

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 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 ___ 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 ___
 - iii. Is member ineligible for cisplatin-containing chemotherapy? 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 requested product 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 requested product be used in combination with chemotherapy as neoadjuvant therapy and may be continued as a single agent as adjuvant treatment after surgery? Yes ___ No ___

(Page 1 of 5 - Please complete and return all pages)

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 metastatic 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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Criteria

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 ___

Hepatocellular Carcinoma (HCC)

- A. Does member have relapsed or progressive disease? Yes ___ No ___
- B. Has member been previously treated with sorafenib? 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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Criteria

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 \geq 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 \geq 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 ___

Tumor Mutational Burden-High (TMB-H) Solid Tumors

- A. Does member have unresectable or metastatic TMB-H [\geq 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)

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Criteria**2. Please indicate the diagnosis and information, continued:** **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 radiotherapy 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 ___
 - ii. Has member previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo[®] (nivolumab)]? 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.****PLEASE PROVIDE THE INFORMATION REQUESTED AND RETURN TO:**University of Oklahoma College of Pharmacy
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