OKLAHOMA Health Care Authority

State of Oklahoma
SoonerCare
Opdivo® (Nivolumab) Prior Authorization Form

Member Name:_____ Date of Birth:_____ Member ID#:_____

Drug Information

Physician billing (HCPCS code:_____) Start Date (or date of next dose):_____

Current weight:_____ (kg) Dose:_____ Dosing Regimen:_____

Billing Provider Information

Provider NPI:_____ Provider Name:_____

Provider Phone:_____ Provider Fax: _____

Prescriber Information

Prescriber NPI:_____ Prescriber Name:_____

Prescriber Phone:_____ Prescriber Fax:_____Specialty:_____

Criteria

Page 1 of 3—Please complete and return <u>all</u> pages. *Failure to complete all pages will result in processing delays*.

Please note: If Opdivo® (nivolumab) is to be used in combination with Yervoy® (ipilimumab), please completely fill out and submit the Yervoy® (ipilimumab) prior authorization form (PHARM-66) that is available at: **https://oklahoma.gov/ohca/rxforms.html**

For Initial Authorization (Initial approval will be for the duration of 6 months):

1. Please indicate the requested information:
   - A. Has the member previously failed PD-1/PD-L1 inhibitors? Yes☐ No☐
   - B. Will nivolumab be used as a single-agent? Yes☐ No☐
   - C. Will nivolumab be used in combination with Yervoy® (ipilimumab)? Yes☐ No☐
   - D. Please indicate member's ECOG performance status:_____
2. Please indicate the diagnosis and information:

☐ **Unresectable or Metastatic Melanoma**
- A. Will nivolumab be used as first-line therapy for untreated melanoma? Yes☐ No☐
- B. Will nivolumab be used as second-line or subsequent therapy for documented disease progression while receiving or since completing most recent therapy? Yes☐ No☐

☐ **Adjuvant treatment of melanoma**
- A. Has member had complete resection of melanoma? Yes☐ No☐
- B. Is diagnosis stage 2B, 2C, 3 or 4 melanoma following complete resection ? Yes☐ No☐

☐ **Hodgkin Lymphoma**
- A. Is diagnosis relapsed or refractory classical Hodgkin lymphoma? Yes☐ No☐
- B. Is diagnosis lymphocyte-predominant Hodgkin lymphoma? Yes☐ No☐
- C. Will nivolumab be used in combination with brentuximab vedotin as second line or subsequent therapy after failure of autologous stem cell transplant (SCT), allogenic SCT, or those who are transplant-ineligible? Yes☐ No☐

☐ **Recurrent or Metastatic Head and Neck Cancer**
- A. Histology: ☐Squamous Cell ☐Other: _____
- B. Has member previously received platinum-containing chemotherapy (cisplatin or carboplatin)? Yes☐ No☐

☐ **Esophageal Squamous Cell Carcinoma (ESCC) or Esophageal or Gastroesophageal Junction (GEJ) Cancer**
- A. **For a diagnosis of ESCC:**
  - i. Is disease unresectable advanced or metastatic? Yes☐ No☐
  - ii. Will nivolumab be used as first-line therapy? Yes☐ No☐
  - iii. Will nivolumab be used in combination with fluoropyrimidine- and platinum-based chemotherapy? Yes☐ No☐
- B. **For a diagnosis of esophageal or GEJ:**
  - i. Has member received preoperative chemoradiation? Yes☐ No☐
  - ii. Has member undergone R0 (complete) resection and has residual disease? Yes☐ No☐

PLEASE PROVIDE THE INFORMATION REQUESTED AND RETURN TO:	CONFIDENTIALITY NOTICE
University of Oklahoma College of Pharmacy Pharmacy Management Consultants Product Based Prior Authorization Unit Fax: 1-800-224-4014 Phone: 1-800-522-0114 Option 4	*This document, including any attachments, contains information which is confidential or privileged. If you are not the intended recipient, be aware that any disclosure, copying, distribution, or use of the contents of this information is prohibited. If you have received this document in error, please notify the sender immediately by telephone to arrange for the return of the transmitted documents or to verify their destruction.*

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Page 2 of 3—Please complete and return all pages. Failure to complete all pages will result in processing delays.

