Opdivo (nivolumab)

NOTICE

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BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Opdivo (nivolumab) drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines, and clinical studies. Opdivo (nivolumab) is a human immunoglobulin G4 (IgG4) monoclonal antibody that binds to the P-1 receptor and blocks its interaction with PD-L1 and PD-L2, releasing PD-1 pathway-mediated inhibition of the immune response, including the anti-tumor response.

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Unresectable or Metastatic Melanoma
   Opdivo (nivolumab), as a single agent or in combination with ipilimumab, is indicated for the treatment of adult and pediatric patients 12 years and older with unresectable or metastatic melanoma.

2. Adjuvant Treatment of Melanoma
   Opdivo is indicated for the adjuvant treatment of adult and pediatric patients 12 years and older with completely resected stage IIB, stage IIC, stage III, or stage IV melanoma.

3. Metastatic Non-Small Cell Lung Cancer
   a. Opdivo, in combination with ipilimumab, is indicated for the first-line treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors express PD-L1 (≥1%) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations.

b. Opdivo, in combination with ipilimumab and 2 cycles of platinum-doublet chemotherapy, is indicated for the first-line treatment of adult patients with metastatic or recurrent NSCLC, with no EGFR or ALK genomic tumor aberrations.
c. Opdivo is indicated for the treatment of adult patients with metastatic NSCLC with progression on or after platinum-based chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving Opdivo.

4. Neoadjuvant Treatment of Resectable Non-Small Cell Lung Cancer.
Opdivo, in combination with platinum-doublet chemotherapy, is indicated for the neoadjuvant treatment of adult patients with resectable (tumors ≥4 cm or node positive) non-small cell lung cancer (NSCLC) and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements, followed by single-agent Opdivo as adjuvant treatment after surgery.

5. Neoadjuvant and Adjuvant Treatment of Resectable Non-Small Cell Lung Cancer.
Opdivo, in combination with platinum-doublet chemotherapy, is indicated as neoadjuvant treatment of adult patients with resectable (tumors ≥4 cm or node positive) non-small cell lung cancer (NSCLC) and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements, followed by single-agent OPDIVO as adjuvant treatment after surgery.

6. Malignant Pleural Mesothelioma
Opdivo, in combination with ipilimumab, is indicated for the first-line treatment of adult patients with unresectable malignant pleural mesothelioma.

7. Advanced Renal Cell Carcinoma
a. Opdivo as a single agent is indicated for the treatment of adult patients with advanced renal cell carcinoma (RCC) who have received prior anti-angiogenic therapy.
b. Opdivo, in combination with ipilimumab, is indicated for the first-line treatment of adult patients with intermediate or poor risk advanced RCC.
c. Opdivo, in combination with cabozantinib, is indicated for the first-line treatment of adult patients with advanced RCC.

8. Classical Hodgkin Lymphoma
Opdivo is indicated for the treatment of adult patients with classical Hodgkin lymphoma (cHL) that has relapsed or progressed after:
a. Autologous hematopoietic stem cell transplantation (HSCT) and brentuximab vedotin, or
b. Three or more lines of systemic therapy that includes autologous HSCT.

9. Squamous Cell Carcinoma of the Head and Neck
Opdivo is indicated for the treatment of adult patients with recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN) with disease progression on or after platinum-based therapy.

10. Urothelial Carcinoma
a. Opdivo is indicated for the adjuvant treatment of adult patients with urothelial carcinoma (UC) who are at high risk of recurrence after undergoing radical resection of UC.
b. Opdivo, in combination with cisplatin and gemcitabine, is indicated for the first-line treatment of adult patients with unresectable or metastatic urothelial carcinoma.
c. Opdivo is indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma who:
i. Have disease progression during or following platinum-containing chemotherapy
ii. Have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

11. Microsatellite Instability-High or Mismatch Repair Deficient Metastatic Colorectal Cancer
    Opdivo, in combination with ipilimumab, is indicated for the treatment of adult and pediatric patients 12 years and older with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer (CRC).

    Opdivo, as a single agent, is indicated for the treatment of adult and pediatric patients 12 years and older with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer (CRC) that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.

12. Hepatocellular Carcinoma
    Opdivo in combination with ipilimumab, is indicated for the first-line treatment of adult patients with unresectable or metastatic hepatocellular carcinoma (HCC). Opdivo, in combination with ipilimumab, is indicated for the treatment of adult patients with unresectable or metastatic HCC who have been previously treated with sorafenib.

13. Esophageal Carcinoma
    a. Opdivo is indicated for the adjuvant treatment of completely resected esophageal or gastroesophageal junction cancer with residual pathologic disease in adult patients who have received neoadjuvant chemoradiotherapy (CRT).
    b. Opdivo, in combination with fluoropyrimidine- and platinum-containing chemotherapy, is indicated for the first-line treatment of adult patients with unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC) whose tumors express PD-L1 (≥ 1) .
    c. Opdivo, in combination with ipilimumab, is indicated for the first-line treatment of adult patients with unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC) whose tumors express PD-L1 (≥ 1).
    d. Opdivo is indicated for the treatment of adult patients with unresectable advanced, recurrent or metastatic esophageal squamous cell carcinoma (ESCC) after prior fluoropyrimidine- and platinum-based chemotherapy.

14. Gastric Cancer, Gastroesophageal Junction Cancer, Esophageal Adenocarcinoma
    Opdivo, in combination with fluoropyrimidine- and platinum-containing chemotherapy, is indicated for the treatment of adult patients with advanced or metastatic gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma whose tumors express PD-L1 (≥ 1).

<u>Compendial Uses</u>

1. Cutaneous melanoma
2. Non-small cell lung cancer
3. Renal cell carcinoma
4. Classical Hodgkin lymphoma
5. Head and neck cancers
6. Urothelial carcinoma
    a. Bladder cancer
    b. Primary carcinoma of the urethra
    c. Upper genitourinary tract tumors
    d. Urothelial carcinoma of the prostate
7. Colorectal cancer, including appendiceal adenocarcinoma and anal adenocarcinoma
8. Hepatocellular carcinoma
9. Uveal Melanoma
10. Anal Carcinoma
11. Merkel Cell Carcinoma

12. Central Nervous System (CNS) brain metastases
13. Gestational trophoblastic neoplasia
14. Pleural mesothelioma
15. Peritoneal mesothelioma
16. Small bowel adenocarcinoma
17. Ampullary Adenocarcinoma
18. Extranodal NK/T-cell lymphoma
19. Endometrial Carcinoma
20. Vulvar Cancer
21. Gastric Cancer
22. Esophageal/Esophagogastric Junction Cancers
23. Small Cell Lung Cancer
24. Cervical Cancer
25. Pediatric Diffuse High-Grade Gliomas
26. Pediatric Primary Mediastinal Large B-cell Lymphoma
27. Kaposi Sarcoma
28. Bone Cancer
29. Biliary Tract Cancers
    a. Cholangiocarcinoma
    b. Gallbladder Cancer
30. Soft Tissue Sarcoma
    a. Extremity/body wall sarcoma
    b. Head/neck sarcoma
    c. Retroperitoneal/intra-abdominal sarcoma
    d. Rhabdomyosarcoma
    e. Angiosarcoma
31. Anaplastic Thyroid Carcinoma
32. Histologic (Richter) transformation to diffuse large B cell lymphoma
33. Vaginal Cancer
34. Squamous cell skin carcinoma

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

A. Documentation of laboratory report confirming MSI-H, mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1) tumor status, where applicable.
B. Documentation of programmed death ligand 1 (PD-L1) tumor expression, where applicable.
C. Documentation of molecular testing for EGFR alterations or ALK, RET, and ROS1 rearrangements, where applicable.

