

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 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

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

Fax completed prior authorization request form to **888-601-8461** or submit Electronic Prior Authorization through CoverMyMeds® or SureScripts. All requested data 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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Member Name: _____ **Date of Birth:** _____ **Member ID#:** _____

Criteria

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 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: _____

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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