MEDICATION POLICY

Generic Name: Pembrolizumab

Therapeutic Class or Brand Name: Keytruda®

Applicable Drugs (if Therapeutic Class)**:** N/A

Date of Origin: 4/19/17 **Date Last Reviewed/Revised:** 5/25/17

GPI Code: 2135305300

Prior Authorization Criteria (may be considered medically necessary when criteria I through III are met):

I. Documented diagnosis of one of the following conditions A through H AND must meet criteria listed under applicable diagnosis:

A. Unresectable or metastatic melanoma and criterion 1 is met:

1. Keytruda® will be used as a single agent.

B. Metastatic non-small cell lung cancer (NSCLC) and criteria 1 through 4 are met:

1. Documentation that tumor has high PD-L1 expression [(Tumor Proportion Score (TPS) ≥50%)] as determined by an FDA-approved test.
2. Documentation that there are no EGFR or ALK genomic tumor aberrations.
3. Documentation that the patient has had no prior systemic chemotherapy treatment for metastatic NSCLC.
4. Keytruda® will be used as a single agent.

C. Metastatic non-small cell lung cancer (NSCLC) and criteria 1 through 4 are met:

1. Documentation that tumor expresses PD-L1 (TPS ≥1%) as determined by an FDA-approved test.
2. Documentation of disease progression on or after platinum-containing chemotherapy.
3. If the patient has EGFR or ALK genomic tumor aberrations, documentation of disease progression on FDA-approved therapy for these aberrations.
4. Keytruda® will be used as a single agent.

D. Metastatic nonsquamous nonsmall cell lung cancer (NSCLC) and criterion 1 is met:

1. Keytruda® will be used in combination with Alimta® (pemetrexed) and carboplatin.

E. Recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) and criteria 1 and 2 are met:

1. Documentation of disease progression on or after platinum-containing chemotherapy.
2. Keytruda® will be used as a single agent.

F. Refractory classical Hodgkin lymphoma (cHL) and criteria 1 and 2 are met:
1. Documentation that disease has relapsed after 3 or more prior lines of therapy.
2. Keytruda® will be used as a single agent.

G. Locally advanced or metastatic urothelial carcinoma and criteria 1 and 2 are met:
1. Documentation of one of the following a or b:
   a. Patient is not eligible for cisplatin-containing chemotherapy.
   b. Disease progression during or following any platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.
2. Keytruda® will be used as a single agent.

H. Unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient solid tumors or colorectal cancer and criteria 1 and 2 are met:
1. One of the following a or b is met:
   a. If the patient has solid tumors, documentation of disease progression following prior treatment and that patient has no satisfactory alternative treatment options.
   b. If the patient has colorectal cancer, documentation of disease progression following prior treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.
2. Keytruda® will be used as a single agent.

II. Minimum age requirement: 2 years old.

III. Prescribing physician is an oncologist or a hematologist.

Exclusion Criteria:

- Prior treatment with a programmed death receptor-1 (PD-1)-blocking antibody or a programmed death-ligand 1 (PD-L1) blocking antibody (i.e. Imfinzi™, Keytruda®, Opdivo®, or Tecentriq®).

Other Criteria:

- N/A

Quantity/Days Supply Restrictions:

- Melanoma:

- 2 mg/kg every 3 weeks.

- NSCLC, HNSCC, & Urothelial carcinoma:
  - 200 mg every 3 weeks x 24 months.
- cHL & MSI-H cancer:
  - Adults: 200mg every 3 weeks x 24 months.
  - Pediatrics: 2mg/kg (up to 200 mg) every 3 weeks x 24 months.

Approval Length:

- **Authorization:** 6 months.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing that current medical necessity criteria are met and that the medication is effective. *Please note:* For all diagnoses except for melanoma (NSCLC, HNSCC, cHL, Urothelial carcinoma, & MSI-H cancer), Keytruda® is only indicated to be given for up to a total of 24 months.

Appendix:

N/A

References:

1. http://www.merck.com/product/usa/pi_circulars/k/keytruda/keytruda_pi.pdf.
2. Medi-Span.
3. http://blue.regence.com/trgmedpol/drugs/dru367.pdf.
4. http://www.bcbsnc.com/assets/services/public/pdfs/medicalpolicy/pd_1_inhibitors.pdf.

MEDICATION POLICY

Historical Tracking Of Changes Made To Policy	
5/25/2017	1. **Changed** "I. Documented diagnosis of one of the following conditions A through E…" **to** "I. Documented diagnosis of one of the following conditions A through H…"**, and added** "D. Metastatic nonsquamous nonsmall cell lung cancer (NSCLC) and criterion 1 is met: 1. Keytruda® will be used in combination with Alimta® (pemetrexed) and carboplatin…G. Locally advanced or metastatic urothelial carcinoma and criteria 1 and 2 are met: 1. Documentation of one of the following a or b: a. Patient is not eligible for cisplatin-containing chemotherapy; b. Disease progression during or following any platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy; 2. Keytruda® will be used as a single agent; H. Unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient solid tumors or colorectal cancer and criteria 1 and 2 are met: 1. One of the following a or b is met: a. If the patient has solid tumors, documentation of disease progression following prior treatment and that patient has no satisfactory alternative treatment options; b. If the patient has colorectal cancer, documentation of disease progression following prior treatment with a fluoropyrimidine, oxaliplatin, and irinotecan; 2. Keytruda® will be used as a single agent…" **under Prior Authorization Criteria**. 2. **Changed** "Unresectable or metastatic melanoma: 2 mg/kg every 3 weeks; Metastatic non-small cell lung cancer (NSCLC) & Recurrent or metastatic head and neck squamous cell carcinoma (HNSCC): 200 mg every 3 weeks x 24 months; Refractory classical Hodgkin lymphoma (cHL): Adults: 200mg every 3 weeks x 24 months; Pediatrics: 2mg/kg (up to 200 mg) every 3 weeks x 24 months" **to** "Melanoma: 2 mg/kg every 3 weeks; NSCLC, HNSCC, & Urothelial carcinoma: 200 mg every 3 weeks x 24 months; cHL & MSI-H cancer: Adults: 200mg every 3 weeks x 24 months; Pediatrics: 2mg/kg (up to 200 mg) every 3 weeks x 24 months" **under Quantity/Days Supply Restrictions**. 3. **Changed** "…Please note: For all diagnoses except for melanoma (NSCLC, HNSCC, & cHL), Keytruda® is only indicated to be given for up to a total of 24 months" **to** "…Please note: For all diagnoses except for melanoma (NSCLC, HNSCC, cHL, Urothelial carcinoma, & MSI-H cancer), Keytruda® is only indicated to be given for up to a total of 24 months" **following Re-Authorization under Approval Length**.
5/18/2017	1. **Added** "Imfinzi™" **to** "Prior treatment…" list **under Exclusion Criteria**.