Opdivo (nivolumab)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Opdivo (nivolumab)

APPROVAL CRITERIA

Requests for Opdivo (nivolumab) may be approved if the following criteria are met:

I. Individual is using for the treatment of Bone cancer, including osteosarcoma, Ewing Sarcoma, chondrosarcoma, and chordoma; **AND**
   A. Individual is using in combination with ipilimumab for unresectable or metastatic disease; **AND**
   B. Individual has failed and progression on prior treatment; **AND**
   C. Individual has no satisfactory alternative treatment options for tissue tumor mutation burden-high (TMB-H) tumors with 10 or more mutations per megabase;

OR

II. Individual has a diagnosis of Colorectal Cancer, including advanced Appendiceal Adenocarcinoma (Label, NCCN 2A); **AND**
   A. Individual meets one of the following criteria:
      1. Individual is using as monotherapy or in combination with ipilimumab in primary treatment for unresectable metachronous metastases (defective mismatch repair/high microsatellite instability [dMMR/MSIH] only) and previous adjuvant FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) within the past 12 months; **OR**
      2. Individual is using as monotherapy or in combination with ipilimumab as subsequent therapy for unresectable advanced or metastatic disease (defective mismatch repair/high microsatellite instability [dMMR/MSIH] only) following previous treatment with fluoropyrimidine-, oxaliplatin-, or irinotecan- based chemotherapy (Label, NCCN 2A);

   AND
   B. Individual has not received another anti-PD-1 or anti-PD-L1 agent; **AND**
   C. Individual has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0-2; **AND**
   D. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

III. Individual has a diagnosis of unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC) (Label); **AND**
   A. Individual is using in one of the following ways:
      1. In combination with ipilmumab (Yervoy); **OR**

2. In combination with fluoropyrimidine- and platinum-containing chemotherapy;

AND

B. Individual is using as first-line treatment; **AND**
C. Individual has a current ECOG performance status of 0-1; **AND**
D. Individual has not received prior treatment with anti-PD-1, anti-PD-L1, any antibody or drug specifically targeting T-cell co-stimulation, or checkpoint pathways; **AND**
E. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

IV. Individual has a diagnosis of unresectable locally advanced, recurrent, or metastatic Esophageal Squamous Cell Carcinoma (ESCC) (Label, NCCN 1); **AND**
A. Individual is using as single agent for second line or subsequent therapy; **AND**
B. Individual has confirmation of disease progression on or had intolerance to fluoropyrimidine- and platinum-based chemotherapy; **AND**
C. Individual has a current ECOG performance status of 0-2 or Karnofsky performance score of 60-100; **AND**
D. Individual has not received treatment with another anti-PD-1, anti-PD-L1 agent, or other checkpoint inhibitor; **AND**
E. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

V. Individual has a diagnosis of *completely resected* Esophageal or Gastroesophageal Junction Cancer (Label, NCCN 1); **AND**
A. Individual is using as single agent for residual pathologic disease; **AND**
B. Individual has received neoadjuvant chemoradiotherapy (CRT); **AND**
C. Individual has a current ECOG performance status of 0-2; **AND**
D. Individual has not received treatment with another anti-PD-1, anti-PD-L1 agent, or other checkpoint inhibitor; **AND**
E. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

VI. Individual has a diagnosis of advanced or metastatic Gastric, Gastroesophageal Junction Cancer, or Esophageal Adenocarcinoma (Label, NCCN 1, 2A); **AND**
A. Individual is using in combination with fluoropyrimidine and platinum-containing chemotherapy; **AND**
B. Individual has HER2 negative disease; **AND**
C. Individual has a current ECOG performance status of 0-2; **AND**
D. Individual has not received treatment with another anti-PD-1, anti-PD-L1 agent, or other checkpoint inhibitor; **AND**
E. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

VII. Individual has a diagnosis of advanced Hepatocellular Carcinoma and the following criteria are met (Label, NCCN 2A):
   A. Individual is using as monotherapy or in combination with ipilimumab for subsequent therapy; **AND**
   B. Individual has a current ECOG performance status of 0-2; **AND**
   C. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
   D. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

VIII. Individual has a diagnosis of Hodgkin Lymphoma and the following criterion is met (Label, NCCN 2A):
   A. Individual is using for relapsed or refractory Hodgkin lymphoma except for those with lymphocyte-predominant Hodgkin lymphoma;

