

Sample Letter of Appeal for Denial of Coverage

The following sample letter is for demonstration purposes only and is meant to provide an authorized treatment center (ATC) or hospital with guidance on how to make their clinical arguments when filing an appeal to overturn the denial for CASGEVY™ (exagamglogene autotemcel) suspension for intravenous infusion coverage. It also includes recommendations for the types of documentation to include to support their clinical decision-making. Attachments to include with the letter of appeal are the original prior authorization (PA) form and letter of medical necessity submitted, a copy of the denial or explanation of benefits (EOB), and any other additional supporting documents.

DISCLAIMERS:

Use of the letter template does not guarantee that the payer will provide coverage or reimbursement and is not intended to be a substitute for, or influence on, the independent medical judgment of the ATC or hospital.

Vertex cannot complete or submit PA forms or write letters of medical necessity/appeal on your patient's behalf. Vertex can provide information and education on what is typically required for these forms and provide sample templates for creating letters of medical necessity/appeal.

[Date]

[Insurance Company Contact]

[Insurance Company Name]

[Insurance Company Address]

[Insurance Company City, State Zip]

[Insured Name and DOB]

[Patient Name]

[Patient Insurance ID#]

[Patient Group#]

[Reference Number if Available]

Dear [Insurance Company Contact]:

I am writing on behalf of my patient, [patient first name last name], to appeal the decision to deny coverage for CASGEVY™ (exagamglogene autotemcel) suspension for intravenous infusion. [Indication statement].

In brief, treatment with CASGEVY is medically appropriate and necessary for [patient name] and should be a covered treatment. This letter outlines [patient name]'s medical history and prognosis, as well as the treatment rationale that supports my decision to prescribe CASGEVY.

[Insert summary of confirmation of coverage and obtaining prior authorization before treatment and include the prior authorization number, if applicable.]

Summary of [Patient Name]'s History and Diagnosis

- [Brief description of the patient's current disease state, symptoms, and severity]
- [Medical history]
- [Laboratory test results and test dates]
- [Patient comorbidities that could serve as contraindications to certain other treatments, if applicable]
- [Comprehensive history of all prior treatments and responses to those treatments]
- [Summary of your professional opinion of the patient's likely prognosis or disease progression without treatment with CASGEVY]
- [The patient/family has been counseled and understands the steps and length of treatment and necessary support (ie, psychological fitness) throughout the procedure]

Rationale for Treatment

Please find additional documents enclosed that support my clinical decision that CASGEVY is an appropriate treatment option for [patient name].

- [Clinical rationale for CASGEVY treatment, including clinical trial data supporting FDA, administration, and dosage information]
- [CASGEVY full Prescribing Information]
- [Consensus statements or treatment guidelines]
- [Link(s) to peer-reviewed journal article(s) and other related medical literature]

Given the patient's history, condition, and the published data supporting the use of CASGEVY™ (exagamglogene autotemcel), it is my professional opinion that treatment of [patient name] with CASGEVY is warranted, appropriate, and medically necessary.

[If you disagree with coverage and uphold this denial, I am requesting a formal reconsideration by a hematologist.]

I look forward to receiving your timely response and reconsideration of this request.

Sincerely,

[Physician's Signature]

[Physician's Name]

[Provider Identification Number]

[Name of ATC/Hospital]

[Phone Number]

Enclosures: [attach as appropriate]

- [CASGEVY Prescribing Information]
- [Patient clinical/diagnostic notes and relevant lab reports]
- [Documentation/publications noted above]