

# Opdivo Qvantig™ (nivolumab and hyaluronidase-nvhy) (Subcutaneous)

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## I. Length of Authorization <sup>△ 1,43,47,49,50,52-54,65,68,72,73,79,81,82,89,130,131</sup>

- Initial: Prior authorization validity will be provided initially for 6 months, unless otherwise specified.
  - Use in the treatment of Cutaneous Melanoma:
    - Cutaneous Melanoma neoadjuvant therapy as a single agent: Prior authorization validity may be provided for a maximum of 4 doses.
  - Merkel Cell Carcinoma neoadjuvant therapy: Prior authorization validity may be provided for up to a maximum of 2 doses.
  - Gastric, Esophageal and Esophagogastric/Gastroesophageal Junction Cancer postoperative therapy after surgery: Prior authorization validity may be provided for a maximum of 36 weeks (9 doses).
- Renewal: Prior authorization validity may be renewed every 6 months thereafter, unless otherwise specified.
  - Non-Small Cell Lung Cancer neoadjuvant treatment followed by optional adjuvant treatment: Prior authorization validity may be provided for a maximum of 4 neoadjuvant doses and 13 adjuvant doses.
  - Prior authorization validity may NOT be renewed for the following indications:
    - Merkel Cell Carcinoma (neoadjuvant therapy)
    - Cutaneous Melanoma (neoadjuvant therapy)
    - Gastric, Esophageal and Esophagogastric/Gastroesophageal Junction Cancer: Post-operative therapy after surgery
  - Prior authorization validity may be renewed up to a maximum of 1 year of therapy\* for the following:
    - Cutaneous Melanoma (adjuvant therapy single agent)
    - Esophageal and Esophagogastric/Gastroesophageal Junction Cancer (adjuvant therapy following neoadjuvant chemoradiotherapy)
    - Urothelial Carcinoma (adjuvant therapy)
  - Prior authorization validity may be renewed up to a maximum of 2 years of therapy\* for the following:

- Cervical Cancer
- Esophageal and Esophagogastric/Gastroesophageal Junction Cancer [induction, first-line, and subsequent therapy (excluding single agent subsequent therapy for squamous cell carcinoma)]
- Gastric Cancer (first-line therapy or subsequent therapy)
- Renal Cell Carcinoma (in combination with cabozantinib)
- Squamous Cell Skin Cancer
- Vaginal Cancer
- Vulvar Cancer
- Urothelial Carcinoma (first line therapy in combination with gemcitabine and cisplatin, followed by single-agent maintenance therapy)

**\*Note: The maximum number of doses is dependent on the dosing frequency and duration of therapy. Refer to Section V for exact dosage.**

Dosing Frequency	Maximum length of therapy	Maximum number of doses
2 weeks	1 year	26 doses
	2 years	52 doses
3 weeks	2 years	35 doses
4 weeks	1 year	13 doses
	2 years	26 doses

## II. Dosing Limits

### Max Units (per dose and over time) [HCPCS Unit]:

- 600 billable units every 4 weeks

## III. Initial Approval Criteria <sup>1</sup>

Prior authorization validity is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

### Universal Criteria

- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy unless otherwise specified <sup>Δ</sup> (Note: Not applicable when used as switch-therapy from intravenous nivolumab); **AND**
- Therapy will not be used concomitantly with intravenous nivolumab; **AND**
- Therapy will not be used concurrently with intravenous chemotherapy agents (not applicable when used for FDA approved combination therapy indicated with †); **AND**
- Intravenous nivolumab must be used in the following:
  - Patients <80 kg; **OR**

- Patients requiring 900 mg/15,000 units dose<sup>α</sup>; **OR**
- Patients receiving therapy in combination with ipilimumab; **AND**

**Substitution/Switch-Therapy for Intravenous Nivolumab ‡** <sup>2,4-6,19,20,24,25,31,33,34,36-39,41,42,47-49,61,63-65,72,79-81,83,84,90,94-97,130,131</sup>

