



# Opdivo® (nivolumab) Injectable Medication Precertification Request

Page 1 of 6

(All fields must be completed and legible for precertification review.)

Aetna Precertification Notification  
Phone: **1-866-752-7021** (TTY: **711**)  
FAX: **1-888-267-3277**

**For Medicare Advantage Part B:**  
Please Use Medicare Request Form

**Please indicate:** ☐ Start of treatment: Start date \_\_\_\_ / \_\_\_\_ / \_\_\_\_  
☐ Continuation of therapy: Date of last treatment \_\_\_\_ / \_\_\_\_ / \_\_\_\_

**Precertification Requested By:** \_\_\_\_\_ **Phone:** \_\_\_\_\_ **Fax:** \_\_\_\_\_

## A. PATIENT INFORMATION

First Name:		Last Name:	
Address:		City:	State: ZIP:
Home Phone:	Work Phone:	Cell Phone:	
DOB:	Allergies:	Email:	
Current Weight: _____ lbs or _____ kgs		Height: _____ inches or _____ cms	

## B. INSURANCE INFORMATION

Aetna Member ID #: _____	Does patient have other coverage? <input type="checkbox"/> Yes <input type="checkbox"/> No
Group #: _____	If yes, provide ID#: _____ Carrier Name: _____
Insured: _____	Insured: _____
Medicare: <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, provide ID #: _____	Medicaid: <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, provide ID #: _____

## C. PRESCRIBER INFORMATION

First Name:		Last Name:		(Check One): <input type="checkbox"/> M.D. <input type="checkbox"/> D.O. <input type="checkbox"/> N.P. <input type="checkbox"/> P.A.	
Address:		City:	State:	ZIP:	
Phone:	Fax:	St Lic #:	NPI #:	DEA #:	UPIN:
Provider Email:		Office Contact Name:		Phone:	
Specialty (Check one): <input type="checkbox"/> Oncologist <input type="checkbox"/> Hematologist <input type="checkbox"/> Other: _____					

## D. DISPENSING PROVIDER/ADMINISTRATION INFORMATION

<b>Place of Administration:</b> <input type="checkbox"/> Self-administered <input type="checkbox"/> Physician's Office <input type="checkbox"/> Outpatient Infusion Center Phone: _____ Center Name: _____ <input type="checkbox"/> Home Infusion Center Phone: _____ Agency Name: _____ <input type="checkbox"/> Administration code(s) (CPT): _____ Address: _____	<b>Dispensing Provider/Pharmacy:</b> <i>Patient Selected choice</i> <input type="checkbox"/> Physician's Office <input type="checkbox"/> Retail Pharmacy <input type="checkbox"/> Specialty Pharmacy <input type="checkbox"/> Other _____ Name: _____ Address: _____ Phone: _____ Fax: _____ TIN: _____ PIN: _____
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## E. PRODUCT INFORMATION

**Request is for: Opdivo (nivolumab) Dose:** \_\_\_\_\_ **Frequency:** \_\_\_\_\_

If used in combination with Yervoy (ipilimumab), please indicate the dosage and instructions for Yervoy (ipilimumab) (Please note: Separate form request for Yervoy (ipilimumab) is NOT needed if dosing and instructions are documented here): \_\_\_\_\_

## F. DIAGNOSIS INFORMATION – Please indicate primary ICD Code and specify any other where applicable.

Primary ICD Code: \_\_\_\_\_ Secondary ICD Code: \_\_\_\_\_ Other ICD Code: \_\_\_\_\_

## G. CLINICAL INFORMATION – Required clinical information must be completed in its entirety for all precertification requests.

