

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 all 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 ___

(continued on next page)

PLEASE PROVIDE THE INFORMATION REQUESTED AND RETURN TO:

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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Criteria

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 Gastroesophageal 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 $\geq 1\%$? 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 ipilimumab 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 ___

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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