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 4—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☐
  - i. If yes, is member ineligible for surgery or definitive chemoradiation? Yes☐ No☐
  - ii. Please indicate the tumor proportion score for PD-L1 expression:_____(%)
- B. Is diagnosis stage 1B (T2a ≥4cm), stage 2, or stage 3A NSCLC? Yes☐ No☐
  - i. Will pembrolizumab be used as adjuvant treatment following resection and platinum-based chemo-therapy? Yes☐ No☐
- C. Is diagnosis resectable (tumors ≥4cm or node positive) NSCLC? Yes☐ No☐
  - i. Will pembrolizumab be used as neoadjuvant treatment in combination with platinum-containing chemotherapy? Yes☐ No☐
  - ii. Will pembrolizumab be continued as a single agent as adjuvant treatment after surgery? Yes☐ No☐

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

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

Criteria

2. Please indicate the diagnosis and information, continued:

☐ **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☐
  - i. If yes and tumor expresses PD-L1, please provide the combined positive score (CPS)_____
  - ii. Will pembrolizumab be used in combination with chemotherapy? Yes☐ No☐
- B. Is diagnosis early stage triple-negative breast cancer? Yes☐ No☐
  - i. If yes, is disease considered high risk? Yes☐ No☐
  - ii. Will pembrolizumab be used in combination with chemotherapy as neoadjuvant therapy? Yes☐ No☐

☐ **Melanoma**
- A. Will pembrolizumab be used as adjuvant treatment of adult and pediatric members 12 years or older with stage 2B, 2C, or 3 melanoma 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☐

☐ **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: ***(select one)***
  - ☐ Disease is human epidermal receptor 2 (HER2)-positive
    - i. Will pembrolizumab be used in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy? Yes☐ No☐
    - ii. Is tumor positive for expression of programmed death ligand 1 (PD-L1) with a combined positive score (CPS) ≥1? Yes☐ No☐
  - ☐ Disease is human epidermal receptor 2 (HER2)-negative
    - i. Will pembrolizumab be used in combination with fluoropyrimidine– and platinum-containing chemotherapy? Yes☐ No☐

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Criteria

2. Please indicate the diagnosis and information, continued:

☐ **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:_____
- D. Will pembrolizumab be used in combination with enfortumab vedotin-ejfv for locally advanced or metastatic urothelial carcinoma? Yes☐ No☐

☐ **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 disease new or recurrent stage 4 clear-cell RCC? Yes☐ No☐
  - i. Has member received previous systemic therapy for advanced disease? Yes☐ No☐
  - ii. Will pembrolizumab be used in combination with axitinib or lenvatinib? Yes☐ No☐
- B. Is RCC at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions? Yes☐ No☐

☐ **Cervical Cancer**

☐ Diagnosis is recurrent or metastatic cervical cancer
- i. If tumor expresses PD-L1, please provide the Combined Positive Score (CPS)_____
- ii. Has member experienced disease progression on or after chemotherapy? Yes☐ No☐
- iii. Will pembrolizumab be used as first-line therapy in combination with chemotherapy, with or without bevacizumab? Yes☐ No☐

☐ Diagnosis is FIGO Stage III-IV cervical cancer
- i. Will pembrolizumab be used in combination with concomitant chemotherapy and radiation? Yes☐ No☐

☐ **Advanced Endometrial Cancer**
- A. Has member experienced disease progression following prior systemic therapy? Yes☐ No☐
- B. Is member a candidate for curative surgery or radiation? Yes☐ No☐
- C. Is endometrial cancer microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)? Yes☐ No☐
  - i. If no, will pembrolizumab be used in combination with lenvatinib for advanced endometrial cancer? Yes☐ No☐

☐ **Biliary Tract Cancer (BTC)**
- A. Is disease locally advanced unresectable or metastatic BTC? Yes☐ No☐
- B. Will pembrolizumab be used in combination with gemcitabine and cisplatin? Yes☐ No☐

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2. Please indicate the diagnosis and information, continued:

☐ **Colorectal Cancer (CRC)**
- A. Is diagnosis unresectable or metastatic CRC? Yes☐ No☐
- B. Is tumor microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)? Yes☐ No☐

☐ **Hodgkin Lymphoma**
- A. For adult members:
  - i. Is diagnosis refractory or relapsed classical Hodgkin lymphoma? Yes☐ No☐
  - ii. Is diagnosis lymphocyte-predominant Hodgkin lymphoma? Yes☐ No☐
  - iii. Will pembrolizumab be used as second-line or subsequent systemic therapy in combination with gemcitabine, vinorelbine, and liposomal doxorubicin? Yes☐ No☐
- B. For pediatric members:
  - 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:** _____

Additional Information: _____

_____

_____

_____

_____

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 list adverse drug 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. *Failure to complete this form in full will result in processing delays.*

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