Generic Name: Nivolumab

Therapeutic Class or Brand Name: Opdivo®

Applicable Drugs (if Therapeutic Class): N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 4/19/2017

Date Last Reviewed / Revised: 12/8/2022

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I though V are met)

I. Documented diagnosis of one of the following conditions A through L 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 one of the following criteria are met:
   1. Metastatic NSCLC and documentation:
      a) The cancer is expressing PD-L1 (≥1%) as determined by an FDA-approved test.
      b) EGFR or ALK genomic tumor aberrations are not present.
      c) Opdivo® will be used as first line treatment in combination with ipilimumab.
   2. Metastatic or recurrent NSCLC and documentation:
      a) EGFR or ALK genomic tumor aberrations are not present.
      b) Opdivo® will be used as first line treatment in combination with ipilimumab and 2 cycles of platinum-doublet chemotherapy.
   3. Metastatic or recurrent NSCLC with EGFR or ALK genomic tumor aberrations:
      a) Documentation of disease progression on or after platinum-based chemotherapy and the FDA approved treatments for tumors with EGFR and ALK have been used prior to receiving treatment.

D. Neoadjuvant Treatment of Resectable Non-Small Cell Lung Cancer (NSCLC).
   1. The patient's cancer is resectable (tumors ≥4 cm or node positive).
   2. Opdivo will be used as neoadjuvant treatment in combination with platinum-doublet chemotherapy.

E. Unresectable malignant pleural mesothelioma
    1. Opdivo® will be used as a first line treatment in combination with ipilimumab.
F. Advanced renal cell carcinoma (RCC) and one of the following criteria 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 of Advanced disease.
        a) Opdivo® will be used in combination with Cometriq® (cabozantinib)
    3. Documentation disease is intermediate or poor risk and criteria a is met:
        a) Opdivo® will be used in combination with ipilimumab.
G. Classical Hodgkin lymphoma and criteria 1 through 3 are met:
    1. Documentation that disease has relapsed or progressed after post-transplantation and Adcetris® (brentuximab vedotin) or 3 other lines of systemic chemotherapy that includes HSCT.
    2. Opdivo® will be used as a single agent.
H. 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.
I. Locally advanced or metastatic urothelial carcinoma and criteria 1 or 2 is met:
    1. The patient has undergone radical resection of urothelial carcinoma and is at high risk of recurrence.
        a) Opdivo® will be used as adjuvant treatment.
    2. 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.
J. 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 irinotecan.
    2. Opdivo® will be used as a single agent or in combination with ipilimumab.

K. Hepatocellular carcinoma and criteria 1and 2 are met:
   1. Previously treated with sorafenib
   2. Opdivo® will be used as a single agent or in combination with ipilimumab.

L. Esophageal Cancer and criteria 1 OR 2 are met:
   1. Completely resected esophageal or gastroesophageal junction cancer with residual pathologic disease and criteria a and b are met:
      a) Opdivo® will be used as adjuvant treatment.
      b) The patient has received neoadjuvant chemoradiotherapy (CRT).
   2. Unresectable advanced, recurrent, or metastatic esophageal squamous cell carcinoma (ESCC) and one of the following criteria a through C is met:
      a) Previously treated with fluoropyrimidine and platinum-based chemotherapy and Opdivo® will be used as a single agent.
      b) Opdivo will be used as first line agent in combination with fluoropyrimidine- and platinum-containing chemotherapy.
      c) Opdivo will be used as first line agent in combination with ipilimumab.

M. Advanced or metastatic gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma and criteria 1and 2 are met:
   1. Opdivo® will be used in combination with fluoropyrimidine- and platinum-containing chemotherapy

II. Minimum age requirement: 18 years old, unless noted under Quantity/Day supply.

III. Treatment must be prescribed by or in consultation with an oncologist or a hematologist.

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

V. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to the preferred product(s).