- Used as substitution for OR switch-therapy from intravenous nivolumab; **AND**
  - Patient has previously met criteria for use of intravenous nivolumab [see *Opdivo IV policy – Document Number: IC-0226*]; **AND**
    - Patient has been receiving treatment with intravenous nivolumab and has shown a beneficial disease response and absence of unacceptable toxicity while on therapy; **OR**
  - Patient currently meets criteria for use of intravenous nivolumab [see *Opdivo IV policy – Document Number: IC-0226*]; **AND**
- Patient has any of the following indications for treatment (*may not be all inclusive*):
  - Ampullary Adenocarcinoma
  - Anal Carcinoma
  - Urothelial Carcinoma (Bladder Cancer)
  - Adult Central Nervous System (CNS) Cancers
  - Cervical Cancer
  - Colorectal Cancer (CRC)
  - Appendiceal Adenocarcinoma – Colon Cancer
  - Gastric Cancer/Esophageal Cancer/Gastroesophageal Junction (GEJ) Cancer
  - Gestational Trophoblastic Neoplasia
  - Squamous Cell Carcinoma of the Head and Neck (SCCHN)
  - Hepatocellular Carcinoma (HCC)
  - Kaposi Sarcoma
  - Renal Cell Carcinoma (RCC)
  - Cutaneous Melanoma
  - Uveal Melanoma
  - Merkel Cell Carcinoma
  - Peritoneal or Pleural Mesothelioma (*Note: May also be used for pericardial mesothelioma and tunica vaginalis testis mesothelioma*)
  - Non-Small Cell Lung Cancer (NSCLC)
  - Small Bowel Adenocarcinoma
  - Small Cell Lung Cancer (SCLC)
  - Soft Tissue Sarcoma

- Endometrial carcinoma (Uterine Neoplasms)
- Vulvar Cancer
- Thyroid Carcinoma
- Vaginal Cancer
- Squamous Cell Skin Cancer

### Urothelial Carcinoma (Bladder Cancer) † <sup>1,2,30,51,62,92</sup>

- Used as a single agent; **AND**
  - Used for locally advanced or metastatic disease that progressed during or following platinum-containing chemotherapy\* OR progression with 12 months of neoadjuvant or adjuvant treatment with a platinum-containing regimen; **OR**
  - Used as adjuvant therapy in patients who are at a high risk for disease recurrence\*\* after undergoing surgical resection; **OR**
- Used in combination with cisplatin and gemcitabine; **AND**
  - Used as first line therapy in patients with unresectable or metastatic disease

**\* Note:** <sup>10,51,60,70</sup>

– If patient was progression free for >12 months after platinum therapy, consider re-treatment with platinum-based therapy if the patient is still platinum eligible (see below for cisplatin- or platinum-ineligible comorbidities).

- Cisplatin-ineligible comorbidities may include the following: CrCl < 60 mL/min, ECOG PS ≥ 2 or KPS ≤ 70%, hearing loss of ≥ 25 decibels (dB) at two contiguous frequencies, grade ≥ 2 peripheral neuropathy, or NYHA Heart Failure class ≥ 3. Carboplatin may be substituted for cisplatin in the metastatic setting for cisplatin-ineligible patients such as those with a GFR less than 60 mL/min.
- Platinum-ineligible comorbidities may include the following: CrCl < 30 mL/min, ECOG PS ≥ 3, grade ≥ 2 peripheral neuropathy, or NYHA Heart Failure class > 3, etc.

**\*\* Note:** <sup>1,62</sup>

– High risk for disease recurrence is defined as:

- ypT2-ypT4a or ypN+ for patients who received neoadjuvant platinum-based therapy (excluding urothelial carcinoma of the prostate with stromal invasion); **OR**
- pT3-pT4a or pN+ for patients who did not receive neoadjuvant platinum-based therapy

### Colorectal Cancer (CRC) † <sup>1,2,31,32</sup>

- Patient has microsatellite instability-high (MSI-H)/mismatch repair deficient (dMMR) disease as determined by an FDA-approved or CLIA-compliant test❖; **AND**
- Used as a single agent; **AND**
- Used as subsequent therapy for metastatic disease; **AND**
- Patient has disease progression following treatment with a fluoropyrimidine, oxaliplatin and irinotecan regimen

