OKLAHOMA Health Care Authority

State of Oklahoma
SoonerCare
Keytruda® (Pembrolizumab) Prior Authorization Form

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

Drug Information

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

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 3—Please complete and return all pages. Failure to complete all pages will result in processing delays.

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 other PD-1 inhibitors [e.g., Opdivo® (nivolumab)]? Yes ☐ No ☐
   - B. Will pembrolizumab be used as a single-agent? Yes ☐ No ☐
   - C. Will pembrolizumab be used as first-line therapy? Yes ☐ No ☐
   - D. Does tumor express programmed death ligand 1 (PD-L1)? Yes ☐ No ☐
   - E. Please indicate member's ECOG performance status (0-5):_____
2. **Please indicate the diagnosis and information:**

❑ **Metastatic Non-Small Cell Lung Cancer (NSCLC)**

- A. Please indicate the tumor proportion score for PD-L1 expression:_____(%)
- B. Will pembrolizumab be used for previously untreated metastatic squamous NSCLC in combination with carboplatin and either paclitaxel or nab-paclitaxel? Yes ☐ No ☐
- C. Will pembrolizumab be used for previously untreated metastatic non-squamous NSCLC in combination with pemetrexed and carboplatin? Yes ☐ No ☐
- D. Will pembrolizumab be used following disease progression on or after platinum-containing chemotherapy (cisplatin or carboplatin)? Yes ☐ No ☐
- E. Does tumor express sensitizing EGFR mutations or ALK translocations? Yes ☐ No ☐
- F. If tumor is EGFR-mutation-positive or has ALK genomic tumor aberrations, has member had disease progression on FDA-approved therapy for these aberrations prior to receiving pembrolizumab? Yes ☐ No ☐
  - i. If yes, please provide information on previous therapy: _____

❑ **Nonmetastatic Non-Small Cell Lung Cancer (NSCLC)**

- A. Is diagnosis stage 3 NSCLC? Yes ☐ No ☐
- B. Is member ineligible for surgery or definitive chemoradiation? Yes ☐ No ☐
- C. Please indicate the tumor proportion score for PD-L1 expression:_____(%)

❑ **Metastatic Small Cell Lung Cancer (SCLC)**

- A. Has member progressed on or following a platinum-based regimen and at least 1 other regimen? Yes ☐ No ☐

❑ **Breast Cancer**

- A. Is diagnosis locally recurrent unresectable or metastatic triple-negative breast cancer? Yes ☐ No ☐
- B. If tumor expresses PD-L1, please provide the Combined Positive Score (CPS)_____

❑ **Melanoma**

- A. Will pembrolizumab be used as adjuvant treatment of melanoma with involvement of lymph node(s) following complete resection? Yes ☐ No ☐
- B. Is diagnosis unresectable or metastatic melanoma? Yes ☐ No ☐
- C. Will pembrolizumab be used as second-line or subsequent therapy for disease progression if not previously used? Yes ☐ No ☐

PLEASE PROVIDE THE INFORMATION REQUESTED AND RETURN TO:	CONFIDENTIALITY NOTICE
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	*This document, including any attachments, contains information which is confidential or privileged. If you are not the intended recipient, be aware that any disclosure, copying, distribution, or use of the contents of this information is prohibited. If you have received this document in error, please notify the sender immediately by telephone to arrange for the return of the transmitted documents or to verify their destruction.*

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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:

