



State of Oklahoma SoonerCare

Opdivo[®] and Opdivo Qvantig[™] Prior Authorization Form (Nivolumab and Nivolumab/Hyaluronidase-nvhy)

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

Drug Information

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

Current weight: _____ (kg) Dose: _____ 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 4 - 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 requested product be used as a single-agent? Yes ___ No ___
 - C. Will requested product be used in combination with Yervoy[®] (ipilimumab)? Yes ___ No ___
 - D. Please indicate member's ECOG performance status: _____
2. Please indicate the diagnosis and information:
 - Cutaneous Melanoma**
 - A. Is diagnosis stage 2B, 2C, 3, or 4 melanoma following complete resection? Yes ___ No ___
 - B. Is diagnosis stage 3 disease with clinically positive nodes? Yes ___ No ___
 - i. If yes, will requested product be used as neoadjuvant therapy? Yes ___ No ___
 - C. Is diagnosis unresectable or metastatic melanoma? Yes ___ No ___
 - i. If yes, will requested product be used as first-line therapy for untreated melanoma? Yes ___ No ___
 - ii. Will requested product be used as second-line or subsequent therapy for documented disease progression while receiving or since completing most recent therapy? Yes ___ No ___
 - Renal Cell Cancer (RCC)**
 - A. **For monotherapy:**
 - i. Is diagnosis relapsed or surgically unresectable stage IV disease? Yes ___ No ___
 - ii. Has member previously failed sunitinib, sorafenib, pazopanib, or axitinib? Yes ___ No ___
 - B. **For use in combination with ipilimumab:**
 - i. Is diagnosis relapsed or surgically unresectable stage IV disease in the initial treatment of a member with intermediate or poor risk, previously untreated advanced RCC? Yes ___ No ___
 - C. **For use in combination with cabozantinib:**
 - i. Is diagnosis relapsed or surgically unresectable stage IV disease in the initial treatment of a member with advanced RCC? Yes ___ No ___

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

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Page 2 of 4 - Please complete and return all pages. Failure to complete all pages will result in processing delays.

2. Please indicate the diagnosis and information, continued:

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 requested product be used as first-line therapy? Yes ___ No ___
- iii. Will requested product be used in combination with fluoropyrimidine- and platinum-based chemotherapy?
Yes ___ No ___
- iv. Is tumor positive for expression of programmed death ligand 1 (PD-L1) with a combined positive score (CPS) ≥ 1 ? Yes ___ No ___

B. For a diagnosis of esophageal or GEJ:

- i. Has member received preoperative chemoradiation? Yes ___ No ___
 - a. If yes, has member undergone R0 (complete) resection and has residual disease? Yes ___ No ___
- ii. Will requested product be used as induction therapy and member is medically fit and planned for esophagectomy? Yes ___ No ___
 - a. Squamous cell histology? Yes ___ No ___
 - b. Is tumor positive for expression of PD-L1 with a CPS ≥ 1 or is tumor microsatellite-instability high (MSI-H) or mismatch repair deficient (dMMR)? Yes ___ No ___
 - c. Will requested product be used in combination with fluoropyrimidine- and platinum-based chemotherapy?
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 ___
- iv. Used in first-line setting? Yes ___ No ___
 - a. Used in combination with oxaliplatin and fluorouracil or capecitabine? Yes ___ No ___
 - b. Adenocarcinoma pathology? Yes ___ No ___
 - c. Is tumor positive for expression of PD-L1 with a CPS ≥ 1 ? Yes ___ No ___
- v. Used in second-line or greater setting? Yes ___ No ___
 - a. Squamous cell pathology? Yes ___ No ___

Gastric Cancer

- A. Is diagnosis locally advanced, recurrent, or metastatic human epidermal receptor 2 (HER2) negative disease?
Yes ___ No ___
- B. Is tumor positive for expression of programmed death ligand 1 (PD-L1) with a combined positive score (CPS) ≥ 1 ? Yes ___ No ___
- C. Will requested product be used in combination with fluoropyrimidine- and platinum-containing chemotherapy?
Yes ___ No ___

Mesothelioma

- A. Is diagnosis malignant pleural mesothelioma that cannot be surgically removed? Yes ___ No ___
- B. Will requested product 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 ___

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2. Please indicate the diagnosis and information, continued:

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 $\geq 1\%$? Yes ___ No ___
 - c. Will requested product 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 requested product 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 ≥ 4 cm or node positive):

- i. Will requested product 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 requested product 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 ___
- C. Will requested product be used as first-line systemic therapy in combination with ipilimumab? Yes ___ No ___
 - i. Has member previously had anti-CTLA-4 combination therapy? Yes ___ No ___
- D. Will requested product be used as subsequent therapy, as a single agent? Yes ___ No ___
 - i. Has member been treated with another checkpoint inhibitor as subsequent therapy? Yes ___ No ___

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 disease? Yes ___ No ___
 - i. If yes, is requested product 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 requested product being used as first-line therapy? Yes ___ No ___
 - ii. Will requested product be used in combination with cisplatin and gemcitabine? Yes ___ No ___
 - iii. Will initial treatment be followed by maintenance treatment with nivolumab for a maximum duration of 24 months of therapy? Yes ___ No ___

Colorectal Cancer (CRC)

- A. Is diagnosis unresectable or metastatic CRC? Yes ___ No ___
- B. Is tumor microsatellite-instability high (MSI-H), mismatch repair deficient (dMMR)? Yes ___ No ___
- C. Does tumor have polymerase epsilon/delta [POLE/POLD1] mutation with ultra-hypermuted phenotype [e.g., tumor mutational burden (TMB) >50mut/Mb]? Yes ___ No ___

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2. Please indicate the diagnosis and information, continued:

Hodgkin Lymphoma

- A. Is diagnosis previously untreated, stage III or IV classical Hodgkin lymphoma? Yes ___ No ___
 - i. Will requested product be used in combination with doxorubicin, vinblastine, and dacarbazine (AVD)? Yes ___ No ___
- B. Is diagnosis relapsed or refractory classical Hodgkin lymphoma? Yes ___ No ___
 - i. Does member have lymphocyte-predominant Hodgkin lymphoma? Yes ___ No ___
 - ii. Will requested product be used in combination with doxorubicin, vinblastine, and dacarbazine (AVD) for primary systemic therapy in stage III-IV disease or together with involved-site radiation therapy (ISRT) for stage I-II (unfavorable) disease? Yes ___ No ___
 - iii. Will requested product be used in combination with ISRT plus brentuximab vedotin or as a single agent for primary systemic therapy in a member who is not a candidate for anthracyclines? Yes ___ No ___
 - iv. Will requested product be used in combination with brentuximab vedotin or ifosfamide, carboplatin, and etoposide (ICE) as second line or subsequent therapy after failure of autologous stem cell transplant (SCT), allogeneic SCT, or those who are transplant-ineligible? Yes ___ No ___

Primary Mediastinal Large B-Cell Lymphoma

- A. Does member have CD30+ disease? Yes ___ No ___
- B. Is disease relapsed or refractory primary mediastinal large B-Cell lymphoma? Yes ___ No ___
- C. Will requested product be used in combination with brentuximab vedotin? Yes ___ No ___

Head and Neck Cancer

- A. Is diagnosis recurrent or metastatic head and neck cancer? Yes ___ No ___
- B. Squamous cell histology? Yes ___ No ___
- C. Has member previously received platinum-containing chemotherapy (cisplatin or carboplatin)? 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: _____

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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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