### For All Requests (clinical documentation required):

Please list **all** additional medications that will be used as part of this treatment regimen (This includes supportive care agents such as anti-emetics, growth factors, etc.)  
A copy of the complete order may be submitted in lieu of listing out each treatment:

Medication: _____	Dose: _____	Frequency: _____
Medication: _____	Dose: _____	Frequency: _____
Medication: _____	Dose: _____	Frequency: _____
Medication: _____	Dose: _____	Frequency: _____
Medication: _____	Dose: _____	Frequency: _____
Medication: _____	Dose: _____	Frequency: _____

☐ Yes ☐ No Has the patient experienced disease progression while receiving another programmed death receptor-1 (PD-1) or programmed death ligand 1 (PD-L1) inhibitor [e.g., Opdivo (nivolumab), Keytruda (pembrolizumab), Tecentriq (atezolizumab), Bavencio (avelumab), Imfinzi (durvalumab)]?

→ ☐ Yes ☐ No Is the requested drug prescribed as second-line or subsequent treatment for metastatic or unresectable melanoma?

→ ☐ Yes ☐ No Will the requested drug be used in combination with ipilimumab (Yervoy) following disease progression on single agent anti-PD-1 immunotherapy?

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**G. CLINICAL INFORMATION (continued)** – Required clinical information must be completed in its entirety for all precertification requests.

☐ **Ampullary adenocarcinoma**

- ☐ Yes ☐ No Will the requested drug be used in combination with ipilimumab (Yervoy)?  
☐ Yes ☐ No Is the tumor microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)?  
Please select the clinical setting in which the requested drug will be used:  
☐ Progressive disease ☐ Unresectable disease ☐ Metastatic disease ☐ Other

☐ **Anal carcinoma**

- ☐ Yes ☐ No Will the requested drug be used as a single agent?  
Please indicate the clinical setting in which the requested drug will be used: ☐ Metastatic disease ☐ Other  
What is the place in therapy in which the requested drug will be used? ☐ First-line treatment ☐ Subsequent treatment

☐ **Biliary Tract Cancer (Cholangiocarcinoma and Gallbladder Cancer)**

- ☐ Yes ☐ No Will the requested drug be used in combination with ipilimumab (Yervoy)?  
Please indicate the place in therapy in which the requested drug will be used: ☐ First-line treatment ☐ Subsequent treatment  
Please indicate the clinical setting in which the requested drug will be used: ☐ Unresectable gross residual (R2) disease ☐ Metastatic disease  
☐ Resected gross residual (R2) disease ☐ Progressive disease ☐ Other  
☐ Yes ☐ No ☐ Unknown Is the tumor mutation burden-high (TMB-H)?

☐ **Bladder cancer**

- ☐ Yes ☐ No Will the requested drug be used as a single agent?  
Please indicate the clinical setting in which the requested drug will be used: ☐ Locally advanced disease ☐ Metastatic disease ☐ Recurrent disease  
☐ Persistent disease ☐ High risk of recurrence after undergoing resection ☐ Other  
What is the place in therapy in which the requested drug will be used? ☐ First-line treatment ☐ Subsequent treatment ☐ Adjuvant treatment

☐ **Bone cancer**

- ☐ Yes ☐ No Will the requested drug be used in combination with ipilimumab (Yervoy)?  
Please indicate the clinical setting in which the requested drug will be used: ☐ Metastatic disease ☐ Unresectable disease ☐ Other  
☐ Yes ☐ No ☐ Unknown Is the tumor mutation burden-high (TMB-H) [ $\geq 10$  mutations/megabase (mut/Mb)] tumors?  
☐ Yes ☐ No Has the disease progressed following prior treatment?  
☐ Yes ☐ No Are there satisfactory alternative treatment options available for the patient's disease?

