AMBELVIST® (gadoquatrane) Sample Letter of Appeal

Navigating the Appeals Process

If a prior authorization is denied, **an appeal may be required.** Health plans will notify you of the reason the initial request for coverage was denied. Oftentimes, **providing complete and accurate information** that was missing from the original submission will help correct the denial.

Resubmitting the request through an appeal is a crucial step to ensuring that the patient has access to AMBELVIST. One way to request an appeal is by submitting a letter of appeal via fax or mail.

Supporting Documentation

Providing as much supporting information as possible may facilitate timely consideration of your request by the health plan. In addition to the formal request presented in an appeal letter, the following documentation may be submitted to support the process:

- A Letter of Medical Necessity for AMBELVIST
- Photocopies of the patient's health plan and/or prescription cards
- Copies of the denial letter, benefits information, and the original claim/prescription request
- The Prescribing Information for AMBELVIST
- The patient's medical records, including any relevant lab and/or diagnostic results
- The patient's authorization of information release

Note: Because each plan has its own appeals process, the required information may vary.

Considerations When Filing an Appeal for AMBELVIST

- Photocopy all documents that are being submitted, as well as any formal correspondence with the health plan
- The patient's benefit information should be verified to ensure that the appeal request is valid
- Appeal guidelines vary from plan to plan and should be confirmed before submitting an appeal.
- Plan-specific guidelines may include a deadline for filing, a submission fax number or mailing address that is specifically used for an appeal or similar requests, how many times an appeal may be submitted, and whether the patient or the physician is required to submit the appeal
- Appeal departments for health plans generally have readily available contact information with individuals who can answer any questions that you or your office may have relating to the appeal process
- Verification of submission should be obtained. Receipt of faxed submissions can be verified with a follow-up phone call shortly after submission, and mailed submissions can be sent with tracking information, with a scheduled verification phone call 2 to 3 business days after the package is delivered

How to Use a Sample Letter of Appeal Template

- The letter template starting on page 3 includes bracketed placeholders to be replaced with the relevant patient, healthcare provider, and office information
- When submitting the letter, please use your office letterhead

Please see Important Safety Information on the next page.

Please see Full Prescribing Information for Ambelvist®

Ambelvist®
(gadoquatrane) injection
0.1 mmol/mL

INDICATIONS

Ambelvist® (gadoquatrane) is a gadolinium-based contrast agent indicated in adult and pediatric patients, including term neonates, for use with magnetic resonance imaging (MRI) to detect and visualize lesions with abnormal vascularity in:

- the central nervous system (brain, spine, and associated tissues)
- the body (head and neck, thorax, abdomen, pelvis, and musculoskeletal system)

IMPORTANT SAFETY INFORMATION

WARNING: RISK ASSOCIATED WITH INTRATHECAL USE and NEPHROGENIC SYSTEMIC FIBROSIS

Risk Associated with Intrathecal Use

Intrathecal administration of gadolinium-based contrast agents (GBCAs) can cause serious adverse reactions including death, coma, encephalopathy, and seizures. AMBELVIST is not approved for intrathecal use.

Nephrogenic Systemic Fibrosis

GBCAs increase the risk for nephrogenic systemic fibrosis (NSF) among patients with impaired elimination of the drugs. Avoid use of AMBELVIST in these patients unless the diagnostic information is essential and not available with non-contrasted MRI or other modalities. NSF may result in fatal or debilitating fibrosis affecting the skin, muscle, and internal organs.

The risk for NSF appears highest among patients with:

- Chronic, severe kidney disease (GFR <30 mL/min/1.73 m^2), or
- Acute kidney injury.

Screen patients for acute kidney injury and other conditions that may reduce renal function. For patients at risk for chronically reduced renal function (for example, age > 60 years, hypertension, or diabetes), estimate the glomerular filtration rate (GFR) through laboratory testing.

For patients at highest risk for NSF, do not exceed the recommended AMBELVIST dose and allow a sufficient period of time for elimination of the drug from the body prior to any re-administration.

