MEDICATION POLICY:

Opdivo®

Generic Name: Nivolumab

Therapeutic Class or Brand Name: Opdivo®

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 2135304100

Preferred: N/A

Non-preferred: N/A

Date of Origin: 4/19/2017

Date Last Reviewed / Revised: 1/16/2020

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I though 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. Opdivo® will be used as a single agent or in combination with Yervoy® (ipilimumab).

B. 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.

C. 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

D. Metastatic small cell lung cancer
   1. Documentation of disease progression on or after platinum-based chemotherapy and one other line of chemotherapy.
   2. Opdivo® will be used as a single

E. Advanced renal cell carcinoma (RCC) and criteria 1 OR 2 are met:
   1. Documentation of disease progression on or after prior anti-angiogenic therapy.
      a) Opdivo® will be used as a single agent.
   2. Documentation disease is intermediate or poor risk and criteria 1 or 2 are met:
      a) Disease is previously untreated
      b) Opdivo® will be used in combination with Yervoy® (ipilimumab).

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 and Adcetris® (brentuximab vedotin) or 3 other lines of systemic chemotherapy that includes HSCT.
3. Opdivo® will be used as a single agent.
4. Minimum age requirement: 18 years old

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.

I. 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 or in combination with Yervoy® (ipilimumab).

J. 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, unless noted above.

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.

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
1/16/2020	1. **Removed** "BRAF V600 wild-type unresectable or metastatic melanoma and criterion 1 is met :Opdivo® will be used as a single agent" and "BRAF V600 mutation-positive unresectable or metastatic melanoma and criterion 1 is met: Opdivo® will be used as a single agent" under **Prior Authorization Criteria.** 2. **Added** "as a single agent" to A.1. **under Prior Authorization Criteria**. 3. **Added** "Metastatic small cell lung cancer. Documentation of disease progression on or after platinum-based chemotherapy and one other line of chemotherapy. Opdivo® will be used as a single agent" as a new indication **under Prior Authorization Criteria**. 4. **Added** "other lines of systemic chemotherapy" to F.2. **under Prior Authorization Criteria**. 5. **Added "**18 years old" to F.4. **under Prior Authorization Criteria.** 6. **Added** "combination with Yervoy® (ipilimumab)" to I.2. **under Prior Authorization Criteria**.
7/14/2020	1. **Changed Dosing (correction)** for Advanced Renal Cell Carcinoma from 1 mg/kg to 3 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	1. **Added** "Imfinzi™" **to** "Prior treatment…" list **under Exclusion Criteria**.

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.