

**OPDIVO QVANTIG**  
**(nivolumab and hyaluronidase-nvhy)**

## **Pre - PA Allowance**

None

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## **Prior-Approval Requirements**

**Age** 18 years of age or older

### **Diagnoses**

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

1. Unresectable or metastatic melanoma
  - a. Used as a single agent
2. Adjuvant treatment of melanoma post resection
  - a. Stage IIB, Stage IIC, Stage III, or Stage IV melanoma
  - b. Used as a single agent
3. Resectable non-small cell lung cancer (NSCLC)
  - a. Tumors  $\geq 4$  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
    - i. Disease progressed on or after platinum-based chemotherapy
    - ii. Used as a single agent
  - b. Positive for EGFR or ALK genomic tumor aberrations
    - i. Patient had disease progression on FDA approved therapy
    - ii. Used as a single agent
5. Advanced renal cell carcinoma with **ONE** of the following:
  - a. First-line treatment in combination with cabozantinib
  - b. Prior treatment with anti-angiogenic therapy
    - i. Used as a single agent
  - c. Patient is considered to have an intermediate or poor prognosis
    - i. Used as first-line treatment following intravenous nivolumab in combination with ipilimumab
    - ii. Used as a single agent



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6. Recurrent or metastatic squamous cell carcinoma of the head and neck
  - a. Disease must have progressed while on or after platinum-based chemotherapy
  - b. Used as a single agent
7. Urothelial carcinoma with **ONE** of the following:
  - a. Patient is at high risk of recurrence after undergoing radical resection
    - i. Used as adjuvant treatment
    - ii. Used as a single agent
  - 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, used as a single agent 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
8. Hepatocellular carcinoma
  - a. Prior treatment with sorafenib
  - b. Following treatment with intravenous nivolumab in combination with ipilimumab
  - c. Used as a single agent
9. Completely resected esophageal or gastroesophageal junction cancer with residual pathologic disease
  - a. Patient has received neoadjuvant chemoradiotherapy (CRT)
  - b. Used as a single agent
10. 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 fluoropyrimidine- and platinum-containing chemotherapy



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11. Unresectable advanced, recurrent, or metastatic esophageal squamous cell carcinoma (ESCC)
  - a. Prior treatment with fluoropyrimidine- and platinum-based chemotherapy
  - b. Used as a single agent
12. Microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer
  - a. Progressed following treatment with fluoropyrimidine, oxaliplatin, and irinotecan
  - b. Diagnosis has to be confirmed by PCR-based assay genetic testing
  - c. Used as a single agent
13. 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

## **Prior - Approval Limits**

**Duration** 6 months

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## **Prior – Approval *Renewal* Requirements**

**Age** 18 years of age or older

### **Diagnoses**

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

1. Unresectable or metastatic melanoma
  - a. Used as a single agent
2. Adjuvant treatment of melanoma post resection: one renewal **only**
  - a. Stage IIB, Stage IIC, Stage III, or Stage IV melanoma
  - b. Used as a single agent
3. Resectable non-small cell lung cancer (NSCLC)
  - a. Used as a single agent after surgery as adjuvant treatment



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- b. **NO** known EGFR mutations or ALK rearrangements
- 4. Metastatic non-small cell lung cancer
  - a. Used as a single agent
- 5. Advanced renal cell carcinoma
  - a. **IF** used in combination with cabozantinib: one renewal **only**
- 6. Recurrent or metastatic squamous cell carcinoma of the head and neck
  - a. Used as a single agent
- 7. Urothelial carcinoma
  - a. **IF** used as adjuvant treatment in patients at high risk of recurrence after radical resection: one renewal **only**
    - i. Used as a single agent
  - b. **IF** used for unresectable or metastatic urothelial carcinoma, as first-line treatment in combination with cisplatin and gemcitabine: one renewal **only**
- 8. Hepatocellular carcinoma
  - a. Used as a single agent
- 9. Completely resected esophageal or gastroesophageal junction cancer with residual pathologic disease: one renewal **only**
  - a. Used as a single agent
- 10. 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. Used as a single agent
- 11. Unresectable advanced, recurrent, or metastatic esophageal squamous cell carcinoma (ESCC)
  - a. Prior treatment with fluoropyrimidine- and platinum-based chemotherapy
  - b. Used as a single agent

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12. Microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer
  - a. Used as a single agent
  
13. Advanced or metastatic gastric cancer, gastroesophageal junction cancer, or esophageal adenocarcinoma
  - a. Used in combination with fluoropyrimidine- and platinum-containing chemotherapy: one renewal **only**

**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

## **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
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 or metastatic urothelial carcinoma (first-line, in combination with cisplatin and gemcitabine)	18 months	One renewal only

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Esophageal squamous cell carcinoma	18 months	<u>Used with 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><b>NOT</b> being used with cabozantinib:</u>  Until disease progression or unacceptable toxicity
<b>All other indications</b>	18 months	Until disease progression or unacceptable toxicity

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