Sample Format: Letter of Medical Necessity

FOR INFORMATIONAL USE ONLY: This is a Sample Letter of Medical Necessity. It is not intended to substitute for a healthcare professional's medical judgment when providing a diagnosis of the patient's medical condition or recommendation for a particular treatment. Please transfer this sample letter onto the appropriate letterhead before printing. Magenta information within brackets is templated and should be replaced with pertinent information for the individual patient on whose behalf you are submitting the letter.

[Physician Letterhead]

[Date]

[Name of Plan Contact or Medical Director]
[Department Name]
[Health Insurance Plan Name]
[Mailing Address]
[City, State ZIP]

Re: Letter of Medical Necessity for AQVESME™ (mitapivat)
Subscriber: [Subscriber's Name]
Patient: [Patient's Name]
Policy #: [Policy #]
Group #: [Group #]
Denial Date: (If applicable) [Month Day, Year]
Reference #: (If applicable) [Reference #]

Dear [Contact Name],

I am writing on behalf on my patient, [patient's name] (DOB: [DOB]), to document medical necessity for AQVESME™ (mitapivat) for the treatment of [anemia in adults with alpha- or beta-thalassemia] [(ICD-10 code)].

In my clinical opinion, initiating treatment with AQVESME is medically necessary and should be covered for this patient. I maintain that AQVESME [list all dosage strengths, frequency] is the appropriate therapy for this patient based on clinical criteria in the Prescribing Information.

Outlined below is a summary of the patient's history and my rationale for treatment:

[List relevant medical information to support your diagnosis and medical necessity for treatment with AQVESME, which may include:

- Comprehensive list of current and previous treatments or those used for complication management
- Summary of disease impact on quality of life
- Other clinical rationale supported by the Prescribing Information
- Clinical attributes of AQVESME and relevance to the patient
- Requested dosage forms
- Documented diagnosis of β-thalassemia, HbE/β-thalassemia, or α-thalassemia/HbH disease
- Transfusion-dependent: History of red blood cell (RBC) transfusions, units, and dates in the 24-week period prior to treatment initiation
- Non–transfusion-dependent: Confirmation of <6 RBC transfusions in the 24-week period prior to treatment initiation, and baseline hematological laboratory results (hemoglobin, CBC, haptoglobin)]

The following items are also enclosed for your review:

[List additional documents you plan to attach to further support your clinical rationale, which may include the Prescribing Information, clinical notes, medical records (eg, baseline and/or current laboratory results, which may include hemoglobin electrophoresis or high-performance liquid chromatography), FDA approval letter, relevant research/studies, or clinical practice guidelines]

Based on the enclosed items, the patient's condition and medical history, and my experience treating patients with [alpha- or beta-thalassemia], I believe treatment with AQVESME is medically necessary. On behalf of the patient, I am requesting approval for use and subsequent coverage for treatment.

If you have any further questions about this matter, please feel free to contact me at [physician's phone number] or via email at [physician's email]. Thank you for your time and consideration. I look forward to receiving your timely response and approval of this request.

Sincerely,
[Physician's Name and Signature]
[Phone Number]
[Fax Number]

[ENCLOSURES: Remember to attach the additional documents listed above]