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: Age ≥18 years.
    - 240 mg every 2 weeks, or 480 every 4 weeks as a single agent
    - 1 mg/kg every 3 weeks with ipilimumab for maximum 4 doses, then 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: Age ≥18 years.
    - 240 mg every 2 weeks or 480 mg every 4 weeks
- Metastatic non-small cell lung cancer: Age ≥18 years.
    - 3 mg/kg every 2 weeks with ipilimumab 1 mg/kg every 6 weeks.
    - 360 mg every 3 weeks with ipilimumab 1 mg/kg every 6 weeks and 2 cycles of platinum-doublet chemotherapy.
    - 240 mg every 2 weeks or 480 mg every 4 weeks as a single agent
- Neoadjuvant Treatment of Resectable Non-Small Cell Lung Cancer: Age ≥18 years.
    - 360mg every 3 weeks with platinum-doublet chemotherapy on the same day every 3 weeks for 3 cycles
- Malignant pleural mesothelioma: Age ≥18 years.
    - 360 mg every 3 weeks with ipilimumab 1 mg/kg every 6 weeks.
- Advanced Renal Cell Carcinoma: Age ≥18 years.
    - 240 mg ever 2 weeks or 480 mg every 4 weeks as a single agent
    - Opdivo® 3 mg/kg, followed by ipilimumab on the same day, every 3 weeks for 4 doses, then Opdivo® 240 mg every 2 weeks, or 480 every 4 weeks
- Classical Hodgkin lymphoma: Age ≥18 years.
    - 240 mg every 2 weeks or 480 mg every 4 weeks as a single agent
- Recurrent or metastatic squamous cell carcinoma of head and neck: Age ≥18 years.
    - 240 mg every 2 weeks or 480 mg every 4 weeks
- Locally advanced or metastatic urothelial carcinoma: Age ≥18 years.
    - 240 mg every 2 weeks or 480 mg every 4 weeks as a single agent
- Microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer: Age ≥12 years.

- Adult and pediatric patients ≥40 kg: 240 mg every 2 weeks or 480 mg every 4 weeks.
- Pediatric patients <40 kg: 3 mg/kg every 2 weeks.
- Adult and pediatric patients ≥40 kg: 3 mg/kg followed by ipilimumab 1 mg/kg on the same day every 3 weeks for 4 doses, then 240 mg every 2 weeks or 480 mg every 4 weeks.

- Hepatocellular carcinoma: Age ≥18 years.
  - 240 mg every 2 weeks or 480 mg every 4 weeks.
  - Opdivo® 1 mg/kg followed by ipilimumab 3 mg/kg on the same day every 3 weeks for 4 doses, then 240 mg every 2 weeks or 480 mg every 4 weeks.
- Esophageal squamous cell carcinoma: Age ≥18 years.
  - 240 mg every 2 weeks or 480 mg every 4 weeks as a single agent
  - 3mg/kg every 2 weeks or 360mg every 3 weeks with ipilimumab
- Advanced or metastatic gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma: Age ≥18 years.
  - 240 mg every 2 weeks with fluoropyrimidine- and platinum-containing chemotherapy every 2 weeks
  - 360mg every 3 weeks with fluoropyrimidine- and platinum-containing chemotherapy every 3 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. Opdivo. Prescribing information. Bristol-Myers Squibb Company. 2022. Accessed December 8, 2022. http://packageinserts.bms.com/pi/pi_opdivo.pdf.
2. Medi-Span.
3. NCCN Clinical Practice Guidelines in Oncology. Melanoma: Cutaneous V.3.2022. Updated April 11, 2022. Accessed December 8, 2022. https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf.

4. NCCN Clinical Practice Guidelines in Oncology. Non-Small Cell lung Cancer V.6.2022. Updated December 2, 2022. Accessed December 8, 2022. https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf.
5. NCCN Clinical Practice Guidelines in Oncology. Head and Neck cancers V.2.2022. Updated April 26, 2022. Accessed December 8, 2022. https://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf.
6. NCCN Clinical Practice Guidelines in Oncology. Esophageal and Esophagogastric junction cancers V.5.2022. Updated December 5, 2022. Accessed December 8, 2022. https://www.nccn.org/professionals/physician_gls/pdf/esophageal.pdf.
7. NCCN Clinical Practice Guidelines in Oncology. Kidney Cancer V.3.2023. Updated September 22, 2022. Accessed December 8, 2022. https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf.