OKLAHOMA Health Care Authority

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

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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 doxorubicin, vinblastine, and dacarbazine (AVD) for primary systemic therapy in stage III-IV disease? Yes☐ No☐
- D. 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☐

Fax completed prior authorization request form to 888-601-8461 or submit Electronic Prior Authorization through CoverMyMeds® or SureScripts. All requesteddata must be provided. Incomplete forms or forms without the chart notes will be returned. Pharmacy Coverage Guidelines are available at AetnaBetterHealth.com/Oklahoma.

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2. Please indicate the diagnosis and information, continued:

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 (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☐
      a. Epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations? Yes☐ No☐
      b. Does tumor express PD-L1 ≥1%? Yes☐ No☐
      c. 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☐
      a. Will nivolumab be used in the neoadjuvant setting in combination with platinum-doublet chemotherapy for up to 3 treatment cycles? Yes☐ No☐

B. For **resectable disease** (tumors ≥4cm or node positive):
   i. Will nivolumab be used in the neoadjuvant setting in combination with platinum-doublet chemotherapy, followed by single-agent nivolumab as adjuvant treatment after surgery? Yes☐ No☐
   ii. Are there known EGFR mutations or ALK rearrangements? Yes☐ No☐

C. 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☐

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2. Please indicate the diagnosis and information, continued:

☐ **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☐
- 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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