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 Opdualag™ (nivolumab and relatlimab-rmbw)

Dear <<Medical/Pharmacy Director Name>>,

I am writing on behalf of <<patient's name>> to request coverage for Opdualag™ (nivolumab and relatlimab-rmbw), which has been FDA approved for the treatment of adult and pediatric patients 12 years of age or older with unresectable or metastatic melanoma. *International Classification of Diseases, 10th Revision, Clinical Modification* diagnosis code <<diagnosis code>>. I have reviewed your drug coverage policy and believe that the appropriate treatment decision at this time is to initiate treatment with Opdualag. This letter provides the clinical rationale and relevant information about the patient's medical history.

Opdualag is a fixed-dose combination of nivolumab and relatlimab that was approved by the US Food and Drug Administration on March 18, 2022. At this time, relatlimab is not available as a single agent, in its own vial. The current formulation of Opdualag is 240 mg of nivolumab and 80 mg of relatlimab per 20 mL (12 mg and 4 mg per mL, respectively) in a single-dose vial.

The patient is <<a/an age>>-year-old <<male/female>> who was diagnosed with <<diagnosis>> on <<date>>. Below is the rationale for prescribing Opdualag based on my patient's disease summary.

Summary of Patient's Medical History:

<<Insert overview of the patient's condition>>

<<*You may want to include:*>>

- Medical literature regarding the use of Opdualag for <ICD-10 Codes> <Diagnosis Name>
- Relevant clinical documentation such as: patient's history, current condition

I am requesting this coverage because <<insert summary of professional opinion of the patient's likely prognosis or disease progression without treatment with Opdualag>>. Please see attached documents to support my clinical findings.

In view of the above information, I believe treatment with Opdualag is medically necessary for my patient. Please contact me at <<physician's phone number>> or via email at <<physician's email>> should you have questions or need additional information.

Thank you for your time and immediate attention to this request.

Sincerely,

<<Provider name, contact information, and signature>>

Enclosures: <<List and attach additional documents to support your treatment rationale>>