☐ **Central nervous system (CNS) brain metastases in patients with melanoma or non-small cell lung cancer**

Please select the requested drug regimen:

- ☐ Single agent  
    → Please indicate the type of underlying cancer the patient has:  
        ☐ Melanoma  
        ☐ Non-small cell lung cancer  
            → ☐ Yes ☐ No ☐ Unknown Is the patient's disease positive for programmed death ligand 1 (PD-L1)?  
        ☐ Other

- ☐ In combination with ipilimumab (Yervoy)  
    → Please indicate the type of underlying cancer the patient has: ☐ Melanoma ☐ Non-small cell lung cancer ☐ Other  
☐ Other

☐ **Cervical cancer**

- ☐ Yes ☐ No Will the requested drug be used as a single agent?  
Please indicate the clinical setting in which the requested drug will be used: ☐ Recurrent disease ☐ Metastatic disease ☐ Other  
What is the place in therapy in which the requested drug will be used? ☐ First-line treatment ☐ Subsequent treatment  
☐ Yes ☐ No ☐ Unknown Is the patient's disease positive for programmed death ligand 1 (PD-L1) (combined positive score [CPS]  $\geq 1$ )?

☐ **Classical Hodgkin lymphoma (cHL)**

- Please indicate the clinical setting in which the requested drug will be used:  
☐ Relapsed disease ☐ Progressive disease ☐ Refractory disease ☐ Other  
☐ Yes ☐ No Will the requested drug be used as a single agent, in combination with brentuximab vedotin or in combination with ICE (ifosfamide, carboplatin, etoposide)?  
    → What is the place in therapy in which the requested drug will be used? ☐ Palliative therapy ☐ Subsequent therapy ☐ Other  
    Which of the following applies to the patient's disease?  
        ☐ The patient has received high-dose therapy and autologous stem cell rescue (HDT/ASCR) ☐ The patient is transplant ineligible  
        ☐ The patient has been either heavily pretreated or there was a decrease in cardiac function ☐ The patient is post-allogeneic transplant ☐ Other  
    → ☐ Single agent  
        → ☐ Yes ☐ No Is the disease refractory to at least three lines of prior therapy?  
        ☐ In combination with brentuximab vedotin ☐ In combination with ICE (ifosfamide, carboplatin, etoposide)

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**G. CLINICAL INFORMATION (continued)** – Required clinical information must be completed in its entirety for all precertification requests.

☐ **Colorectal cancer (including appendiceal adenocarcinoma and anal adenocarcinoma)**

☐ Yes ☐ No ☐ Unknown Is the tumor microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)?

Please indicate the clinical setting in which the requested drug will be used:

☐ Inoperable disease ☐ Unresectable disease ☐ Metastatic disease ☐ Advanced disease ☐ Other

Please indicate the regimen: ☐ Single agent ☐ In combination with ipilimumab (Yervoy) ☐ Other

☐ **Cutaneous melanoma**

Please select the requested drug regimen: ☐ Single agent ☐ In combination with ipilimumab (Yervoy) (4 doses of ipilimumab, followed by Opdivo as a single agent) ☐ Other

Please indicate how the requested drug will be used: ☐ Treatment of metastatic disease ☐ Treatment of locally recurrent disease ☐ Treatment of progressive disease ☐ Treatment of unresectable disease

☐ Adjuvant treatment

→ Please indicate the clinical setting in which the requested drug will be used:

☐ Stage III to IV disease

→ ☐ Yes ☐ No Will the requested drug be used following complete resection or no evidence of disease?

☐ Stage IIB and IIC

→ ☐ Yes ☐ No Will the requested drug be used following complete resection?

☐ Other

☐ **Endometrial carcinoma**

☐ Yes ☐ No ☐ Unknown Is the tumor microsatellite-instability high (MSI-H) or mismatch repair deficient (dMMR)?

Please indicate the clinical setting in which the requested drug will be used: ☐ Recurrent disease ☐ Metastatic disease ☐ Other

What is the place in therapy in which the requested drug will be used? ☐ First-line therapy ☐ Subsequent therapy

☐ **Esophageal and esophagogastric junction carcinoma**

☐ Yes ☐ No Will the requested drug be used as adjuvant treatment of completely resected esophageal or gastroesophageal junction cancer?

