OKLAHOMA Health Care Authority

State of Oklahoma
SoonerCare

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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☐

Fax completed prior authorization request form to 888-601-8461 or submit Electronic Prior Authorization through CoverMyMeds® or SureScripts. All requesteddata must be provided. Incomplete forms or forms without the chart notes will be returned. Pharmacy Coverage Guidelines are available at AetnaBetterHealth.com/Oklahoma.	CONFIDENTIALITY NOTICE *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.*

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 and may be continued as a single agent as adjuvant treatment after surgery? 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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***Member Name:*_____ *Date of Birth:*_____ *Member ID#:*_____**

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 members ineligible for cisplatin-containing chemotherapy or any platinum-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☐
- iv. Will pembrolizumab be used as second-line or subsequent therapy as a single agent? Yes☐ No☐

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

☐ **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. Does member have advanced endometrial cancer that is 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☐
- D. Is diagnosis primary advanced (newly diagnosed stage III/IVA or stage IVB) or recurrent endometrial cancer? Yes☐ No☐
  - i. If yes, will pembrolizumab be used in combination with carboplatin and paclitaxel followed by single-agent maintenance pembrolizumab? Yes☐ No☐

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Criteria

2. Please indicate the diagnosis and information, continued:

☐ **Mesothelioma**
- A. Is disease unresectable advanced or metastatic malignant pleural mesothelioma? Yes☐ No☐
- B. Will pembrolizumab be used in combination with pemetrexed and platinum chemotherapy? 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☐

☐ **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 (GVD) or ifosfamide, carboplatin, and etoposide (ICE)? 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☐
  - iii. Has a decrease in cardiac function been observed? 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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