

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 ___
 - 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 chemotherapy? Yes ___ No ___
 - ii. 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 ___

Page 1 of 4
(please complete and return all pages)

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

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Criteria

2. Please indicate the diagnosis and information, continued:

 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 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:
 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 ___

 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: _____ 3. Peripheral neuropathy grade: _____
 2. Heart failure NYHA class: _____ 4. Hearing loss grade: _____

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Criteria

- 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 ___
- Recurrent or Metastatic Cervical Cancer**
- A. If tumor expresses PD-L1, please provide the Combined Positive Score (CPS) _____
- B. Has member experienced disease progression on or after chemotherapy? Yes ___ No ___
- C. Will pembrolizumab be used as first-line therapy in combination with chemotherapy, with or without bevacizumab? 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 ___
- 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:** _____

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Criteria

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: _____

DRAFT

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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