→ Please select the clinical setting in which the requested drug will be used:

☐ Patient is not a surgical candidate ☐ Unresectable locally advanced disease ☐ Recurrent disease ☐ Metastatic disease

→ What is the place in therapy in which the requested drug will be used?

☐ First-line therapy

☐ Subsequent therapy

→ Please indicate the requested regimen: ☐ In combination with ipilimumab (Yervoy) ☐ In combination with fluoropyrimidine and platinum containing chemotherapy ☐ Other

☐ Neoadjuvant treatment OR ☐ Perioperative treatment

→ ☐ Yes ☐ No Will the requested drug be used to treat esophageal or esophagogastric junction adenocarcinoma?

☐ Yes ☐ No ☐ Unknown Is the tumor microsatellite-instability high (MSI-H) or mismatch repair deficient (dMMR)?

☐ Yes ☐ No Is the patient medically fit for surgery?

Please indicate the requested regimen: ☐ Single agent ☐ In combination with ipilimumab (Yervoy) ☐ Other

☐ Other

☐ **Extranodal NK/T-cell lymphoma**

Please select the clinical setting in which the requested drug will be used:

☐ Relapsed disease ☐ Refractory disease ☐ Other

☐ **Gastric cancer**

Please select the clinical setting in which the requested drug will be used:

☐ Patient is not a surgical candidate ☐ Unresectable locally advanced disease ☐ Recurrent disease ☐ Metastatic disease

→ ☐ Yes ☐ No Will the requested drug be used in combination with ipilimumab (Yervoy) or chemotherapy?

☐ Neoadjuvant treatment OR ☐ Perioperative treatment

☐ Yes ☐ No Will the requested drug be used to treat gastric adenocarcinoma?

☐ Yes ☐ No ☐ Unknown Is the tumor microsatellite-instability high (MSI-H) or mismatch repair deficient (dMMR)?

☐ Yes ☐ No Is the patient medically fit for surgery?

Please indicate the requested regimen: ☐ Single agent ☐ In combination with ipilimumab (Yervoy) ☐ Other

☐ Other

☐ **Gestational Trophoblastic Neoplasia**

☐ Yes ☐ No Will the requested drug be used as a single agent?

☐ Yes ☐ No Is the disease resistant to multi-agent chemotherapy?

Please select which of the following applies to the patient's disease:

☐ Recurrent intermediate trophoblastic tumor (placental site trophoblastic tumor or epithelioid trophoblastic tumor)

→ ☐ Yes ☐ No Has the patient had treatment with platinum-based regimen (e.g., cisplatin, carboplatin)?

☐ High-risk disease

☐ Other

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**G. CLINICAL INFORMATION (continued)** – Required clinical information must be completed in its entirety for all precertification requests.

