Opdivo® (nivolumab) Injectable Medication Precertification Request

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

Aetna Precertification Notification
Phone: 1-866-752-7021
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 #: _____
Group #: _____
Insured: _____

Does patient have other coverage? ☐ Yes ☐ No
If yes, provide ID#: _____ Carrier Name: _____
Insured: _____

Medicare: ☐ Yes ☐ No If yes, provide ID #: _____ **Medicaid**: ☐ Yes ☐ No If yes, provide ID #: _____

C. PRESCRIBER INFORMATION

First Name:	Last Name: *(Check One):* ☐ M.D. ☐ D.O. ☐ N.P. ☐ P.A.				
Address:	City:	State:	ZIP:		
Phone:	Fax:	St Lic #:	NPI #:	DEA #:	UPIN:
Provider Email:	Office Contact Name:	Phone:			

Specialty *(Check one):* ☐ **Oncologist** ☐ **Hematologist** ☐ **Other**: _____

D. DISPENSING PROVIDER/ADMINISTRATION INFORMATION

Place of Administration:
☐ Self-administered ☐ Physician's Office
☐ Outpatient Infusion Center Phone: _____
Center Name: _____
☐ Home Infusion Center Phone: _____
Agency Name: _____
☐ Administration code(s) (CPT): _____
Address: _____

Dispensing Provider/Pharmacy: *Patient Selected choice*
☐ Physician's Office ☐ Retail Pharmacy
☐ Specialty Pharmacy ☐ Other _____
Name: _____
Address: _____
Phone: _____ Fax: _____
TIN: _____ PIN: _____

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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☐ **Ampullary adenocarcinoma**
- ☐ Yes ☐ No Will the requested drug be used in combination with ipilimumab?
- ☐ 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, please identify: _____
- What is the place in therapy in which the requested drug will be used? ☐ First-line treatment ☐ Subsequent treatment

☐ **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

☐ **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 Yervoy (ipilimumab)
  - → Please indicate the type of underlying cancer the patient has: ☐ Melanoma ☐ Non-small cell lung cancer ☐ Other
- ☐ Other, please explain: _____

☐ **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:
- ☐ Persistent disease ☐ 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] ≥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 in combination with brentuximab vedotin?
  - → 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 heavily pretreated or there was a decrease in cardiac function
    - ☐ The patient is post-allogeneic transplant
    - ☐ Other

☐ **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 ☐ Other

☐ **Cutaneous melanoma**
- Please select the requested drug regimen: ☐ Single agent ☐ In combination with Yervoy (ipilimumab) ☐ Other
- Please indicate how the requested drug will be used:
- ☐ Adjuvant treatment
  - → ☐ Yes ☐ No Has the patient had a complete resection or no evidence of disease?
  - ☐ 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: ☐ Stage III disease ☐ Stage IV disease ☐ Other
- ☐ Treatment of metastatic disease
- ☐ Treatment of locally recurrent disease
- ☐ Treatment of unresectable disease

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☐ **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 medication be used as postoperative therapy following preoperative chemoradiation and complete tumor resection?
  - → Please indicate the patient's histology:
    - ☐ Squamous cell carcinoma
      - → What is the place in therapy in which the requested drug will be used?
        - ☐ First-line treatment
          - → Please select the clinical setting in which the requested drug will be used:
            ☐ Unresectable advanced disease ☐ Metastatic disease ☐ Other
            Please indicate the regimen: ☐ In combination with ipilimumab ☐ In combination with fluoropyrimidine- and platinum-containing chemotherapy (e.g., cisplatin, carboplatin) ☐ Other
        - ☐ Subsequent treatment
          - → Please select the clinical setting in which the requested drug will be used:
            ☐ Unresectable advanced disease ☐ Recurrent disease ☐ Metastatic disease ☐ Other
    - ☐ Adenocarcinoma
      - → 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 ☐ Other
        ☐ Yes ☐ No Will the requested medication be used in combination with chemotherapy?
  - → ☐ Yes ☐ No Does the patient have residual pathologic disease?

☐ **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 ☐ Other
- ☐ Yes ☐ No Will the requested drug be used in combination with chemotherapy?

☐ **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)?
    - → Name: _____ Dates: ____/____/____ to ____/____/____
- ☐ Progressive 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)?
    - → Name: _____ Dates: ____/____/____ to ____/____/____
- ☐ High-risk disease
- ☐ Other, please identify: _____

☐ **Head and neck cancers**
- Please select the clinical setting in which the requested drug will be used:
  ☐ Unresectable disease ☐ Recurrent disease ☐ Metastatic disease ☐ Other
- Which of the following applies to the patient's disease?
  - ☐ Non-nasopharyngeal cancer
    - → Please indicate the place in therapy in which the requested drug will be used: ☐ First-line treatment ☐ Subsequent treatment
  - ☐ Nasopharyngeal cancer
    - → ☐ Yes ☐ No Will the requested drug be used in combination with cisplatin and gemcitabine?