## Gastric Cancer/Esophageal Cancer/Gastroesophageal Junction (GEJ) Cancer †<sup>1,2,44,52,56,69</sup>

- Used as a single agent; **AND**
  - Used as adjuvant treatment of completely resected esophageal or GEJ cancer with residual pathologic disease in patients who have received neoadjuvant chemoradiotherapy (CRT).; **OR**
  - Used as subsequent therapy after prior fluoropyrimidine- and platinum-based chemotherapy; **AND**
    - Used for unresectable advanced, recurrent, or metastatic esophageal squamous cell carcinoma (ESCC); **OR**
- Used in combination with fluoropyrimidine- and platinum-containing chemotherapy; **AND**
  - Used as first-line therapy; **AND**
  - Tumor expresses PD-L1 (CPS ≥1) as determined by an FDA-approved or CLIA compliant test❖; **AND**
    - Used in patients with unresectable, advanced or metastatic esophageal squamous cell carcinoma (ESCC); **OR**
    - Used for advanced or metastatic gastric, GEJ, or esophageal adenocarcinomas

## Squamous Cell Carcinoma of the Head and Neck (SCCHN) †<sup>1,2,29,78</sup>

- Used as single-agent therapy; **AND**
- Patient has metastatic disease with disease progression on or after platinum-based therapy; **AND**
- Patient does not have disease of the nasopharynx

## Hepatocellular Carcinoma (HCC) †<sup>1,2,21,86,87</sup>

- Used as a single agent; **AND**
- Patient was previously treated with sorafenib and following treatment with intravenous nivolumab/ipilimumab

## Renal Cell Carcinoma (RCC) †<sup>1,2,25,26</sup>

- Used as a single agent; **AND**
  - Used as first line therapy in patients with intermediate or poor risk advanced disease following treatment with intravenous nivolumab/ ipilimumab; **OR**
  - Used as subsequent therapy after prior anti-angiogenic therapy; **OR**
- Used in combination with cabozantinib (Cabometyx only); **AND**
  - Used as first-line therapy for advanced disease

## Cutaneous Melanoma †<sup>1,2,15-18,82,93</sup>

- Used as single agent therapy; **AND**

- Used as first-line therapy for unresectable or metastatic disease; **OR**
- Used as subsequent therapy for unresectable or metastatic disease following treatment with intravenous nivolumab/ipilimumab; **OR**
- Used as adjuvant treatment and patient has stage IIB, stage IIC, stage III or metastatic disease and has undergone complete resection

#### **Non-Small Cell Lung Cancer (NSCLC) †** <sup>1,2,22,23,43,45,46</sup>

- Used as single-agent therapy; **AND**
  - Used for metastatic disease; **AND**
  - Used as subsequent therapy on or after platinum-based chemotherapy (Note: Patients with EGFR or ALK genomic tumor aberrations should have disease progression on targeted therapies prior to receiving subcutaneous nivolumab); **OR**
- Used in combination with platinum-doublet chemotherapy; **AND**
  - Used as neoadjuvant therapy in patients who have resectable (tumors  $\geq$  4 cm or node positive) disease; **OR**
  - Used as neoadjuvant therapy in resectable disease with the option of continuing to single-agent subcutaneous nivolumab therapy as adjuvant treatment after surgery

❖ *If confirmed using an FDA approved assay – <http://www.fda.gov/companiondiagnostics>*

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Ⓞ Orphan Drug

#### **IV. Renewal Criteria** <sup>△ 1,2,4-6,15-42,43,47,49,50,52-54,68,72,73,79,81,82,89</sup>

Prior authorization validity can be renewed based upon the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Duration of authorization has not been exceeded (*refer to Section I*); **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis/renal dysfunction, rash/dermatitis [including Stevens-Johnson syndrome (SJS), drug rash with eosinophilia and systemic symptoms (DRESS), and toxic epidermal necrolysis (TEN)], myocarditis, pericarditis, vasculitis, solid organ transplant rejection, etc.), severe infusion-related reactions, complications of allogeneic hematopoietic stem cell transplantation (HSCT), etc.