- ☐ In combination with ipilimumab (Yervoy)  
→ What is the patient's histology? ☐ Clear cell ☐ Non-clear cell  
What is the place in therapy in which the requested drug will be used?  
☐ First-line treatment  
→ What is the patient's risk status? ☐ Poor risk ☐ Intermediate risk ☐ Favorable risk  
☐ Subsequent treatment  
☐ In combination with cabozantinib  
☐ Other
- ☐ **Small bowel adenocarcinoma**  
Please identify the requested drug regimen: ☐ Single agent ☐ In combination with ipilimumab (Yervoy) ☐ Other  
Please indicate the clinical setting in which the requested drug will be used: ☐ Advanced disease ☐ Metastatic disease ☐ Other  
☐ Yes ☐ No ☐ Unknown Is the tumor microsatellite-instability high (MSI-H) or mismatch repair deficient (dMMR)?
- ☐ **Small Cell Lung Cancer**  
Please select the clinical setting in which the requested drug will be used: ☐ Relapsed disease ☐ Progressive disease ☐ Other  
What is the place in therapy in which the requested drug will be used? ☐ First-line treatment ☐ Subsequent treatment  
☐ Yes ☐ No Will the requested drug be used as a single agent?
- ☐ **Soft Tissue Sarcoma**  
Please indicate sarcoma type: ☐ Extremity/body wall sarcomas ☐ Head/neck sarcomas ☐ Retroperitoneal/intra-abdominal sarcomas  
☐ Rhabdomyosarcoma ☐ Angiosarcoma ☐ Other  
Please identify the requested drug regimen: ☐ Single agent ☐ In combination with ipilimumab (Yervoy) ☐ Other
- ☐ **Upper Genitourinary tract tumor**  
☐ Yes ☐ No Will the requested drug be given as a single agent?  
Please indicate the place in therapy in which the requested drug will be used: ☐ First-line treatment ☐ Subsequent treatment ☐ Adjuvant treatment  
Please indicate the clinical setting in which the requested drug will be used: ☐ Locally advanced disease ☐ Metastatic disease  
☐ High risk of recurrence after undergoing resection ☐ Other
- ☐ **Urothelial carcinoma of the prostate**  
☐ Yes ☐ No Will the requested drug be given as a single agent?  
Please indicate the place in therapy in which the requested drug will be used: ☐ First-line treatment ☐ Subsequent treatment ☐ Adjuvant treatment  
Please indicate the clinical setting in which the requested drug will be used: ☐ Locally advanced disease ☐ Metastatic disease  
☐ High risk of recurrence after undergoing resection ☐ Other
- ☐ **Uveal Melanoma**  
Please indicate the clinical setting in which the requested drug will be used: ☐ Metastatic disease ☐ Unresectable disease ☐ Other  
Please identify the requested drug regimen: ☐ Single agent ☐ In combination with ipilimumab (Yervoy) ☐ Other
- ☐ **Vulvar cancer**  
Please indicate the clinical setting in which the requested drug will be used:  
☐ Advanced disease ☐ Recurrent disease ☐ Metastatic disease ☐ Other  
☐ Yes ☐ No Is the disease HPV-related?  
Please indicate the place in therapy in which the requested drug will be used: ☐ First-line treatment ☐ Subsequent treatment  
☐ Yes ☐ No Will the requested drug be given as a single agent?

**For Continuation Requests (clinical documentation required):**

- ☐ Yes ☐ No Is there evidence of disease progression or unacceptable toxicity while on the current regimen?
- ☐ Yes ☐ No Is this infusion request in an outpatient hospital setting?  
→ ☐ Yes ☐ No Is the patient continuing on a maintenance regimen that includes provider administered combination chemotherapy?  
→ Please indicate the regimen:  
☐ Opdivo used in combination with Yervoy for non-small cell lung cancer (NSCLC)  
☐ Other, Please explain: \_\_\_\_\_
- ☐ Yes ☐ No Is the patient experiencing severe toxicity requiring continuous monitoring (e.g. Grade 2-4 bullous dermatitis, transaminitis, pneumonitis, Stevens-Johnson syndrome, acute pancreatitis, primary adrenal insufficiency aseptic meningitis, encephalitis, transverse myelitis, myocarditis, pericarditis, arrhythmias, impaired ventricular function, conduction abnormalities)?  
→ Please explain: \_\_\_\_\_
- ☐ Yes ☐ No Has the patient experienced an adverse event with the requested product that has not responded to conventional interventions (e.g., acetaminophen, steroids, diphenhydramine, fluids, other pre-medications or slowing of infusion rate) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion?  
→ Please explain: \_\_\_\_\_
- ☐ Yes ☐ No Does the patient have severe venous access issues that require the use of special interventions only available in the outpatient hospital setting?  
→ Please explain: \_\_\_\_\_

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**G. CLINICAL INFORMATION (continued)** – Required clinical information must be completed in its entirety for all precertification requests.