☐ **Hepatocellular carcinoma**
- Please select the requested drug regimen: ☐ In combination with Yervoy (ipilimumab)
  ☐ Other, please specify: _____
- Please indicate the place in therapy in which the requested drug will be used: ☐ First-line treatment ☐ Subsequent treatment

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☐ **Kaposi sarcoma**
- Please indicate the type: ☐ Classic Kaposi sarcoma ☐ Other
- ☐ 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 therapy ☐ Subsequent treatment
- Please select the clinical setting in which the requested drug will be used: ☐ Relapsed/refractory disease ☐ Other

☐ **Malignant pleural or peritoneal mesothelioma, including pericardial mesothelioma and tunica vaginalis testis mesothelioma**
- What is the place in therapy in which the requested drug will be used? ☐ First-line therapy ☐ Subsequent therapy
- Please select the requested drug regimen: ☐ Single agent ☐ In combination with Yervoy (ipilimumab) ☐ Other

☐ **Merkel Cell Carcinoma**
- Please indicate the clinical setting in which the requested drug will be used:
- ☐ Node positive disease
  - → ☐ Yes ☐ No Will the requested drug be used as neoadjuvant treatment?
- ☐ Metastatic disease
- ☐ Other, please specify: _____

☐ **Non-small cell lung cancer (NSCLC)**
- Please indicate the clinical setting in which the requested drug will be used:
- ☐ Recurrent disease ☐ Advanced disease ☐ Metastatic disease ☐ Resectable disease ☐ Other
- Please indicate the requested regimen:
- ☐ As a single agent
  - → Please indicate the place in therapy in which the requested drug will be used: ☐ First-line treatment ☐ Subsequent treatment
- ☐ In a regimen containing ipilimumab
  - → ☐ Yes ☐ No ☐ Unknown Are there no EGFR exon 19 deletions or L858R mutations or ALK rearrangements?
    - → ☐ Yes ☐ No Is testing for these genomic tumor aberrations not feasible due to insufficient tissue?
- ☐ In combination with platinum-doublet chemotherapy (e.g., docetaxel and cisplatin)
  - → ☐ Yes ☐ No Will the requested drug be used as neoadjuvant treatment?
- ☐ Other

☐ **Pediatric Diffuse High-Grade Gliomas**
- Please indicate the clinical setting in which the requested drug will be used:
- ☐ As adjuvant treatment ☐ Recurrent disease ☐ Progressive disease ☐ Other, please explain: _____
- ☐ Yes ☐ No Is the tumor hypermutant?

☐ **Primary carcinoma of the urethra**
- ☐ 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:
- ☐ Recurrent disease ☐ Locally advanced disease ☐ Metastatic disease ☐ High risk of recurrence after undergoing resection
- ☐ Other, please explain: _____

☐ **Renal cell carcinoma**
- Please indicate patient's disease state: ☐ Relapsed disease ☐ Advanced disease ☐ Stage IV disease ☐ Other, please identify: _____
- Please select how the requested drug will be used:
- ☐ Single agent
  - → ☐ Yes ☐ No Does the patient have documentation of predominant clear cell histology?
    - → ☐ Yes ☐ No Does the patient have documentation of non-clear cell histology?
      - → What is the place in therapy in which the requested drug will be used? ☐ First-line treatment ☐ Subsequent treatment
- ☐ In combination with ipilimumab
  - → 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, please explain: _____

☐ **Small bowel adenocarcinoma**
- Please identify the requested drug regimen: ☐ Single agent ☐ In combination with Yervoy (ipilimumab) ☐ Other, please specify: _____
- Please indicate the clinical setting in which the requested drug will be used:
- ☐ Advanced disease ☐ Metastatic disease ☐ Other, please explain: _____
- ☐ Yes ☐ No ☐ Unknown Is the tumor microsatellite-instability high (MSI-H) or mismatch repair deficient (dMMR)?

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☐ **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?

☐ **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, please explain: _____

☐ **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, please explain: _____

☐ **Uveal Melanoma**
Please indicate the clinical setting in which the requested drug will be used: ☐ Distant metastatic disease ☐ Other, please explain: _____
Please identify the requested drug regimen: ☐ Single agent ☐ In combination with Yervoy (ipilimumab)
☐ Other, please specify: _____

☐ **Vulvar squamous cell carcinoma**
Please indicate the clinical setting in which the requested drug will be used:
☐ Advanced disease ☐ Recurrent disease ☐ Metastatic disease ☐ Other, please explain: _____
☐ 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: _____
☐ 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: _____

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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 only and malignant or peritoneal 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.