Sample Letter of Medical Necessity

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 explain their rationale for prescribing CASGEVY™ (exagamglogene autotemcel) suspension for intravenous infusion treatment and reinforce why they believe it is medically necessary for the named patient. It also suggests the types of documentation to include to support their clinical decision-making.

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 prior authorization (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's first name, last name, date of birth], to demonstrate the medical necessity and support for the coverage of CASGEVY™ (exagamglogene autotemcel) suspension for intravenous infusion. [Indication statement].

[Patient's name] has been under my care since [date] for the treatment of sickle cell disease (SCD). [Patient's name] was referred by [enter name of referring physician] as a candidate for CASGEVY. Below I have included information on [patient name]'s medical history, including prior therapies, and [his/her] current condition and diagnosis.

Patient Information

- ☐ [Records/clinical notes detailing the patient's diagnosis and date of diagnosis]
- ☐ [Medical history]
- ☐ [Laboratory test results and test dates]
- ☐ [Brief description of the patient's current disease state, symptoms, severity, and comorbidities]
- ☐ [Comprehensive history of all prior treatments and responses to those treatments
    - Previous therapies that were tried and ineffective, not tolerated, or are now contraindicated]
- ☐ [Rationale for selecting CASGEVY]
- ☐ [Requested CASGEVY regimen]
- ☐ [Projected start date]

Rationale for Treatment

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

- ☐ [Patient's diagnosis of SCD with recurrent vaso-occlusive crises for which CASGEVY is FDA-approved to treat]
- ☐ [Severity of patient's condition]
- ☐ [Relevant peer-reviewed journal articles and other related medical literature]
- ☐ [Treatment studies or data from CASGEVY clinical trial]
- ☐ [Consensus statements or treatment guidelines]
- ☐ [Clinical rationale for CASGEVY treatment, including clinical trial data supporting FDA approval, administration, and dosage information]
- ☐ [CASGEVY™ (exagamglogene autotemcel) Prescribing Information]
- ☐ [Summary of your professional opinion of the patient's likely prognosis or disease progression without treatment]
- ☐ [Provide any information that a health plan administrator may not know]

It is my professional opinion that treatment of [patient name] with CASGEVY is medically necessary based on the evidence summarized above. If you need additional information for a timely approval, please do not hesitate to contact my office at [phone number].

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]