

Pre - PA Allowance

None

Prior-Approval Requirements

Age 12 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Unresectable or metastatic melanoma
 - a. Used as a single agent **OR** in combination with ipilimumab
2. Adjuvant treatment of melanoma post resection
 - a. Stage IIB, Stage IIC, Stage III, or Stage IV melanoma
3. Resectable non-small cell lung cancer (NSCLC)
 - a. Tumors ≥ 4 cm **OR** node positive
 - b. Used in combination with platinum-doublet chemotherapy in the neoadjuvant setting
4. Metastatic non-small cell lung cancer (NSCLC) with **ONE** of the following:
 - a. **NO** EGFR or ALK genomic tumor aberrations with **ONE** of the following:
 - i. Disease progressed on or after platinum-based chemotherapy
 - ii. Tumors express PD-L1 as determined by a FDA-approved test **AND** used as first-line treatment in combination with ipilimumab
 - iii. Used as first-line treatment in combination with ipilimumab and 2 cycles of platinum-doublet chemotherapy
 - b. Positive for EGFR or ALK genomic tumor aberrations
 - i. Disease must have progressed while on or after platinum-based chemotherapy
 - ii. Patient had disease progression on FDA approved therapy
5. Recurrent non-small cell lung cancer (NSCLC)
 - a. **NO** EGFR or ALK genomic tumor aberrations
 - b. Used as first-line treatment in combination with ipilimumab and 2 cycles of platinum-doublet chemotherapy
6. Advanced renal cell carcinoma with **ONE** of the following:
 - a. First-line treatment in combination with cabozantinib
 - b. Prior treatment with anti-angiogenic therapy
 - c. Patient is considered to have an intermediate or poor prognosis
 - i. Used as first-line treatment in combination with ipilimumab

7. Relapsed or progressed classical Hodgkin lymphoma with **ONE** of the following:
 - a. Patient has had autologous hematopoietic stem cell transplantation (HSCT) and post-transplantation therapy with brentuximab vedotin
 - b. Patient has had 3 or more lines of systemic therapy that includes autologous HSCT
8. Recurrent or metastatic squamous cell carcinoma of the head and neck
 - a. Disease must have progressed while on or after platinum-based chemotherapy
9. Urothelial carcinoma with **ONE** of the following:
 - a. Patient is at high risk of recurrence after undergoing radical resection
 - i. Used as adjuvant treatment
 - b. Unresectable or metastatic urothelial carcinoma
 - i. Used as first-line treatment in combination with cisplatin and gemcitabine
 - c. Locally advanced or metastatic urothelial carcinoma with **ONE** of the following:
 - i. Disease must have progressed while on or after platinum-based chemotherapy
 - ii. Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy
10. Unresectable or metastatic hepatocellular carcinoma (HCC)
 - a. Used as first-line treatment **OR** patient has had prior treatment with sorafenib
 - b. Used in combination with ipilimumab
11. Completely resected esophageal or gastroesophageal junction cancer with residual pathologic disease
 - a. Patient has received neoadjuvant chemoradiotherapy (CRT)
12. Unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC)
 - a. Tumors express PD-L1 as determined by an FDA-approved test
 - b. Used as first-line treatment
 - c. Used in combination with **ONE** of the following:
 - i. Fluoropyrimidine- and platinum-containing chemotherapy
 - ii. Ipilimumab
13. Unresectable advanced, recurrent, or metastatic esophageal squamous cell carcinoma (ESCC)

- a. Prior treatment with fluoropyrimidine- and platinum-based chemotherapy
- 14. Microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer (CRC) with **ONE** of the following:
 - a. Used as a single agent
 - i. Disease is metastatic
 - ii. Progressed following treatment with fluoropyrimidine, oxaliplatin, and irinotecan
 - iii. Diagnosis confirmed by PCR-based assay genetic testing
 - b. Used in combination with ipilimumab
 - i. Disease is unresectable or metastatic
 - ii. Diagnosis confirmed by PCR-based assay genetic testing
- 15. Unresectable malignant pleural mesothelioma
 - a. Used as first-line treatment in combination with ipilimumab
- 16. Advanced or metastatic gastric cancer, gastroesophageal junction cancer, or esophageal adenocarcinoma
 - a. Tumors express PD-L1 as determined by an FDA-approved test
 - b. Used in combination with fluoropyrimidine- and platinum-containing chemotherapy
- 17. Small cell lung cancer
- 18. Metastatic anal carcinoma
- 19. Merkel cell carcinoma

AND ALL of the following for **ALL** indications:

- a. Prescriber agrees to discontinue treatment for any immune mediated adverse reaction (encephalitis, nephritis, rash, decreased renal function and endocrinopathies) or disease progression
- b. Female patients of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Opdivo and for 5 months after the last dose