OR

IX. Individual has a diagnosis of relapsed/refractory advanced classic Kaposi Sarcoma and the following criteria are met (NCCN 2A):
   A. Individual is using in combination with ipilimumab (Yervoy); **AND**
   B. Individual is using as subsequent systemic therapy;

OR

X. Individual has a diagnosis of unresectable Malignant Pleural or Peritoneal Mesothelioma and using as first line therapy (Label, NCCN 2A); **AND**
   A. Individual is using in combination with ipilimumab (Yervoy); **AND**
   B. Individual has a ECOG performance status of 0-2; **AND**
   C. Has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
   D. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

XI. Individual has a diagnosis of Malignant Pleural or Peritoneal Mesothelioma (NCCN 2A); **AND**
   A. Individual is using as a single agent, or in combination with ipilimumab (Yervoy) for subsequent therapy; **AND**
   B. Individual has a ECOG performance status of 0-2; **AND**
   C. Has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
   D. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

XII. Individual has a diagnosis of Melanoma (Cutaneous or Uveal) when the following criteria are met (Label):
   A. Individual has unresectable or metastatic melanoma; **AND**
      1. Individual is using as a single agent, or in combination with ipilimumab; **AND**
      2. Individual has a current ECOG performance status of 0-2; **AND**
      3. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
      4. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

B. Individual has resected advanced melanoma (Label, NCCN 2A); **AND**
    1. Individual is using as a single agent for adjuvant therapy; **AND**
    2. Individual has resected stage IIB, stage IIC, stage III, or stage IV disease; **AND**
    3. Individual has a current ECOG performance status of 0-2; **AND**
    4. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
    5. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

C. Individual has Melanoma (Cutaneous or Uveal) (Label); **AND**
    1. One of the following:
        i. Individual has melanoma with involvement of lymph nodes; **OR**
        ii. Individual has metastatic melanoma and has undergone complete resection;

    AND
    2. Individual is using as a single agent for adjuvant therapy;

OR

XIII. Individual has a diagnosis of metastatic Melanoma with brain metastases and the following criteria are met (NCCN 2A):
A. Individual has a primary diagnosis of melanoma; **AND**
B. Individual has asymptomatic brain metastases (Long 2017, 2018, Tawbi 2017); **AND**
C. Individual is using as monotherapy or in combination with ipilimumab; **AND**
D. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
E. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

XIV. Individual has a diagnosis of Merkel Cell Carcinoma and the following criteria are met (Label, NCCN 2A):
A. Individual is using as a single agent; **AND**
B. Individual has presence of metastatic or recurrent locoregional MCC determined to be not amenable to definitive surgery or radiation therapy; **AND**
C. Individual has a current ECOG performance status of 0-2; **AND**
D. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
E. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

XV. Individual has a diagnosis of Non-Small Cell Lung Cancer (NSCLC) and the following criteria are met (Label, NCCN 2A):
A. Individual has metastatic NSCLC; **AND**
    1. Individual is using as a single agent; **AND**
    2. Individual has confirmation of disease progression on or after platinum-containing chemotherapy; **AND**
    3. Individual has a current ECOG performance status of 0-2; **AND**
    4. Individual has not received treatment with another anti-PD-1 or anti-PD-L1

agent; **AND**
5. Individual is not receiving therapy for an autoimmune disease, chronic condition or interstitial lung disease with a systemic immunosuppressant;

OR

B. Individual has recurrent, advanced, or metastatic NSCLC and using as first-line therapy (Label, NCCN 1); **AND**
   1. Individual is using in combination with ipilimumab; **AND**
   2. Individual does not have presence of actionable molecular markers*; **AND**
   3. Individual has PD-L1 expression positive (≥1%) tumor; **AND**
   4. Current ECOG performance status of 0-2; **AND**
   5. Has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
   6. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

C. Individual has recurrent, advanced, or metastatic NSCLC and using as first-line therapy (Label, NCCN 1, 2A); **AND**
   1. Individual is using in combination with ipilimumab *and* 2 (two) cycles of platinum-doublet chemotherapy (i.e., platinum-based chemotherapy with pemetrexed, or carboplatin with paclitaxel); **AND**
   2. Individual does not have presence of actionable molecular markers*; **AND**
   3. Current ECOG performance status of 0-2; **AND**
   4. Has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
   5. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