##### ^ Notes:

- Patients responding to therapy who relapse  $\geq$  6 months after discontinuation due to duration are eligible

to re-initiate PD-directed therapy.

- Patients previously presenting with aggressive disease who are exhibiting stable disease on treatment as their best response (or if therapy improved performance status) may be eligible for continued therapy without interruption or discontinuation.
- Patients who complete adjuvant therapy and progress  $\geq$  6 months after discontinuation are eligible to re-initiate PD-directed therapy for metastatic disease.
- Patients whose tumors, upon re-biopsy, demonstrate a change in actionable mutation (e.g., MSS initial biopsy; MSI-H subsequent biopsy) may be eligible to re-initiate PD-directed therapy and will be evaluated on a case-by-case basis.
- Patients diagnosed with Renal Cell Carcinoma with clear cell histology who have received previous immuno-oncology therapy may be eligible for treatment with nivolumab as subsequent therapy and will be evaluated on a case-by-case basis.

## V. Dosage/Administration <sup>Δ 1,14,19,20,27,28,31-42,48-50,52-54,55,58,59,61,65,67,68,71-87,89,91,93,96,98-119,122-125,128-</sup>

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Indication	Dose
Renal Cell Carcinoma	<ul style="list-style-type: none"> <li>– 600 mg/10,000 units every 2 weeks or 1,200 mg/20,000 units every 4 weeks, until disease progression or unacceptable toxicity; <b>OR</b></li> <li>– 600 mg/10,000 units every 2 weeks or 1,200 mg/20,000 units every 4 weeks administered in combination with cabozantinib up to a maximum of 2 years of therapy</li> </ul>
Cutaneous Melanoma	<p><b><u>Unresectable or metastatic disease:</u></b></p> <ul style="list-style-type: none"> <li>– 600 mg/10,000 units every 2 weeks or 1,200 mg/20,000 units every 4 weeks, until disease progression or unacceptable toxicity</li> </ul> <p><b><u>Adjuvant treatment:</u></b></p> <ul style="list-style-type: none"> <li>– 600 mg/10,000 units every 2 weeks or 1,200 mg/20,000 units every 4 weeks until disease recurrence or unacceptable toxicity for up to 1 year</li> </ul> <p><b><u>Neoadjuvant treatment:</u></b></p> <ul style="list-style-type: none"> <li>– 600 mg/10,000 units every 14 days for 4 doses</li> </ul>
Uveal Melanoma	<ul style="list-style-type: none"> <li>– 600 mg/10,000 units every 2 weeks, until disease progression or unacceptable toxicity</li> </ul>
Merkel Cell Carcinoma	<p><b><u>Neoadjuvant treatment:</u></b></p> <ul style="list-style-type: none"> <li>– 600 mg/10,000 units every 2 weeks (days 1 and 15) for a total of 2 doses_</li> </ul> <p><b><u>All other settings:</u></b></p> <ul style="list-style-type: none"> <li>– 600 mg/10,000 units every 2 weeks, until disease progression or unacceptable toxicity</li> </ul>
NSCLC	<p><b><u>Neoadjuvant treatment: †</u></b></p> <ul style="list-style-type: none"> <li>• <sup>α</sup>900 mg/15,000 units with platinum-doublet chemotherapy on the same day every 3 weeks for up to 4 cycles</li> </ul> <p><b><u>Adjuvant treatment:</u></b></p> <ul style="list-style-type: none"> <li>– 1,200 mg/20,000 units every 4 weeks after surgery for up to 13 cycles (up to one year) or until disease progression, recurrence, or unacceptable toxicity</li> </ul>