Prior - Approval Limits

Duration 6 months

Prior – Approval *Renewal* Requirements

Age 12 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Unresectable or metastatic melanoma
2. Adjuvant treatment of melanoma post resection: one renewal **only**
 - a. Stage IIB, Stage IIC, Stage III, or Stage IV melanoma
3. Resectable non-small cell lung cancer (NSCLC)
 - a. Used as a single agent after surgery as adjuvant treatment
 - b. **NO** known EGFR mutations or ALK rearrangements
4. Metastatic non-small cell lung cancer
 - a. **IF** used in combination with ipilimumab: one renewal **only**
5. Recurrent non-small cell lung cancer
 - a. Used in combination with ipilimumab: one renewal **only**
6. Advanced renal cell carcinoma
 - a. **IF** used in combination with cabozantinib: one renewal **only**
7. Relapsed or progressed classical Hodgkin lymphoma
8. Recurrent or metastatic squamous cell carcinoma of the head and neck
9. Urothelial carcinoma
 - a. **IF** used as adjuvant treatment in patients at high risk of recurrence after radical resection: one renewal **only**
 - b. **IF** used for unresectable or metastatic urothelial carcinoma, as first-line treatment in combination with cisplatin and gemcitabine: one renewal **only**
10. Unresectable or metastatic hepatocellular carcinoma (HCC)
11. Completely resected esophageal or gastroesophageal junction cancer with residual pathologic disease: one renewal **only**
12. Unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC)
 - a. Used in combination with **ONE** of the following:
 - i. Fluoropyrimidine- and platinum-containing chemotherapy: one renewal **only**
 - ii. Ipilimumab: one renewal **only**

13. Unresectable advanced, recurrent, or metastatic esophageal squamous cell carcinoma (ESCC)
 - a. Prior treatment with fluoropyrimidine- and platinum-based chemotherapy
14. Unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer (CRC)
15. Unresectable malignant pleural mesothelioma
 - a. Used in combination with ipilimumab: one renewal **only**
16. Advanced or metastatic gastric cancer, gastroesophageal junction cancer, or esophageal adenocarcinoma
 - a. Used in combination with fluoropyrimidine- and platinum-containing chemotherapy: one renewal **only**
17. Small cell lung cancer
18. Metastatic anal carcinoma
19. Merkel cell carcinoma

AND ALL of the following for **ALL** indications:

- a. **NO** disease progression or unacceptable toxicity
- b. Prescriber agrees to discontinue treatment for any immune mediated adverse reaction (encephalitis, nephritis, rash, decreased renal function and endocrinopathies) or disease progression
- c. Female patients of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Opdivo and for 5 months after the last dose

Prior - Approval *Renewal* Limits

Duration*

Indication	Renewal PA Duration*	Number of Renewals Allowed
Adjuvant treatment of melanoma post resection	6 months	One renewal only
Adjuvant treatment of urothelial carcinoma (patients at high risk of recurrence after radical resection)	6 months	One renewal only

**OPDIVO
(nivolumab)**

Completely resected esophageal or gastroesophageal junction cancer with residual pathological disease	6 months	One renewal only
Resectable non-small cell lung cancer (NSCLC) as adjuvant treatment after surgery	12 months	One renewal only
Advanced or metastatic gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma	18 months	One renewal only
Unresectable malignant pleural mesothelioma	18 months	One renewal only
Unresectable or metastatic urothelial carcinoma (first-line, in combination with cisplatin and gemcitabine)	18 months	One renewal only
Unresectable or metastatic hepatocellular carcinoma	18 months	One renewal only
Metastatic non-small cell lung cancer (NSCLC) **	18 months	<u>Used with ipilimumab</u> One renewal only
		<u>As a single agent</u> Until disease progression or unacceptable toxicity
Recurrent non-small cell lung cancer (NSCLC)**	18 months	One renewal only
Unresectable or metastatic MSI-H or dMMR colorectal cancer (CRC)	18 months	<u>Used with ipilimumab followed by Opdivo as a single agent:</u> One renewal only
Metastatic MSI-H or dMMR colorectal cancer (CRC)	18 months	<u>Prior treatment with fluoropyrimidine, oxaliplatin, and irinotecan:</u> Until disease progression or unacceptable toxicity

**OPDIVO
(nivolumab)**

Esophageal squamous cell carcinoma	18 months	<u>Used with ipilimumab or fluoropyrimidine- and platinum-containing chemotherapy:</u> One renewal only
		<u>Prior treatment with fluoropyrimidine- and platinum-based chemotherapy:</u> Until disease progression or unacceptable toxicity
Advanced renal cell carcinoma	18 months	<u>Used with cabozantinib:</u> One renewal only
		<u>NOT being used with cabozantinib:</u> Until disease progression or unacceptable toxicity
All other indications	18 months	Until disease progression or unacceptable toxicity

****NO** renewal for Resectable non-small cell lung cancer (NSCLC) used as neoadjuvant treatment