D. Individual is using for continuation treatment of recurrent, advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) (NCCN 1, 2A); **AND**
   1. Individual is using in combination with ipilimumab (Yervoy); **AND**
   2. Individual achieved a response or has stable disease following first line therapy of nivolumab + ipilimumab +/- chemotherapy given; **AND**
   3. Individual does not have presence of actionable molecular markers*; **AND**
   4. Current ECOG performance status of 0-2; **AND**
   5. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

E. Individual has resectable NSCLC and using as neoadjuvant therapy (Label, NCCN 2A); **AND**
   1. Individual is using in combination with platinum-doublet chemotherapy (e.g. paclitaxel and carboplatin); **AND**
   2. Resectable is defined as tumors ≥ 4 cm or node positive; **AND**
   3. Current ECOG performance status of 0-2; **AND**
   4. Has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
   5. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

XVI. Individual has a diagnosis of metastatic NSCLC with brain metastases and the following criteria are met (NCCN 2A):
A. Individual has a primary diagnosis of non-small cell lung cancer; **AND**
B. Individual is using as single agent for brain metastases; **AND**
C. Individual has PD-L1 expression positive (≥ 1%) tumors; **AND**
D. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
E. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

XVII. Individual has a diagnosis of Renal Cell Carcinoma (RCC) (Label, NCCN 2A); **AND**
A. Individual has advanced or metastatic RCC; **AND**
1. Individual is using as monotherapy; **AND**
2. Histologic confirmation of RCC with clear-cell component; **AND**
3. Individual has confirmation of disease progression after one or two prior anti-angiogenic regimens (for example, axitinib, bevacizumab [or bevacizumab biosimilar], pazopanib, sorafenib, sunitinib, etc.) for treatment of advanced or metastatic disease; **AND**
4. Individual has a current ECOG performance status 0-2; **AND**
5. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
6. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with an immunosuppressant;

OR

B. Individual has intermediate- or poor-risk, advanced RCC; **AND**
1. Individual is using in combination with ipilimumab, for four cycles followed by single agent Opdivo (nivolumab) as first-line therapy for previously untreated RCC; **OR**
2. Individual is using in combination with ipilimumab for four cycles followed by single agent Opdivo (nivolumab), as subsequent therapy, if no checkpoint blockade (PD-1, PD-L1, or CTLA-4) antibody treatment has been previously administered (NCCN 2A); **AND**
3. Histologic confirmation of RCC with clear-cell component; **AND**
4. Individual has a current ECOG performance status 0-2; **AND**
5. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
6. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

C. Individual has relapsed, recurrent, or advanced RCC (Label, NCCN 2A); **AND**
1. Individual is using as first-line therapy in combination with cabozantinib tablets; **AND**
2. Current ECOG performance status of 0-2; **AND**
3. Has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
4. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

XVIII. Individual has a diagnosis of Small Bowel Adenocarcinoma (SBA) and meets the following criteria (NCCN 2A):
- A. Individual has advanced or metastatic disease (deficient mismatch repair/microsatellite instability-high [dMMR/MSI-H] only); **AND**
- B. Individual is using as monotherapy or in combination with ipilimumab as subsequent therapy; **AND**
- C. Current ECOG performance status of 0-2; **AND**
- D. Has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
- E. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

XIX. Individual has a diagnosis of Small Bowel Adenocarcinoma (SBA)—Advanced ampullary cancer and meets the following criteria (NCCN 2A);
- A. Individual has advanced or metastatic disease (deficient mismatch repair/microsatellite instability-high [dMMR/MSI-H] only); **AND**
- B. Individual is using as initial or subsequent therapy as monotherapy or in combination with ipilimumab; **AND**
- C. Current ECOG performance status of 0-2; **AND**
- D. Has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
- E. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

XX. Individual has a diagnosis of Squamous Cell Carcinoma of the Head and Neck (SCCHN) and meet the following criteria:
- A. Individual has recurrent, unresectable, or metastatic SCCHN; **AND**
  1. Individual is using as monotherapy; **AND**
  2. Individual has confirmation of disease progression on or after platinum-containing chemotherapy; **AND**
  3. Individual has a current ECOG performance status of 0-2; **AND**
  4. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
  5. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