	<p><b><u>Single agent:</u></b></p> <ul style="list-style-type: none"> <li>– 600 mg/10,000 units every 2 weeks or 1,200 mg/20,000 units every 4 weeks, until disease progression or unacceptable toxicity</li> </ul>
Urothelial Carcinoma	<p><b><u>Adjuvant treatment:</u></b></p> <ul style="list-style-type: none"> <li>– 600 mg/10,000 units every 2 weeks or 1,200 mg/20,000 units every 4 weeks, until disease recurrence or unacceptable toxicity for up to 1 year</li> </ul> <p><b><u>Disease progression or second-line treatment:</u></b></p> <ul style="list-style-type: none"> <li>– 600 mg/10,000 units every 2 weeks or 1,200 mg/20,000 units every 4 weeks, until disease progression or unacceptable toxicity</li> </ul> <p><b><u>First-line therapy: †</u></b></p> <ul style="list-style-type: none"> <li>– <sup>α</sup>900 mg/15,000 units every 3 weeks with cisplatin and gemcitabine on the same day for up to 6 cycles, followed by:</li> <li>– 600 mg/10,000 units every 2 weeks or 1,200 mg/20,000 units every 4 weeks, until disease progression or unacceptable toxicity for up to 2 years</li> </ul>
Esophageal and Esophagogastric/Gastroesophageal Junction Cancer	<p><b><u>First-line therapy (MSI-H/dMMR adenocarcinoma and squamous cell carcinoma):</u></b></p> <ul style="list-style-type: none"> <li>– 600 mg/10,000 units every 2 weeks or 1,200 mg/20,000 units every 4 weeks, until disease progression or unacceptable toxicity for up to 2 years</li> </ul> <p><b><u>First line therapy (PD-L1 positive disease): †</u></b></p> <ul style="list-style-type: none"> <li>– 600 mg/10,000 units every 2 weeks in combination with fluoropyrimidine- and platinum-containing chemotherapy every 2 weeks, until disease progression or unacceptable toxicity for up to 2 years</li> <li>– <sup>α</sup>900 mg/15,000 units every 3 weeks with fluoropyrimidine- and platinum containing chemotherapy every 3 weeks, until disease progression or unacceptable toxicity for up to 2 years</li> </ul> <p><b><u>Subsequent therapy (MSI-H/dMMR adenocarcinoma and squamous cell carcinoma):</u></b></p> <ul style="list-style-type: none"> <li>– 600 mg/10,000 units every 2 weeks or 1,200 mg/20,000 units every 4 weeks, until disease progression or unacceptable toxicity for up to 2 years</li> </ul> <p><b><u>Subsequent therapy (squamous cell carcinoma):</u></b></p> <ul style="list-style-type: none"> <li>– 600 mg/10,000 units every 2 weeks or 1,200 mg/20,000 units every 4 weeks, until disease progression or unacceptable toxicity</li> </ul> <p><b><u>Post-operative therapy (MSI-H/dMMR adenocarcinoma following preoperative therapy with intravenous nivolumab/ipilimumab):</u></b></p> <ul style="list-style-type: none"> <li>– 1,200 mg/20,000 units every 4 weeks for 36 weeks (9 doses)</li> </ul> <p><b><u>Adjuvant therapy following neoadjuvant chemoradiotherapy:</u></b></p> <ul style="list-style-type: none"> <li>– 600 mg/10,000 units every 2 weeks or 1,200 mg/20,000 units every 4 weeks, until disease progression or unacceptable toxicity for up to 1 year</li> </ul> <p><b><u>Induction therapy for relieving dysphagia (MSI-H/dMMR squamous cell carcinoma):</u></b></p> <ul style="list-style-type: none"> <li>– 600 mg/10,000 units every 2 weeks or 1,200 mg/20,000 units every 4 weeks, until disease progression or unacceptable toxicity for up to 2 years</li> </ul>