Contraindication and Important Information about Hypersensitivity Reactions: Ambelvist® is contraindicated in patients with a history of severe hypersensitivity reactions to Ambelvist®. Serious hypersensitivity reactions have occurred with GBCAs. Before Ambelvist® administration, assess all patients for any history of a reaction to contrast media, bronchial asthma, and/or allergic disorders. These patients may have an increased risk for a hypersensitivity reaction to Ambelvist®.

Gadolinium Retention: Gadolinium is retained for months or years in several organs. Linear GBCAs cause more retention than macrocyclic GBCAs. At equivalent doses, retention varies among the linear agents. Retention is lowest and similar among the macrocyclic GBCAs. Consequences of gadolinium retention in the brain have not been established, but they have been established in the skin and other organs in patients with impaired renal function. While clinical consequences of gadolinium retention have not been established in patients with normal renal function, certain patients might be at higher risk. These include patients requiring multiple lifetime doses, pregnant and pediatric patients, and patients with inflammatory conditions. Consider the retention characteristics of the agent and minimize repetitive GBCA studies, when possible.

Acute kidney Injury: In patients with chronic renal impairment, acute kidney injury sometimes requiring dialysis has been observed with the use of some GBCAs. Do not exceed the recommended dose; the risk of acute kidney injury may increase with higher than recommended doses.

Interference with Lesion Visualization
As with other GBCAs, Ambelvist® may obscure certain lesions that are visible on non-contrast MRI. When available, non-contrast MRI images should be reviewed during the interpretation of Ambelvist® MRI scans.

Adverse Reactions: The most frequently observed adverse reactions (incidence ≥ 0.2%) were dizziness, headache, injection site reactions, nausea, vomiting, feeling hot, paresthesia, and pruritus.

Please see Full Prescribing Information for Ambelvist®

MAC-AMB-US-0008-1 June 2026

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(gadoquatrane) injection
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Sample Letter of Appeal for AMBELVIST® (gadoquatrane)

[Date]
[Contact Name and Title – usually the health plan's medical or pharmacy director]
[Name of Health Insurance Plan]
[Health Plan Mailing Address]

Insured: [First and Last Name]
Patient (if different from insured): [First and Last Name]
Patient Date of Birth: [Insert MM/DD/YEAR]
Policy Number: [Insert Number]
Group Number: [Insert Number]

Re: Denial for AMBELVIST® (gadoquatrane)

Dear [NAME OF CONTACT AT PAYER],

I am writing on behalf of [NAME OF PATIENT] who has been denied the use of AMBELVIST, which is indicated in adult and pediatric patients, including term neonates, for use with magnetic resonance imaging (MRI) to detect and visualize lesions with abnormal vascularity in the central nervous system (brain, spine, and associated tissues) and the body (head and neck, thorax, abdomen, pelvis, and musculoskeletal system).[1] Based on your letter of denial dated [date and denial letter #], coverage for AMBVELVIST was denied because [insert specific reason as stated in denial letter].

Please accept this letter as [PATIENT NAME]'s appeal to [PAYER NAME]'s decision to deny coverage for AMBELVIST.

[PATIENT NAME] requires an MRI with contrast for [reason for MRI, including ICD-10 and CPT code(s)].

I believe that [PATIENT NAME] would benefit from AMBELVIST for the following reason(s):
- [Summary of relevant medical history, condition/symptoms, addressing reason for denial, if possible]
- [Prior imaging results, if applicable]
- [Prior contrast agents used and any adverse events experienced, if applicable]

Based upon the patient's medical history and the indicated use for AMBELVIST, MRI with AMBELVIST is medically necessary and clinically appropriate for [PATIENT NAME].

Thank you in advance for your review and consideration of the appeal. If you have any questions or require additional information regarding this patient, please contact me at [PHYSICIAN TELEPHONE NUMBER].

Sincerely,
[PRESCRIBER NAME AND SIGNATURE]

Attachments: [ORIGINAL CLAIM FORM, DENIAL LETTER, AMBELVIST PRESCRIBING INFORMATION, ETC]