Ambelvist®
(gadoquatrane) injection
0.1 mmol/mL

AMBELVIST® (gadoquatrane) Sample Letter of Medical Necessity

A letter of medical necessity may be submitted to a patient's health plan in multiple scenarios, for example:

- When your patient does not meet the health plan's coverage criteria for product use
- When your patient's health plan requires additional justification (or documentation) for coverage
- When the plan does not pay the claim for AMBELVIST (Submitted with the Appeal Letter)

The Sample Letter of Medical Necessity serves as a helpful template for medical staff to reference when submitting these requests to the patient's health plan. In addition to a Letter of Medical Necessity, health plans may also require the following items as supporting evidence:

- The patient's medical records including any relevant lab and/or diagnostic results that document the medical necessity and coverage criteria requirements have been met,
- Clinical studies and/or relevant guidelines that support the treatment decision and use of AMBELVIST for this patient
- The AMBELVIST Prescribing Information

Each insurance plan determines their own unique coverage criteria and determines the required information to support the medical necessity so required documentation may vary. If the plan requests specific information, be sure to provide exactly what is requested. Providing all requested information quickly will help facilitate timely claim processing by the health plan.

The attached letter template is a sample to communicate effectively with the plan when information is required. Replace the bracketed placeholders with relevant information as requested by the plan. This letter serves as a sample template and all information may be adjusted to individualize the request for the patient.

When submitting the letter, please use your office letterhead.

This sample letter is offered as a model and is intended to be tailored according to the individual prescriber's and patient's needs.

If you have any questions, please contact the Bayer Radiology Helpline at 1-800-423-7539 or BayerImaging@thepinnaclehealthgroup.com.

Please see Important Safety Information on the next page.

Please read the full Prescribing Information for AMBELVIST.

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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®

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AMBELVIST® (gadoquatrane) Sample Letter of Medical Necessity

[Date]
[Contact Name and Title – Health plan medical department/director]
[Name of Health Insurance Plan]
[Health Plan Mailing Address]

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

Re: Request for AMBELVIST® (gadoquatrane)

Dear [NAME OF CONTACT AT PAYER],

I am writing on behalf of my patient listed above to request that the plan approve coverage for 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]

This letter documents the medical necessity for use of AMBELVIST for my patient and provides information regarding my patient's medical history, relevant test results and support for the importance for ordering the study. I have included a copy of the AMBELVIST prescribing information.

Patient's medical history includes:
- [Diagnosis or reason for MRI, including ICD-10 and CPT® code(s), and date of diagnosis]
- [Relevant medical history]
- [Prior imaging results, if applicable]
- [Prior contrast agents used and any adverse events experienced, if applicable]
- [Additional lower-dose contrast considerations, if applicable]

Based upon the patient's medical history and the indicated use for AMBELVIST, the medical necessity and clinical need is supported for this patient. We request a prompt approval for this patient based upon the information provided.

If you have any questions, please contact me at the phone or email provided below. I appreciate your immediate attention to this request.

Sincerely,
[PHYSICIAN]
[PHYSICIAN PHONE]
[PHYSICIAN EMAIL]

[Attachments as appropriate]