Exclusions

Coverage will not be provided for members who have experienced disease progression while on programmed death receptor-1 (PD-1) or programmed death ligand 1 (PD-L1) inhibitor therapy unless any of the following apply:

- The requested medication will be used for treatment of metastatic or unresectable melanoma
- The requested medication will be used for treatment of metastatic or unresectable small bowel adenocarcinoma in combination with ipilimumab following progression on single agent checkpoint inhibitor therapy

- The requested medication will be used for treatment of hepatocellular carcinoma following progression on therapy with atezolizumab plus bevacizumab

Criteria for Initial Approval

A. Cutaneous Melanoma

Authorization of 6 months may be granted for treatment of cutaneous melanoma when any of the following settings:

1. The requested medication will be used as a single agent or in combination with ipilimumab (4 doses of ipilimumab, followed by Opdivo as a single agent) for unresectable or metastatic disease.
2. The requested medication will be used as a single agent or in combination with ipilimumab (4 doses of ipilimumab, followed by Opdivo as a single agent) as adjuvant treatment of stage III or IV disease following complete resection or no evidence of disease.
3. The requested medication will be used as single agent adjuvant treatment of stage IIB and IIC disease following complete resection.
4. The requested medication will be used as a single agent or in combination with ipilimumab (4 doses of ipilimumab, followed by Opdivo as a single agent) as neoadjuvant treatment.

B. Non-Small Cell Lung Cancer (NSCLC)

1. Authorization of 6 months may be granted for treatment of recurrent, advanced or metastatic non-small cell lung cancer when both of the following criteria are met:
   i. There are no EGFR exon 19 deletions, exon 21 L858R mutations or ALK, RET, or ROS1 rearrangements (unless testing is not feasible due to insufficient tissue).
   ii. The requested medication will be used in a regimen containing ipilimumab or as single agent subsequent therapy.
2. Authorization of 3 months (for up to 3 cycles total) may be granted for neoadjuvant treatment of resectable non-small cell lung cancer (NSCLC) in combination with platinum-doublet chemotherapy when there are no known EGFR mutations or ALK rearrangements (unless testing is not feasible due to insufficient tissue).
3. Authorization of 6 months may be granted for neoadjuvant and adjuvant treatment of resectable non-small cell lung cancer (NSCLC) when both of the following conditions are met:
   i. There are no EGFR mutations or ALK rearrangements (unless testing is not feasible due to insufficient tissue)
   ii. The requested medication is used in combination with platinum doublet chemotherapy (for up to 4 cycles total), followed by single agent adjuvant therapy (for up to 13 cycles)

C. Renal Cell Carcinoma

Authorization of 6 months may be granted for treatment of relapsed, advanced, or stage IV renal cell carcinoma when any of the following criteria are met:

1. The requested medication will be used as a single agent for clear cell histology as subsequent therapy.
2. The requested medication will be used as a single agent for non-clear cell histology.
3. The requested medication will be used in combination with ipilimumab (4 doses of ipilimumab, followed by Opdivo as a single agent) for disease with clear cell histology.
4. The requested medication will be used in combination with cabozantinib.

D. Classic Hodgkin Lymphoma (cHL)

Authorization of 6 months may be granted for treatment of classic Hodgkin lymphoma when the requested regimen will be used in any of the following regimens:

1. As a single agent
2. In combination with brentuximab vedotin
3. In combination with ICE (ifosfamide, carboplatin, etoposide)

4. In combination with AVD (doxorubicin, vinblastine, and dacarbazine)

E. Head and Neck Cancers

Authorization of 6 months may be granted for treatment of head and neck cancers in members with either of the following:

1. Non-nasopharyngeal very advanced head and neck cancer that is unresectable, recurrent, persistent or metastatic, in combination with cetuximab or as a single agent.
2. Nasopharyngeal cancer in combination with cisplatin and gemcitabine for unresectable, recurrent, persistent or metastatic disease.

F. Urothelial Carcinoma – Bladder Cancer

1. Authorization of 6 months may be granted when used in combination with gemcitabine and cisplatin for up to 6 cycles followed by nivolumab maintenance therapy as first line treatment of bladder cancer.
2. Authorization of 6 months may be granted as a single agent for treatment of bladder cancer when any of the following conditions are met:
    a. As subsequent therapy for stage II, locally advanced, recurrent, persistent, or metastatic disease.
    b. As adjuvant therapy in members who are at high risk of recurrence after undergoing resection.

G. Urothelial Carcinoma – Primary Carcinoma of the Urethra

1. Authorization of 6 months may be granted in combination with gemcitabine and cisplatin for up to 6 cycles followed by nivolumab maintenance therapy as first line treatment of primary carcinoma of the urethra.
2. Authorization of 6 months may be granted as a single agent for treatment of primary carcinoma of the urethra when either of the following are met:
    a. As subsequent therapy for recurrent, locally advanced, or metastatic disease.
    b. As adjuvant therapy in members who are at high risk of recurrence after undergoing resection.