Gastric Cancer	<p><b><u>First-line therapy:</u></b></p> <ul style="list-style-type: none"> <li>– 600 mg/10,000 units every 2 weeks or 1,200 mg/20,000 units every 4 weeks, until disease progression or unacceptable toxicity for up to 2 years; <b>OR</b></li> <li>– 600 mg/10,000 units every 2 weeks in combination with fluoropyrimidine- and platinum-containing chemotherapy every 2 weeks, until disease progression or unacceptable toxicity for up to 2 years †.</li> </ul> <p><b><u>Subsequent therapy:</u></b></p> <ul style="list-style-type: none"> <li>– 600 mg/10,000 units every 2 weeks or 1,200 mg/20,000 units every 4 weeks, until disease progression or unacceptable toxicity for up to 2 years</li> </ul> <p><b><u>Post-operative therapy (following preoperative therapy with intravenous nivolumab/ipilimumab):</u></b></p> <ul style="list-style-type: none"> <li>– 1,200 mg/20,000 units every 4 weeks, every 4 weeks for 36 weeks (9 doses)</li> </ul>
Soft Tissue Sarcoma, Kaposi Sarcoma	<ul style="list-style-type: none"> <li>– 1,200 mg/20,000 units every 4 weeks, until disease progression or unacceptable toxicity</li> </ul>
Squamous Cell Skin cancer	<ul style="list-style-type: none"> <li>– 600 mg/10,000 units every 2 weeks until disease progression or unacceptable toxicity for up to 2 years</li> </ul>
Vulvar Cancer, Vaginal Cancer, & Cervical Cancer	<ul style="list-style-type: none"> <li>– 600 mg/10,000 units every 2 weeks or 1,200 mg/20,000 units every 4 weeks, until disease progression or unacceptable toxicity for up to 2 years</li> </ul>
All other indications	<ul style="list-style-type: none"> <li>– 600 mg/10,000 units every 2 weeks or 1,200 mg/20,000 units every 4 weeks, until disease progression or unacceptable toxicity</li> </ul>
<p><b>Note:</b></p> <ul style="list-style-type: none"> <li>– <sup>α</sup> The 900 mg/15,000 units dosing is listed in the prescribing information; however, the IV formulation of nivolumab must be used instead to prevent wastage.</li> <li>– Opdivo Qvantig (nivolumab and hyaluronidase-nvhy) has different dosage and administration instructions than intravenous nivolumab products.</li> <li>– Opdivo Qvantig is for subcutaneous use only in the abdomen or thigh.</li> <li>– Opdivo Qvantig is to be administered by a healthcare professional only.</li> <li>– Opdivo Qvantig is for subcutaneous use only administered over 3-5 minutes.</li> </ul>	

## VI. Billing Code/Availability Information

### HCPCS Code:

- J9289 – Injection, nivolumab, 2 mg and hyaluronidase-nvhy; 1 billable unit = 2 mg

### NDC(s):

- Opdivo Qvantig single-dose vial providing 600 mg nivolumab and 10,000 units hyaluronidase per 5 mL (120 mg/ 2,000 units per mL): 00003-6120-xx

## VII. References

1. Opdivo Qvantig [package insert]. Princeton, NJ; Bristol-Myers Squibb, Inc; June 2025. Accessed September 2025.

2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) nivolumab and hyaluronidase-nvhy. National Comprehensive Cancer Network, 2025. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed September 2025.
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## Appendix A – Non-Quantitative Treatment Limitations (NQL) Factor Checklist

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Medical Necessity Criteria

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Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime’s assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

## Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C00.0	Malignant neoplasm of external upper lip
C00.1	Malignant neoplasm of external lower lip
C00.2	Malignant neoplasm of external lip, unspecified
C00.3	Malignant neoplasm of upper lip, inner aspect
C00.4	Malignant neoplasm of lower lip, inner aspect
C00.5	Malignant neoplasm of lip, unspecified, inner aspect
C00.6	Malignant neoplasm of commissure of lip, unspecified
C00.8	Malignant neoplasm of overlapping sites of lip
C00.9	Malignant neoplasm of lip, unspecified
C01	Malignant neoplasm of base of tongue
C02.0	Malignant neoplasm of dorsal surface of tongue
C02.1	Malignant neoplasm of border of tongue
C02.2	Malignant neoplasm of ventral surface of tongue
C02.3	Malignant neoplasm of anterior two-thirds of tongue, part unspecified
C02.4	Malignant neoplasm of lingual tonsil
C02.8	Malignant neoplasm of overlapping sites of tongue
C02.9	Malignant neoplasm of tongue, unspecified
C03.0	Malignant neoplasm of upper gum
C03.1	Malignant neoplasm of lower gum
C03.9	Malignant neoplasm of gum, unspecified
C04.0	Malignant neoplasm of anterior floor of mouth
C04.1	Malignant neoplasm of lateral floor of mouth

