



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: 4/18/18

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)

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- 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 1 and 2 are met:
1. Documentation that disease has progressed following treatment with fluoropyrimidine, oxaliplatin and irinotecan
 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:

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- 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®: 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
- 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.

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3. https://regence.myprime.com/content/dam/prime/memberportal/forms/AuthorForms/Cambia/Program_Summaries/dru390reg.pdf..

Historical Tracking Of Changes Made To Policy

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Historical Tracking Of Changes Made To Policy	
4/18/2018	<ol style="list-style-type: none"> 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.

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