OKLAHOMA Health Care Authority

State of Oklahoma
SoonerCare

Keytruda® and Keytruda Qlex™ Prior Authorization Form
(Pembrolizumab and Pembrolizumab/Berahyuronidase)

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 5—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 had disease progression previously on other programmed death 1 (PD-1) inhibitors? 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☐ Unknown☐
   - E. Please indicate member's ECOG performance status (0-5):_____
2. **Please indicate the diagnosis and information:**

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

☐ **Bladder Cancer**
- A. Is diagnosis high-risk, non-muscle invasive bladder cancer (NMIBC)? Yes☐ No☐
  - i. If yes, has member failed therapy with Bacillus Calmette-Guerin (BCG)-therapy? Yes☐ No☐
  - ii. Is member ineligible for or elected not to undergo cystectomy? Yes☐ No☐
- B. Is diagnosis muscle invasive bladder cancer? Yes☐ No☐
  - i. If yes, will pembrolizumab be used as neoadjuvant treatment and then continued after cystectomy as adjuvant treatment? Yes☐ No☐
  - ii. Will requested product be used in combination with enfortumab vedotin? Yes☐ No☐

☐ **Breast Cancer**
- A. Is diagnosis locally recurrent unresectable or metastatic triple-negative breast cancer? Yes☐ No☐
  - i. Used in the first-line setting or in later lines of treatment? Yes☐ No☐
  - ii. If yes and tumor expresses PD-L1, please provide the combined positive score (CPS)_____
  - iii. Used in combination with chemotherapy or sacituzumab govitecan-hziy? Yes☐ No☐
- B. Is diagnosis early stage triple-negative breast cancer? Yes☐ No☐
  - i. If yes, is disease considered high risk? Yes☐ No☐
  - ii. Used in combination with chemotherapy as neoadjuvant therapy and may 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

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2. Please indicate the diagnosis and information, continued:

☐ **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 requested product be used as first-line therapy in combination with chemotherapy, with or without bevacizumab? Yes☐ No☐
  - iv. Will requested product be used as second-line or subsequent therapy as a single agent? Yes☐ No☐
- ☐ Diagnosis is FIGO 2014 Stage III-IVA cervical cancer
  - i. Will requested product be used in combination with concomitant chemotherapy and radiation? Yes☐ No☐

☐ **Cutaneous Squamous Cell Carcinoma (cSCC)**
- A. Does member have locally advanced, recurrent or metastatic cSCC? Yes☐ No☐
- B. Is cSCC curable by radiation or surgery? 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 requested product 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 requested product be used in combination with carboplatin and paclitaxel followed by single-agent maintenance pembrolizumab? 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 requested product be used 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 requested product 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 requested product be used in combination with fluoropyrimidine– and platinum-containing chemotherapy? Yes☐ No☐
    - ii. Is tumor positive for expression of PD-L1 with a CPS ≥1? Yes☐ No☐

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2. Please indicate the diagnosis and information, continued:

☐ **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 requested product 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 requested product be used in combination with enfortumab vedotin-ejfv for locally advanced or metastatic urothelial carcinoma? 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☐

☐ **Classical Hodgkin Lymphoma (cHL)**
- A. For adult members:
  - i. Is diagnosis refractory or relapsed classical Hodgkin lymphoma? Yes☐ No☐
  - ii. Does member have lymphocyte-predominant Hodgkin lymphoma? Yes☐ No☐
  - iii. Will requested product 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☐

☐ **Melanoma**
- A. Will requested product 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 requested product 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☐
- C. For Keytruda Qlex™, please provide member's weight: _____(kg)

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

☐ **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☐

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2. Please indicate the diagnosis and information, continued:

☐ **Metastatic Non-Small Cell Lung Cancer (NSCLC)**
- A. Please indicate the tumor proportion score for PD-L1 expression:_____(%)
- B. Will requested product be used for previously untreated metastatic squamous NSCLC in combination with carboplatin and either paclitaxel or nab-paclitaxel? Yes☐ No☐
- C. Will requested product be used for previously untreated metastatic non-squamous NSCLC in combination with pemetrexed and carboplatin? Yes☐ No☐
- D. Will requested product 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: _____

☐ **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☐
- B. For Keytruda Qlex™, please provide member's weight: _____(kg)

☐ **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 requested product be used as adjuvant treatment following resection and platinum-based chemotherapy? Yes☐ No☐
- C. Is diagnosis resectable (tumors ≥4cm or node positive) NSCLC? Yes☐ No☐
  - i. Will requested product be used as neoadjuvant treatment in combination with platinum-containing chemotherapy? Yes☐ No☐
  - ii. Will requested product be continued as a single agent as adjuvant treatment after surgery? 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☐

☐ **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 requested product 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☐
- C. Is diagnosis RCC with a clear cell component at intermediate-high or high risk of recurrence following nephrectomy or following nephrectomy and resection of metastatic lesions? Yes☐ No☐
  - i. Used in combination with belzutifan? Yes☐ No☐

☐ **Hepatocellular Carcinoma (HCC)**
- A. Does member have relapsed or progressive disease? Yes☐ No☐
- B. Has member received prior systemic therapy? Yes☐ No☐

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Criteria

2. Please indicate the diagnosis and information, continued:

☐ **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 requested product be used following disease progression after prior treatment? Yes☐ No☐
- C. For Keytruda Qlex™, please provide member's weight: _____(kg)

☐ **Head and Neck Cancer**
- A. Does member have head and neck squamous cell histology? Yes☐ No☐
- B. How will requested product be used?
  - ☐ First-line or recurrent setting for resectable locally advanced disease:
    - i. Used as neoadjuvant and adjuvant addition to standard care (surgery and adjuvant radio-therapy with or without concomitant chemotherapy)? Yes☐ No☐
    - ii. Tumor expresses PD-L1 [Combined Positive Score (CPS) ≥1]? Yes☐ No☐
  - ☐ In metastatic or unresectable disease, as first-line or subsequent-line therapy, in combination with chemotherapy:
    - i. Was requested product previously used? Yes☐ No☐
  - ☐ As subsequent therapy as a single agent:
    - i. Is disease PD-L1 positive recurrent or metastatic disease? Yes☐ No☐
    - ii. Is disease tumor-mutational burden-high (TMB-H) tumors (≥10 mut/Mb)? Yes☐ No☐
    - iii. Has disease progressed on or after prior platinum therapy? Yes☐ No☐

☐ **Ovarian Cancer**
- A. Is diagnosis epithelial ovarian, fallopian tube, or primary peritoneal carcinoma? Yes☐ No☐
- B. Has member received at least 1 prior systemic treatment regimen? Yes☐ No☐
- C. Is disease platinum-resistant? Yes☐ No☐
- D. Does tumor express programmed death ligand 1 (PD-L1) with a combined positive score (CPS) ≥1? Yes☐ No☐
- E. Used in combination with paclitaxel, with or without bevacizumab? Yes☐ No☐

☐ **Other:** _____

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: _____

(Page 5 of 5 - please complete and return all pages)

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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