C04.8	Malignant neoplasm of overlapping sites of floor of mouth
C04.9	Malignant neoplasm of floor of mouth, unspecified
C05.0	Malignant neoplasm of hard palate
C05.1	Malignant neoplasm of soft palate
C05.8	Malignant neoplasm of overlapping sites of palate
C05.9	Malignant neoplasm of palate, unspecified
C06.0	Malignant neoplasm of cheek mucosa
C06.2	Malignant neoplasm of retromolar area
C06.80	Malignant neoplasm of overlapping sites of unspecified parts of mouth
C06.89	Malignant neoplasm of overlapping sites of other parts of mouth
C06.9	Malignant neoplasm of mouth, unspecified
C09.0	Malignant neoplasm of tonsillar fossa
C09.1	Malignant neoplasm of tonsillar pillar (anterior) (posterior)
C09.8	Malignant neoplasm of overlapping sites of tonsil
C09.9	Malignant neoplasm of tonsil, unspecified
C10.0	Malignant neoplasm of vallecula
C10.1	Malignant neoplasm of anterior surface of epiglottis
C10.2	Malignant neoplasm of lateral wall of oropharynx
C10.3	Malignant neoplasm of posterior wall of oropharynx
C10.4	Malignant neoplasm of branchial cleft
C10.8	Malignant neoplasm of overlapping sites of oropharynx
C10.9	Malignant neoplasm of oropharynx, unspecified
C11.0	Malignant neoplasm of superior wall of nasopharynx
C11.1	Malignant neoplasm of posterior wall of nasopharynx
C11.2	Malignant neoplasm of lateral wall of nasopharynx
C11.3	Malignant neoplasm of anterior wall of nasopharynx
C11.8	Malignant neoplasm of overlapping sites of nasopharynx
C11.9	Malignant neoplasm of nasopharynx, unspecified
C12	Malignant neoplasm of pyriform sinus
C13.0	Malignant neoplasm of postcricoid region
C13.1	Malignant neoplasm of aryepiglottic fold, hypopharyngeal aspect
C13.2	Malignant neoplasm of posterior wall of hypopharynx
C13.8	Malignant neoplasm of overlapping sites of hypopharynx
C13.9	Malignant neoplasm of hypopharynx, unspecified
C14.0	Malignant neoplasm of pharynx, unspecified

C14.2	Malignant neoplasm of Waldeyer's ring
C14.8	Malignant neoplasm of overlapping sites of lip, oral cavity and pharynx
C15.3	Malignant neoplasm of upper third of esophagus
C15.4	Malignant neoplasm of middle third of esophagus
C15.5	Malignant neoplasm of lower third of esophagus
C15.8	Malignant neoplasm of overlapping sites of esophagus
C15.9	Malignant neoplasm of esophagus, unspecified
C16.0	Malignant neoplasm of cardia
C16.1	Malignant neoplasm of fundus of stomach
C16.2	Malignant neoplasm of body of stomach
C16.3	Malignant neoplasm of pyloric antrum
C16.4	Malignant neoplasm of pylorus
C16.5	Malignant neoplasm of lesser curvature of stomach, unspecified
C16.6	Malignant neoplasm of greater curvature of stomach, unspecified
C16.8	Malignant neoplasm of overlapping sites of stomach
C16.9	Malignant neoplasm of stomach, unspecified
C17.0	Malignant neoplasm of duodenum
C17.1	Malignant neoplasm of jejunum
C17.2	Malignant neoplasm of ileum
C17.3	Meckel's diverticulum, malignant
C17.8	Malignant neoplasm of overlapping sites of small intestine
C17.9	Malignant neoplasm of small intestine, unspecified
C18.0	Malignant neoplasm of cecum
C18.1	Malignant neoplasm of appendix
C18.2	Malignant neoplasm of ascending colon
C18.3	Malignant neoplasm of hepatic flexure
C18.4	Malignant neoplasm of transverse colon
C18.5	Malignant neoplasm of splenic flexure
C18.6	Malignant neoplasm of descending colon
C18.7	Malignant neoplasm of sigmoid colon
C18.8	Malignant neoplasm of overlapping sites of colon
C18.9	Malignant neoplasm of colon, unspecified
C19	Malignant neoplasm of rectosigmoid junction
C20	Malignant neoplasm of rectum
C21.0	Malignant neoplasm of anus, unspecified

