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:** 7/14/18

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. Melanoma lymph node involvement or metastatic disease and criteria 1 and 2 are met:

1. Have undergone complete resection
2. Opdivo® will be used in the adjuvant setting.

E. 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.

F. 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.

G. Advanced Renal Cell Carcinoma, Intermediate or poor risk and criteria 1 or 2 are met:

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

H. 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.

I. 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.

J. 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.

K. Microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer and criteria 1and 2 are met:
   1. Documentation that disease has progressed following treatment with fluoropyrimidine, oxaliplatin and ironotecan
   2. Opdivo® will be used as a single agent

L. Hepatocellular carcinoma and criteria 1 met:
   1. Previously treated with sorafenib
   2. Opdivo® will be used as a single agent

II. Minimum age requirement: 12 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. Bavencio®, 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, or 480 every 4 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, or 480 every 4 weeks.
  - Adjuvant treatment: 240 every 2 weeks or 480 mg every 4 weeks
- Adjuvant treatment of melanoma, Metastatic non-small cell lung cancer , Classical Hodgkin lymphoma, Recurrent or metastatic squamous cell carcinoma of head and neck, Locally advanced or metastatic urothelial carcinoma & Hepatocellular carcinoma :
  - 240 mg every 2 weeks or 480 mg every 4 weeks
- Advanced Renal Cell Carcinoma
  - 240 mg ever 2 weeks or 480 mg every 4 weeks
  - With Yervoy®: 3 mg/kg, followed by Yervoy® on the same day, every 3 weeks for 4 doses, then Opdivo® 240 mg every 2 weeks, or 480 every 4 weeks
- Microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR) metatstatic colorectal cancer
  - Opdivo® 240 mg 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. https://regence.myprime.com/content/dam/prime/memberportal/forms/AuthorForms/Cambia/Program_Summaries/dru390reg.pdf..

MEDICATION POLICY

Historical Tracking Of Changes Made To Policy	
7/14/2018	1. **Changed Dosing (correction)** for Advanced Renal Cell Carcinoma from 3mg/kg to 1 mg/kg
4/18/2018	1. **Added** "D.Melanoma lymphnode involvement or metastatic disease criteria 1 and 2 are met ," "G. Advanced Renal cell intermediate or poor risk criteria 1 and 2 are met ," "K. Microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer criteria 1 and 2 are met," "L. Hepatocellular carcinoma criteria 1 and 2 are met " Under **Prior Authorization Criteria I.** 2. **Added** "Bavencio®" Under **Exclusion Criteria:** Prior treatment with a programmed death receptor-1 (PD-1)-blocking antibody or a programmed death-ligand 1 (PD-L1) blocking antibody 3. **Combined** "Adjuvant treatment of melanoma, Metastatic non-small cell lung cancer , Classical Hodgkin lymphoma, Recurrent or metastatic squamous cell carcinoma of head and neck, Locally advanced or metastatic urothelial carcinoma & Hepatocellular carcinoma" under **Quantity/Days Supply** 4. **Added Quantity/Days supply For** Melanoma lymphnode involvement or metastatic disease, Advanced Renal cell intermediate or poor risk, Microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer 5. **Changed Minimum age requirement to** 12 Years Under Prior Authorization Criteria II 6. **Added** "480 mg every 4 weeks" Under **Quantity/Days Supply** for Unresectable or metastatic melanoma, Adjuvant treatment of melanoma, Metastatic non-small cell lung cancer , Classical Hodgkin lymphoma, Recurrent or metastatic squamous cell carcinoma of head and neck, Locally advanced or metastatic urothelial carcinoma & Hepatocellular carcinoma 7. **Added "**480 mg every 4 weeks" And "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, or 480 every 4 weeks" for Advanced Renal Cell Carcinoma under **Quantity/Days Supply** 8. **Deleted "**3 mg/kg every 2 weeks" Under **Quantity/Days Supply for** "Classical Hodgkin lymphoma & Recurrent or metastatic squamous cell carcinoma of the head and neck" 9. **Updated link** "https://regence.myprime.com/content/dam/prime/memberportal/forms/AuthorForms/Cambia/Program_Summaries/dru390reg.pdf."
5/18/2017	**Added** "Imfinzi™" **to** "Prior treatment…" list **under Exclusion Criteria**.