H. Urothelial Carcinoma – Upper Genitourinary Tract Tumors or Urothelial Carcinoma of the Prostate

1. Authorization of 6 months may be granted in combination with gemcitabine and cisplatin for up to 6 cycles followed by nivolumab maintenance therapy as first line treatment of metastatic upper genitourinary (GU) tract tumors or urothelial carcinoma of the prostate.
2. Authorization of 6 months may be granted as a single agent for treatment of upper genitourinary (GU) tract tumors or urothelial carcinoma of the prostate when either of the following are met:
    a. As subsequent therapy for locally advanced or metastatic disease.
    b. As adjuvant therapy in members who are at high risk of recurrence after undergoing resection.

I. Colorectal Cancer

Authorization of 6 months may be granted for treatment of colorectal cancer, including appendiceal adenocarcinoma and anal adenocarcinoma, for microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR) or polymerase epsilon/delta (POLE/POLD1) tumors with ultra-hypermutated phenotype (e.g., tumor mutational burden (TMB) > 50 mut/Mb) when used as a single agent or in combination with ipilimumab (4 doses of ipilimumab, followed by Opdivo as a single agent).

J. Small Bowel Adenocarcinoma

Authorization of 6 months may be granted as a single agent or in combination with ipilimumab (4 doses of ipilimumab, followed by Opdivo as a single agent) for treatment of unresectable, medically inoperable, advanced or metastatic small bowel adenocarcinoma for microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR) or polymerase epsilon/delta (POLE/POLD1) tumors with ultra-hypermutated phenotype (e.g., tumor mutational burden (TMB) > 50 mut/Mb).

K. Ampullary Adenocarcinoma

Authorization of 6 months may be granted in combination with ipilimumab (4 doses of ipilimumab, followed by Opdivo as a single agent) for treatment of progressive or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) ampullary adenocarcinoma.

L. Hepatocellular Carcinoma

Authorization of 6 months may be granted for treatment of hepatocellular carcinoma for either of the following:

1. First-line treatment of unresectable or extrahepatic/metastatic disease in combination with ipilimumab (4 doses of ipilimumab, followed by Opdivo as a single agent).
2. Subsequent treatment as a single agent or in combination with ipilimumab (4 doses of ipilimumab, followed by Opdivo as a single agent).

M. Uveal Melanoma

Authorization of 6 months may be granted as a single agent or in combination with ipilimumab (4 doses of ipilimumab, followed by Opdivo as a single agent) for treatment of uveal melanoma for unresectable or metastatic disease.

N. Anal Carcinoma

Authorization of 6 months may be granted as a single agent for subsequent treatment of metastatic anal carcinoma.

O. Merkel Cell Carcinoma

Authorization of 6 months may be granted for treatment of Merkel cell carcinoma in any of the following settings:

1. Metastatic disease.
2. Neoadjuvant treatment of node positive disease and node negative locally advanced disease when used as a single agent.
3. Unresectable, recurrent, or stage IV disease when used in combination with ipilimumab (4 doses of ipilimumab, followed by Opdivo as a single agent).

P. CNS Brain Metastases

Authorization of 6 months may be granted for treatment of CNS brain metastases when either of the following criteria are met:

1. The requested medication will be used as a single agent or in combination with ipilimumab (4 doses of ipilimumab, followed by Opdivo as a single agent) in members with melanoma.
2. The requested medication will be used as a single agent in members with PD-L1 positive non-small cell lung cancer.

Q. Gestational Trophoblastic Neoplasia

Authorization of 6 months may be granted as a single agent or in combination with ipilimumab for treatment of gestational trophoblastic neoplasia for multiagent chemotherapy-resistant disease when either of the following criteria is met:

1. Member has recurrent or progressive intermediate trophoblastic tumor (placental site trophoblastic tumor or epithelioid trophoblastic tumor).

2. Member has high-risk disease.

R. Pleural or Peritoneal Mesothelioma

Authorization of 6 months may be granted for the treatment of pleural or peritoneal mesothelioma, including pericardial mesothelioma and tunica vaginalis testis mesothelioma, in either of the following settings:

1. The requested medication will be used as first line or induction therapy in combination with ipilimumab.
   The requested medication will be used as subsequent therapy as a single agent or in combination with ipilimumab.

