SAMPLE LETTER OF MEDICAL NECESSITY

Please note that the following letter is intended only as a SAMPLE template Letter of Medical Necessity that outlines information a payer may request from a prescriber to document a patient's medical necessity for treatment in order to obtain coverage for a requested therapy. The prescriber should use their independent medical judgment to decide what information to incorporate regarding their patient's specific needs and medical history. In addition, health plan requirements may vary, so the prescriber should refer to the prior authorization or coverage information specific to their patient's health plan before completing a Letter of Medical Necessity. Please note that some payers may have specific forms that must be completed to request prior authorization or to document medical necessity.

Use of this template or the information in this template does not guarantee reimbursement or coverage.

LETTER OF MEDICAL NECESSITY SHOULD BE ON THE PROVIDER'S LETTERHEAD

[Date]
[Health Plan Name]
ATTN: [Department]
[Medical/Pharmacy Director Name]
[Health Plan Address]
[City, State Zip]

Name: [Patient's Name]
DOB: [XX/XX/XXXX]
Patient Policy ID Number: [Policy ID #]
Reference Number: [Reference #]
Date(s) of Service: [XX/XX/XXXX]

Re: Letter of Medical Necessity for OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy)

Dear [Medical/Pharmacy Director Name],

I am writing to request authorization for the use of OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) for my patient, [Patient Name]. OPDIVO Qvantig™ has been FDA approved for the treatment of [Patient's Condition/Diagnosis]. This letter provides the rationale and relevant information about the patient's medical history.

Summary of Patient's Medical History:

[Briefly describe the patient's diagnosis, relevant medical history, and any previous therapies attempted, including outcomes and challenges]

[Patient Name] has been diagnosed with [Condition/Diagnosis]. *[If applicable]* [Patient Name] has been undergoing treatment with [Name of Therapy]. *[If applicable]* [Patient Name] has experienced [list any barriers or challenges with previous therapy].

[If the patient is currently on an IV therapy] [Patient Name] has experienced [list any barriers or challenges with IV therapy, if applicable].

[If the patient is currently on OPDIVO® (nivolumab) IV] Per the OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) Package Insert, adult patients currently receiving intravenous nivolumab as a single agent, or in combination with chemotherapy or cabozantinib, may switch to subcutaneous OPDIVO Qvantig™ at their next scheduled dose.

Rationale for Subcutaneous Therapy:

OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) is a clinically appropriate treatment for [Patient Name] that is [FDA approved / NCCN recommended] for [Patient's Condition/Diagnosis]. In addition, OPDIVO Qvantig™ is medically necessary for [Patient Name] due to the following factors: [include reasons for medical necessity based on patient circumstances].

Conclusion:

Given the FDA approval of OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) and the rationale provided above, I believe this treatment is medically necessary for [Patient Name]. I request that you approve coverage for OPDIVO Qvantig™ as a covered benefit.

[You may want to include:]

Please find enclosed supporting documentation, including:

- [Relevant clinical notes and history]

- [Scientific literature or clinical guidelines supporting subcutaneous therapy]

- [Treatment plan and anticipated outcomes]

If you require any additional information, please do not hesitate to contact me directly at [Your Phone Number] or [Your Email Address]. Thank you for your timely attention to this request.

Sincerely,

[Your Name, Title]

[Your Practice/Facility Name]

[Your Contact Information]

Enclosures:

[List all enclosed supporting materials]