MEDICATION POLICY

Generic Name: Nivolumab

Therapeutic Class or Brand Name: Opdivo®

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

Date of Origin: 4/19/17 **Date Last Reviewed/Revised:** 5/18/17

GPI Code: 2135304100

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. BRAF V600 wild-type unresectable or metastatic melanoma and criterion 1 is met:

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

B. BRAF V600 mutation-positive unresectable or metastatic melanoma and criterion 1 is met:

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

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

1. Opdivo® will be used in combination with Yervoy® (ipilimumab).

D. Metastatic non-small cell lung cancer (NSCLC) and criteria 1 through 3 are met:

1. Documentation of disease progression on or after platinum-based chemotherapy.
2. If the patient has EGFR or ALK genomic tumor aberrations, documentation of disease progression on FDA-approved therapy for these aberrations.
3. Opdivo® will be used as a single agent.

E. Advanced renal cell carcinoma (RCC) and criteria 1 and 2 are met:

1. Documentation of disease progression on or after prior anti-angiogenic therapy.
2. Opdivo® will be used as a single agent.

F. Classical Hodgkin lymphoma and criteria 1 through 3 are met:

1. Documentation that disease has relapsed or progressed after autologous hematopoietic stem cell transplantation (HSCT).
2. Documentation that disease has relapsed or progressed after post-transplantation Adcetris® (brentuximab vedotin).
3. Opdivo® will be used as a single agent.

G. Recurrent or metastatic squamous cell carcinoma of the head and neck and criteria 1 and 2 are met:
   1. Documentation that disease has progressed on or after a platinum-based therapy.
   2. Opdivo® will be used as a single agent.

H. Locally advanced or metastatic urothelial carcinoma and criteria 1 and 2 are met:
   1. Documentation that one of the following criteria a or b is met:
      a. Patient has disease progression during or following platinum-containing chemotherapy.
      b. Patient has disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.
   2. Opdivo® will be used as a single agent.

II. Minimum age requirement: 18 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:

- Unresectable or metastatic melanoma:
  - As a single agent: 240 mg every 2 weeks.
  - With Yervoy®: 1 mg/kg, followed by Yervoy® on the same day, every 3 weeks for 4 doses, then Opdivo® 240 mg every 2 weeks.
- Metastatic non-small cell lung cancer, Advanced renal cell carcinoma, & Locally advanced or metastatic urothelial carcinoma:
  - 240 mg every 2 weeks.
- Classical Hodgkin lymphoma & Recurrent or metastatic squamous cell carcinoma of the head and neck:
  - 3 mg/kg every 2 weeks.

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.

Appendix:

N/A

References:

1. http://packageinserts.bms.com/pi/pi_opdivo.pdf.
2. Medi-Span.
3. http://blue.regence.com/trgmedpol/drugs/dru390.pdf.
4. http://www.bcbsnc.com/assets/services/public/pdfs/medicalpolicy/pd_1_inhibitors.pdf.

MEDICATION POLICY

Historical Tracking Of Changes Made To Policy	
5/18/2017	1. **Added** "Imfinzi™" **to** "Prior treatment…" list **under Exclusion Criteria**.