S. Esophageal and Esophagogastric Junction Carcinoma

1. Authorization of 6 months may be granted for treatment of esophageal or esophagogastric junction cancer in members who are not surgical candidates or have unresectable locally advanced, recurrent or metastatic disease for either of the following:
   a. First-line therapy when PD-L1 ≥ 1 and the requested medication will be used in combination with ipilimumab or chemotherapy
   b. Subsequent therapy
2. Authorization of 6 months may be granted for adjuvant treatment of completely resected esophageal or esophagogastric junction cancer with residual pathologic disease.
3. Authorization of 6 months may be granted as a single agent or in combination with ipilimumab for treatment of esophageal or esophagogastric junction adenocarcinoma if tumor is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR).
4. Authorization of 6 months may be granted for induction therapy for relieving dysphagia in combination with ipilimumab or chemotherapy for members with PD-L1 ≥ 1 planned for esophagectomy.

T. Extranodal NK/T-Cell Lymphoma

Authorization of 6 months may be granted for treatment of relapsed or refractory extranodal NK/T-cell lymphoma.

U. Endometrial Carcinoma

Authorization of 6 months may be granted as a single agent for subsequent treatment of recurrent microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) endometrial carcinoma.

V. Vulvar Cancer

Authorization of 6 months may be granted for treatment of HPV-related advanced, or recurrent/metastatic vulvar cancer as subsequent therapy as a single agent.

W. Gastric Cancer

Authorization of 6 months may be granted for treatment of gastric cancer in any of the following settings:

1. When the requested medication is being used in members who are not surgical candidates or have unresectable, recurrent, or metastatic disease and PD-L1 ≥ 1, when the requested medication will be used in combination with ipilimumab or chemotherapy.
2. When the requested medication will be used as a single agent, in combination with ipilimumab, or in combination with chemotherapy for treatment of gastric adenocarcinoma if tumor is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR).

X. Small Cell Lung Cancer

Authorization of 6 months may be granted for subsequent treatment of relapsed or progressive small cell lung cancer as a single agent.

Y. Cervical Cancer

Authorization of 6 months may be granted for subsequent treatment of recurrent or metastatic cervical cancer as a single agent if PD-L1 positive (combined positive score [CPS] ≥1).

Z. Pediatric Diffuse High-Grade Gliomas

Authorization of 6 months may be granted for hypermutant tumor pediatric diffuse high-grade glioma as adjuvant treatment or for recurrent or progressive disease.

AA. Pediatric Primary Mediastinal Large B-Cell Lymphoma

Authorization of 6 months may be granted as a single agent or in combination with brentuximab vedotin for treatment of relapsed or refractory primary mediastinal large B-cell lymphoma.

BB. Kaposi Sarcoma

Authorization of 6 months may be granted as a single agent or in combination with ipilimumab for subsequent treatment of relapsed/refractory Kaposi Sarcoma.

CC. Bone Cancer

Authorization of 6 months may be granted in combination with ipilimumab for unresectable or metastatic disease when all of the following are met:

1. Disease has tumor mutation burden-high (TMB-H) [≥10 mutations/megabase (mut/Mb)] tumors
2. Disease has progressed following prior treatment and has no satisfactory alternative treatment options

DD. Biliary Tract Cancers (Cholangiocarcinoma and Gallbladder Cancer)

Authorization of 6 months may be granted in combination with ipilimumab for subsequent treatment of unresectable or resected gross residual (R2) disease, or metastatic disease that is tumor mutation burden-high (TMB-H).

Authorization of 6 months may be granted in combination with ipilimumab for neoadjuvant treatment of resectable locoregionally advanced gallbladder cancer that is tumor mutation burden-high (TMB-H) when disease does not present as jaundice.

EE. Soft Tissue Sarcoma

Authorization of 6 months may be granted for treatment of soft tissue sarcoma in the following settings:

1. The requested medication will be used as a single agent or in combination with ipilimumab for treatment of extremity/body wall sarcomas, head/neck sarcomas and retroperitoneal/intra-abdominal sarcomas and rhabdomyosarcoma.
2. The requested medication will be used in combination with ipilimumab for the treatment of angiosarcoma.