- ❑ **Merkel Cell Carcinoma (MCC)**
  - A. Does member have recurrent, locally advanced or metastatic MCC? Yes ☐ No ☐
  - B. Does member have a history of prior systemic chemotherapy? Yes ☐ No ☐
- ❑ **Cutaneous Squamous Cell Carcinoma (cSCC)**
  - A. Does member have recurrent or metastatic cSCC? Yes ☐ No ☐
  - B. Is cSCC curable by radiation or surgery? Yes ☐ No ☐
- ❑ **Head and Neck Cancer**
  - A. Will pembrolizumab be used in recurrent disease? Yes ☐ No ☐
  - B. Does member have head and neck squamous cell carcinoma? Yes ☐ No ☐
- ❑ **Esophageal or Gastroesophageal Junction (GEJ) Carcinoma**
  - A. Does member have locally advanced, unresectable, or metastatic disease? Yes ☐ No ☐
  - B. For first-line therapy, will pembrolizumab be use In combination with platinum- and fluoropyrimidine-based chemotherapy? Yes ☐ No ☐
  - C. For second-line or greater therapy:
    - i. Has member experienced disease progression after 1 or more prior lines of systemic therapy? Yes ☐ No ☐
    - ii. Histology: ☐ Squamous Cell ☐ Other: _____
    - iii. If tumor expresses PD-L1, please provide the combined positive score (CPS)_____
- ❑ **Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma**
  - A. Does member have locally advanced, unresectable, or metastaic disease? Yes ☐ No ☐
  - B. For first-line therapy:
    - i. Is disease human epidermal receptor 2 (HER2)-positive? Yes ☐ No ☐
    - ii. Will pembrolizumab be used in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy? Yes ☐ No ☐
  - C. For second-line therapy:
    - i. If tumor expresses PD-L1, please provide the combined positive score (CPS)_____
    - ii. Will pembrolizumab be used following disease progression on or after 2 or more lines of therapies (including fluoropyrimidine- and platinum-containing chemotherapy, and if appropriate, HER2/neu-targeted therapy)? Yes ☐ No ☐
- ❑ **Hepatocellular Carcinoma (HCC)**
  - A. Does member have relapsed or progressive disease? Yes ☐ No ☐
  - B. Has member been previously treated with sorafenib? Yes ☐ No ☐
- ❑ **Urothelial Carcinoma**
  - A. Does member have locally advanced or metastatic disease with disease progression during or following platinum-containing chemotherapy? Yes ☐ No ☐
  - B. Is member within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy? Yes ☐ No ☐
  - C. Will pembrolizumab be used in locally advanced or metastatic disease for member not eligible for cisplatin-containing chemotherapy? Yes ☐ No ☐
    - i. If yes, please provide at least 1 of the following:
      1. Baseline creatinine clearance:_____
      2. Heart failure NYHA class:_____
      3. Peripheral neuropathy grade:_____
      4. Hearing loss grade:_____
- ❑ **Bladder Cancer**
  - A. Is diagnosis high-risk, non-muscle invasive bladder cancer? Yes ☐ No ☐
  - B. Has member failed therapy with Bacillus Calmette-Guerin (BCG)-therapy? Yes ☐ No ☐
  - C. Is member ineligible for or elected not to undergo cystectomy? Yes ☐ No ☐
- ❑ **Renal Cell Carcinoma (RCC)**
  - A. Is member's renal cell carcinoma newly diagnosed? Yes ☐ No ☐
  - B. Is disease recurrent stage IV clear-cell RCC? Yes ☐ No ☐
  - C. Has member received previous systemic therapy for advanced disease? Yes ☐ No ☐
  - D. Will pembrolizumab be used in combination with Inlyta® (axitinib)? Yes ☐ No ☐

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Criteria

Page 3 of 3—*Please complete and return <u>all</u> pages. Failure to complete all pages will result in processing delays.

2. Please indicate the diagnosis and information, continued:

- ❑ **Recurrent or Metastatic Cervical Cancer**
  - A. Has member experienced disease progression on or after chemotherapy? Yes ☐ No ☐
  - B. If tumor expresses PD-L1, please provide the Combined Positive Score (CPS)_____
- ❑ **Endometrial Cancer**
  - A. Is diagnosis advanced endometrial cancer that is **NOT** microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)? Yes ☐ No ☐
  - B. Has member experienced disease progression following prior systemic therapy? Yes ☐ No ☐
  - C. Is member a candidate for curative surgery or radiation? Yes ☐ No ☐
  - D. Will pembrolizumab be used in combination with lenvatinib? Yes ☐ No ☐
- ❑ **Colorectal Cancer (CRC)**
  - A. Is disease metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)? Yes ☐ No ☐
  - B. Is disease unresectable? Yes ☐ No ☐
- ❑ **Hodgkin Lymphoma**
  - A. For <u>adult members</u>:
    - i. Is diagnosis refractory or relapsed classical Hodgkin lymphoma? Yes ☐ No ☐
    - ii. Is diagnosis lymphocyte-predominant Hodgkin lymphoma? Yes ☐ No ☐
  - B. For <u>pediatric members</u>:
    - i. Is diagnosis refractory classical Hodgkin lymphoma? Yes ☐ No ☐
    - ii. Has disease relapsed after 2 or more therapies? Yes ☐ No ☐
- ❑ **Primary Mediastinal Large B-cell Lymphoma (PMBCL)**
  - A. Does member have refractory disease? Yes ☐ No ☐
  - B. Has member relapsed after 2 or more prior lines of therapy? Yes ☐ No ☐
  - C. Does member require urgent cytoreduction? Yes ☐ No ☐
- ❑ **Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Solid Tumors (Tissue/Site-Agnostic)**
  - A. Does member have MSI-H or dMMR solid tumors that have progressed following prior treatment with no satisfactory alternative treatment options? Yes ☐ No ☐
- ❑ **Tumor Mutational Burden-High (TMB-H) Solid Tumors**
  - A. Does member have unresectable or metastatic TMB-H [≥10 mutations/megabase (mut/Mb)] solid tumors with no satisfactory alternative treatment options? Yes ☐ No ☐
  - B. Will pembrolizumab be used following disease progression after prior treatment? 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 pembrolizumab? Yes ☐ No ☐
3. Has the member experienced any adverse drug reactions related to pembrolizumab therapy? Yes ☐ No ☐
   *If yes, please specify adverse reactions:*_____

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. *Please do not send in chart notes. Specific information will be requested if necessary. Failure to complete this form in full will result in processing delays.*

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