2. Please indicate the diagnosis and information, continued:

C. **For use as palliative therapy (Esophageal Squamous Cell Carcinoma (ESCC) or Esophageal or Gastroesphageal Junction (GEJ) Cancer**
- i. Is member a surgical candidate? Yes☐ No☐
- ii. Is disease unresectable locally advanced, recurrent, or metastatic? Yes☐ No☐
- iii. Is disease human epidermal receptor 2 (HER2) negative? Yes☐ No☐
  - a. Histology: ☐Adenocarcinoma ☐Squamous Cell ☐Other: _____
    1. If adenocarcinoma, will nivolumab be used as first-line therapy in combination with oxaliplatin and fluorouracil or capecitabine? Yes☐ No☐
    2. If squamous cell, will nivolumab be used as second-line or greater therapy? Yes☐ No☐

☐ **Gastric Cancer**
- A. Is diagnosis advanced or metastatic disease? Yes☐ No☐
- B. Will nivolumab be used in combination with fluoropyrimidine- and platinum- containing chemotherapy [e.g., folinic acid, fluorouracil, and oxaliplatin (FOLFOX) or capecitabine and oxaliplatin (CapeOX)]? Yes☐ No☐

☐ **Mesothelioma**
- A. Is diagnosis malignant pleural mesothelioma that cannot be surgically removed? Yes☐ No☐
- B. Will nivolumab be used as first-line therapy? Yes☐ No☐

☐ **Small Cell Lung Cancer**
- A. Did disease relapse within 6 months of initial chemotherapy? Yes☐ No☐
- B. Is disease progressive on initial chemotherapy? Yes☐ No☐

☐ **Non-Small Cell Lung Cancer (NSCLC)**
- A. For **first-line** therapy:
  - i. Is diagnosis recurrent, advanced, or metastatic disease? Yes☐ No☐
    1. Epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations? Yes☐ No☐
    2. Does tumor express PD-L1 ≥1%? Yes☐ No☐
    3. Will nivolumab be given in combination with 2 cycles of platinum-doublet chemotherapy? Yes☐ No☐
  - ii. Is disease resectable (>4cm or node positive)? Yes☐ No☐
    1. Will nivolumab be used in the neoadjuvant setting in combination with platinum-doublet chemotherapy for up to 3 treatment cycles? Yes☐ No☐
- B. For **second-line** therapy:
  - i. Is diagnosis metastatic disease? Yes☐ No☐
  - ii. Histology: ☐Adenocarcinoma ☐Squamous Cell ☐Large Cell ☐Other:_____
  - iii. Will nivolumab be used following disease progression on or after platinum-containing chemotherapy (cisplatin or carboplatin)? Yes☐ No☐

☐ **Hepatocellular Carcinoma**
- A. Does member have unresectable disease and is not a candidate for transplant? Yes☐ No☐
- B. Does member have metastatic disease or extensive liver tumor burden? Yes☐ No☐
  - i. Will nivolumab be used as first-line therapy? Yes☐ No☐
    - a. Is member ineligible for tyrosine kinase inhibitors or anti-angiogenic agents? Yes☐ No☐
  - ii. Will nivolumab be used as second-line or greater therapy? Yes☐ No☐
    - a. Has member failed other checkpoint inhibitors? Yes☐ No☐

☐ **Renal Cell Cancer monotherapy**
- A. Is diagnosis relapsed or surgically unresectable stage IV disease? Yes☐ No☐
- B. Has member previously failed sunitinib, sorafenib, pazopanib, or axitinib? Yes☐ No☐

☐ **Renal Cell Cancer for use in combination with ipilumumab or cabozantinib**
- A. Is diagnosis relapsed or surgically unresectable stage IV disease in the initial treatment of a member with previously untreated advanced renal cell cancer? Yes☐ No☐
  - i. If answer to previous question is 'yes', please provide the following:
    - ☐ Intermediate risk
    - ☐ Poor risk
    - ☐ Other:_____

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☐ **Urothelial Bladder Cancer**
- A. Has member undergone radical resection? Yes☐ No☐
- B. Is disease at high risk of recurrence? Yes☐ No☐
- C. Is diagnosis metastatic or unresectable locally advanced cancer? Yes☐ No☐
  - i. If yes, is nivolumab being used as second-line or greater therapy? Yes☐ No☐
    - a. Has member previously failed a platinum-containing regimen? Yes☐ No☐
- D. Is diagnosis metastatic or unresectable urothelial carcinoma? Yes☐ No☐
  - i. If yes, is nivolumab being used as first-line therapy? Yes☐ No☐
  - ii. Will nivolumab be used in combination with cisplatin and gemcitabine? Yes☐ No☐

☐ **Colorectal Cancer**
- A. Is diagnosis unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer? Yes☐ No☐

☐ **If answer is none of the above, please indicate diagnosis:**_____

For Continued Authorization:

1. Date of last dose:_____
2. Does member have any evidence of progressive disease while on nivolumab? Yes☐ No☐
3. Has the member experienced any adverse drug reactions related to nivolumab therapy? Yes☐ No☐

Additional Information: _____

_____

_____

_____

Prescriber Signature:_____ Date:_____

I certify that the indicated treatment is medically necessary and all information is true and correct to the best of my knowledge. *Failure to complete this form in full will result in processing delays.*

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