FF. Anaplastic Thyroid Carcinoma

Authorization of 6 months may be granted as a single agent for treatment of stage IVC anaplastic thyroid carcinoma.

GG. Histologic (Richter) transformation to diffuse large B-cell lymphoma

Authorization of 6 months may be granted for treatment of Histologic (Richter) transformation to diffuse large B-cell lymphoma as a single agent or in combination ibrutinib.

HH. Vaginal Cancer

Authorization of 6 months may be granted as subsequent therapy for recurrent or metastatic vaginal cancer when the requested medication will be used as a single agent.

II. Squamous Cell Skin Cancer

Authorization of 6 months may be granted as a single agent for treatment of locally advanced, recurrent, unresectable, inoperable, incompletely resected, or metastatic squamous cell carcinoma that is not curable by surgery or radiation.

Continuation of Therapy

A. Adjuvant treatment of melanoma

Authorization of 6 months may be granted (up to 12 months total) for continued treatment in members requesting reauthorization for cutaneous melanoma who have not experienced disease recurrence or an unacceptable toxicity.

B. Urothelial Carcinoma

1. Authorization of 6 months may be granted (up to 12 months total) for continued treatment in members requesting reauthorization for adjuvant treatment of urothelial carcinoma who have not experienced disease recurrence or an unacceptable toxicity.
2. Authorization of 6 months may be granted (up to 24 months total) for continued treatment in members requesting reauthorization for urothelial carcinoma when the requested medication is used in combination with gemcitabine and cisplatin for up to 6 cycles followed by nivolumab maintenance therapy when the member has not experienced disease progression or an unacceptable toxicity

C. Non-small cell lung cancer or pleural or peritoneal mesothelioma

Authorization of 6 months may be granted (up to 24 months total when used in combination with ipilimumab) for continued treatment in members requesting reauthorization for non-small cell lung cancer (NSCLC) or pleural or peritoneal mesothelioma, including pericardial mesothelioma and tunica vaginalis testis mesothelioma subtypes, when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Neoadjuvant treatment of resectable NSCLC will be approved for a total of 3 months of therapy (up to 3 cycles) when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Authorization of 6 months may be granted for neoadjuvant treatment of resectable NSCLC (up to 4 cycles in combination with chemotherapy, followed by single agent adjuvant treatment up to 13 cycles) when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

D. Renal Cell Carcinoma

Authorization of 6 months may be granted (up to 24 months total when used in combination with cabozantinib) for continued treatment in members requesting reauthorization for renal cell carcinoma when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

E. Gastric Cancer, Esophageal Cancer, and Esophagogastric Junction Carcinoma

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for gastric cancer, esophageal cancer, and esophagogastric junction carcinoma when there is no evidence of unacceptable toxicity or disease progression while on the current regimen for the following durations of therapy:

3. Esophageal squamous cell carcinoma in combination with ipilimumab or chemotherapy for up to 24 months
4. Unresectable advanced, recurrent or metastatic esophageal squamous cell carcinoma as a single agent until disease progression or unacceptable toxicity
5. Adjuvant treatment of resected esophageal or esophagogastric junction cancer as a single agent for up to 12 months
6. Gastric cancer, esophagogastric junction cancer, and esophageal adenocarcinoma in combination with chemotherapy for up to 24 months
7. Gastric cancer in members who have completed endoscopic resection for up to 24 months

F. Biliary Tract Cancer (in combination with ipilimumab)
Authorization of 6 months may be granted (for 2 to 6 months total for neoadjuvant treatment, and for up to 24 months total for other clinical settings) for continued treatment in members requesting reauthorization for biliary tract cancer when requested medication is being used in combination with ipilimumab and when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

G. Squamous Cell Skin Cancer
Authorization of 6 months may be granted (up to 24 months total) for continued treatment in members requesting reauthorization for squamous cell skin cancer when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

H. All other indications
Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for all other indications listed in Criteria for Initial Approval Section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Opdivo is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosage and Administration
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J9299- Injection, nivolumab, 1mg

REFERENCES

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POLICY HISTORY

Policy #: 05.20.52
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