icd-10-codes/2024-icd-10-cm **5.** Appealing a health plan decision. HealthCare.gov website. Accessed February 19, 2024. https://www.healthcare.gov/appeal-insurance-company-decision/internal-appeals/

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Sample letter of claims appeal

A letter of claims appeal is typically used to address the specific reasons for coverage denial and demonstrate the physician's rationale for why VYVGART Hytrulo is the most appropriate therapy for the patient.

The following is a sample letter of claims appeal that can be customized for your patient's medical information, denial disposition, and supporting documentation. It is recommended the letter be drafted onto your practice's letterhead before submitting it to a payer. It should be submitted along with a copy of the patient's relevant medical records and explain why the use of VYVGART Hytrulo is appropriate for the patient. Some payers may have specific forms that must be completed to document this claims appeal.

[Physician letterhead]
[Date]
[Contact Name], [Title]
[Payer Name]
[Payer Address]

RE: [Patient Full Name]

Date of Birth: [Patient Birth Date]

Member ID: [Patient Member ID Number], Policy or Group Number: [Patient Policy or Group Number]

To Whom It May Concern,
I am writing to acknowledge that I have reviewed the rationale in the denial letter. This is a request to reconsider your coverage denial of VYVGART® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) for my patient, [Patient Full Name]. Your reason[s] for the denial [was/were] [List reason for the denial].

Patient's Clinical/Medical History
[Patient Name] is a[n] [age]-year-old patient who has been diagnosed with chronic inflammatory demyelinating polyneuropathy (CIDP) [ICD-10 code], as of [date of diagnosis].

[Include relevant medical information to support your reason for treatment with VYVGART Hytrulo. An example may include evidence that the patient's CIDP symptoms and disabilities have been progressing despite their current therapies.

Additional information may include:
- Supporting information as requested by the plan in its denial letter
- Clinical attributes of VYVGART Hytrulo and relevance to patient]

Previous Therapies, Reasons for Discontinuation, and Duration of Therapy:
History of previous CIDP therapies: [Treatment #1], [Treatment #2]
Reasons for discontinuation of previous therapies: [Treatment #1], [Treatment #2]
Duration of previous therapies: [Treatment #1], [Treatment #2]

Summary
Based on the patient's condition and medical history, as well as my experience treating adult patients with CIDP, I strongly believe treatment with VYVGART Hytrulo is indicated and medically necessary for this patient because [Briefly summarize reasons for the patient to use VYVGART Hytrulo].
Please find the enclosed additional documents [eg, list enclosures such as supporting clinical documentation, prescribing information, clinical notes/medical records, letter of medical necessity, etc] that support my [level of request] letter of appeal. If you need additional information for a timely approval, please contact my office at [insert office phone number].

Sincerely,
[Physician Name]
[Physician Address]
[Physician Phone]

Provide relevant medical information and attach patient's medical records and supporting documents for payers to review

Download a copy of the Full Prescribing Information

Check with the payer to identify specific documentation that needs to be submitted with a letter of claims appeal

Disclaimer: This sample is provided for general reference only. Use of the information in this template letter does not guarantee that the insurance company will provide coverage or reimbursement for the prescribed medication. The sample letter is provided for your guidance only; it is not intended to be a substitute for, or an influence on, the independent medical judgment of the physician.

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VYVGART® Hytrulo

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

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

Immunization with vaccines during VYVGART HYTRULO treatment has not been studied; the safety with live or live-attenuated vaccines and the response to immunization with any vaccine are unknown. Because VYVGART HYTRULO causes a reduction in immunoglobulin G (IgG) levels, vaccination with live-attenuated or live vaccines is not recommended during VYVGART HYTRULO treatment. Evaluate the need to administer age-appropriate vaccines according to immunization guidelines before initiation of a new treatment cycle with VYVGART HYTRULO.

Hypersensitivity Reactions

In clinical trials, hypersensitivity reactions, including rash, angioedema, and dyspnea were observed in patients treated with VYVGART HYTRULO or intravenous efgartigimod alfa-fcab. Urticaria was also observed in patients treated with VYVGART HYTRULO. Hypersensitivity reactions were mild or moderate, occurred within 1 hour to 3 weeks of administration, and did not lead to treatment discontinuation 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.

Infusion-Related Reactions

Infusion-related reactions have been reported with intravenous efgartigimod alfa-fcab in postmarketing experience. The most frequent symptoms and signs were hypertension, chills, shivering, and thoracic, abdominal, and back pain. Infusion-related reactions occurred during or within an hour of administration and led to infusion discontinuation. If a severe infusion-related reaction occurs, initiate appropriate therapy. Consider the risks and benefits of readministering VYVGART HYTRULO following a severe infusion-related reaction. If a mild to moderate infusion-related reaction occurs, patients may be rechallenged with close clinical observation, slower infusion rates, and pre-medications.

ADVERSE REACTIONS

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. Risks and benefits should be considered prior to administering live or live-attenuated vaccines to infants exposed to VYVGART HYTRULO in utero.

Lactation

There is no information regarding the presence of efgartigimod alfa or hyaluronidase, from administration of VYVGART HYTRULO, in human milk, the effects on the breastfed infant, or the effects on milk production. Maternal IgG is known to be present in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for VYVGART HYTRULO and any potential adverse effects on the breastfed infant from VYVGART HYTRULO or from the underlying maternal condition.

Please see the full Prescribing Information 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).

Additional Resources

If you have additional questions about **VYVGART Hytrulo**, please contact **My VYVGART Path** at **1-833-MY-PATH-1 (1-833-697-2841)** where you can be connected to the appropriate resource.

You can access downloadable resources by visiting:
vyvgarthcp.com/vyvgarthytrulo-cidp/access

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