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 2—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 III 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___

❑ **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____
- C. **For use as palliative therapy:**
  - 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____

<u>PLEASE PROVIDE THE INFORMATION REQUESTED AND RETURN TO:</u>

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

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

2. Please indicate the diagnosis and information, continued:

❑ **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:_____

❑ **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___

❑ **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____

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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