XXI. Individual has Urothelial carcinoma and meets the following criteria:
- A. Individual has locally advanced or metastatic disease; **AND**
  1. Individual is using as a single agent; **AND**
  2. Individual meets the following criteria:
     - i. Confirmation of disease progression on or after platinum-containing chemotherapy; **OR**
     - ii. Confirmation of disease progression within 12 months of receiving neoadjuvant or adjuvant treatment with platinum-containing chemotherapy;

  OR
- B. Individual is using as single agent for adjuvant therapy;

AND

C. Individual is at high risk of recurrence after having radical resection; **AND**
D. Individual has a current ECOG performance status of 0-2; **AND**
E. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
F. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

XXII. Individual has relapsed or refractory Primary Mediastinal Large B-Cell Lymphoma; **AND**
A. Individual is using as a single agent; OR
B. Individual is using in combination with brentuximab vedotin.

***Note:** Actionable molecular markers include EGFR, ALK, ROS1, BRAF, NTRK, MET, RET, and ERBB2 (HER2) mutations. The NCCN panel recommends testing prior to initiating therapy to help guide appropriate treatment. If there is insufficient tissue to allow testing for all of these markers, repeat biopsy and/or plasma testing should be done. If these are not feasible, treatment is guided by available results and, if unknown, these patients are treated as though they do not have driver oncogenes (NCCN 1, 2A).

Opdivo (nivolumab) may not be approved when the above criteria are not met and for all other indications.

Key References:

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18. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. January 24, 2023
    a. Ampullary Adenocarcinoma. V2.2022. Revised December 6, 2022.
    b. Anal Carcinoma V1.2023. Revised January 9, 2023.
    c. B-Cell Lymphomas. V5.2022. Revised July 12, 2022.
    d. Bladder Cancer V3.2022. Revised December 21, 2022.
    e. Bone Cancer. V2.2023. Revised September 28, 2022.
    f. Central Nervous System Cancers V2.2022. Revised September 29, 2022.
    g. Cervical Cancer. V1.2023. Revised January 6, 2023.
    h. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma. V1.2023. Revised August 30, 2022.
    i. Colon Cancer V2.2022. Revised October 27, 2022.
    j. Cutaneous Melanoma. V1.2023. December 22, 2022.
    k. Esophageal and Esophagogastric Junction Cancers. V5.2022. Revised December 5, 2022.
    l. Gastric Cancer. V2.2022. Revised January 11, 2022.
    m. Gestational Trophoblastic Neoplastic. V1.2023. Revised December 20, 2022.
    n. Head and Neck Cancer V1.2023. Revised December 20, 2022.
    o. Hepatobiliary Cancers V5.2022. Revised January 13, 2023.
    p. Hodgkin Lymphoma V2.2023. Revised November 8, 2022.
    q. Kaposi Sarcoma. V1.2023. Revised December 20, 2022.
    r. Kidney Cancer. V4.2023. Revised January 18, 2023.
    s. Merkel Cell Carcinoma. V2.2022. Revised March 24, 2022.
    t. Malignant Pleural Mesothelioma V1.2023. Revised December 15, 2022.
    u. Malignant Peritoneal Mesothelioma. V1.2023. Revised December 15, 2022.
    v. Cutaneous Melanoma V1.2022. Revised December 3, 2021.
    w. Neuroendocrine and Adrenal Tumors. V2.2022. Revised December 21, 2022.
    x. Non-Small Cell Lung Cancer. V1.2023. Revised December 22, 2022.
    y. Pediatric Aggressive Mature B-Cell Lymphomas. V3.2022. Revised October 19, 2022.
    z. Pediatric Central Nervous System Cancers. V2.2023. Revised October 31, 2022.
    aa. Pediatric Hodgkin Lymphoma. V1.2023. Revised January 12, 2023.
    bb. Rectal Cancer V3.2022. Revised October 27, 2022.
    cc. Small Bowel Adenocarcinoma V1.2023. Revised January 9, 2023.
    dd. Small Cell Lung Cancer. V3.2023. Revised December 21, 2022.
    ee. T-Cell Lymphomas. V1.2023. Revised January 5, 2023.
    ff. Uterine Neoplasms. V1.2023. Revised December 22, 2022.
    gg. Uveal Melanoma V2.2022. Revised April 5, 2022.
    hh. Vulvar Cancer (Squamous Cell Carcinoma). V1.2023. Revised December 22, 2022.
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Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.