- ☐ Yes ☐ No Does the patient have significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND the patient does not have access to a caregiver?  
→ Please explain: \_\_\_\_\_
- ☐ Yes ☐ No Is the patient medically unstable which may include respiratory, cardiovascular, or renal conditions that may limit the member's ability to tolerate a large volume or load or predispose the member to a severe adverse event that cannot be managed in an alternate setting without appropriate medical personnel and equipment?  
→ Please provide a description of the condition:  
☐ Cardiopulmonary: \_\_\_\_\_  
☐ Respiratory: \_\_\_\_\_  
☐ Renal: \_\_\_\_\_  
☐ Other: \_\_\_\_\_
- ☐ Yes ☐ No Is the patient within the initial 6 months of starting therapy?  
→ Please indicate how many continuous months of treatment the patient has received with the requested drug: \_\_\_\_\_

**For cutaneous melanoma or urothelial carcinoma only:**

- ☐ Yes ☐ No Is this request for adjuvant treatment of cutaneous melanoma or urothelial carcinoma?  
→ Please provide the initial start date of requested drug adjuvant therapy: \_\_\_\_/\_\_\_\_/\_\_\_\_  
How many continuous months of adjuvant treatment has the patient received? \_\_\_\_\_
- ☐ Yes ☐ No Is there evidence of disease recurrence or unacceptable toxicity on the current regimen?

**For esophageal cancer and esophagogastric junction carcinoma:**

Please indicate which of the following applies to the patient's disease:

- ☐ Esophageal squamous cell carcinoma in combination with ipilimumab  
→ Please indicate how many continuous months of treatment the patient has received with the requested drug: \_\_\_\_\_
- ☐ Esophageal squamous cell carcinoma in combination with chemotherapy  
→ Please indicate how many continuous months of treatment the patient has received with the requested drug: \_\_\_\_\_
- ☐ Unresectable advanced esophageal squamous cell carcinoma single agent treatment
- ☐ Recurrent esophageal squamous cell carcinoma single agent treatment
- ☐ Metastatic esophageal squamous cell carcinoma single agent treatment
- ☐ Resected esophageal cancer used as a single agent adjuvant treatment  
→ Please indicate how many continuous months of treatment the patient has received with the requested drug: \_\_\_\_\_
- ☐ Resected esophagogastric junction cancer used as a single adjuvant agent treatment  
→ Please indicate how many continuous months of treatment the patient has received with the requested drug: \_\_\_\_\_
- ☐ Esophagogastric junction cancer in combination with chemotherapy  
→ Please indicate how many continuous months of treatment the patient has received with the requested drug: \_\_\_\_\_
- ☐ Esophageal adenocarcinoma in combination with chemotherapy  
→ Please indicate how many continuous months of treatment the patient has received with the requested drug: \_\_\_\_\_
- ☐ Other

**For gastric cancer only:**

- ☐ Yes ☐ No Will the requested drug be used in combination with chemotherapy?  
→ Please indicate how many continuous months of treatment the patient has received with the requested drug: \_\_\_\_\_

**For non-small cell lung cancer and malignant pleural mesothelioma, including pericardial mesothelioma and tunica vaginalis testis mesothelioma only:**

- ☐ Yes ☐ No Will the requested drug be used in combination with Yervoy (ipilimumab) or in combination with platinum-doublet chemotherapy?  
→ Please indicate how many continuous months of treatment the patient has received with the requested drug: \_\_\_\_\_

**For renal cell carcinoma only:**

- ☐ Yes ☐ No Will the requested drug be used in combination with cabozantinib?  
→ Please indicate how many continuous months of treatment the patient has received with the requested drug: \_\_\_\_\_

**H. ACKNOWLEDGEMENT**

**Request Completed By (Signature Required):** \_\_\_\_\_ **Date:** \_\_\_\_/\_\_\_\_/\_\_\_\_

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties.

The plan may request additional information or clarification, if needed, to evaluate requests.