C21.1	Malignant neoplasm of anal canal
C21.2	Malignant neoplasm of cloacogenic zone
C21.8	Malignant neoplasm of overlapping sites of rectum, anus and anal canal
C22.0	Liver cell carcinoma
C22.8	Malignant neoplasm of liver, primary, unspecified as to type
C22.9	Malignant neoplasm of liver, not specified as primary or secondary
C24.1	Malignant neoplasm of ampulla of Vater
C30.0	Malignant neoplasm of nasal cavity
C31.0	Malignant neoplasm of maxillary sinus
C31.1	Malignant neoplasm of ethmoidal sinus
C32.0	Malignant neoplasm of glottis
C32.1	Malignant neoplasm of supraglottis
C32.2	Malignant neoplasm of subglottis
C32.3	Malignant neoplasm of laryngeal cartilage
C32.8	Malignant neoplasm of overlapping sites of larynx
C32.9	Malignant neoplasm of larynx, unspecified
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C43.0	Malignant melanoma of lip
C43.111	Malignant melanoma of right upper eyelid, including canthus

C43.112	Malignant melanoma of right lower eyelid, including canthus
C43.121	Malignant melanoma of left upper eyelid, including canthus
C43.122	Malignant melanoma of left lower eyelid, including canthus
C43.20	Malignant melanoma of unspecified ear and external auricular canal
C43.21	Malignant melanoma of right ear and external auricular canal
C43.22	Malignant melanoma of left ear and external auricular canal
C43.30	Malignant melanoma of unspecified part of face
C43.31	Malignant melanoma of nose
C43.39	Malignant melanoma of other parts of face
C43.4	Malignant melanoma of scalp and neck
C43.51	Malignant melanoma of anal skin
C43.52	Malignant melanoma of skin of breast
C43.59	Malignant melanoma of other part of trunk
C43.60	Malignant melanoma of unspecified upper limb, including shoulder
C43.61	Malignant melanoma of right upper limb, including shoulder
C43.62	Malignant melanoma of left upper limb, including shoulder
C43.70	Malignant melanoma of unspecified lower limb, including hip
C43.71	Malignant melanoma of right lower limb, including hip
C43.72	Malignant melanoma of left lower limb, including hip
C43.8	Malignant melanoma of overlapping sites of skin
C43.9	Malignant melanoma of skin, unspecified
C44.00	Unspecified malignant neoplasm of skin of lip
C44.02	Squamous cell carcinoma of skin of lip
C44.09	Other specified malignant neoplasm of skin of lip
C44.121	Squamous cell carcinoma of skin of unspecified eyelid, including canthus
C44.1221	Squamous cell carcinoma of skin of right upper eyelid, including canthus
C44.1222	Squamous cell carcinoma of skin of right lower eyelid, including canthus
C44.1291	Squamous cell carcinoma of skin of left upper eyelid, including canthus
C44.1292	Squamous cell carcinoma of skin of left lower eyelid, including canthus
C44.221	Squamous cell carcinoma of skin of unspecified ear and external auricular canal
C44.222	Squamous cell carcinoma of skin of right ear and external auricular canal
C44.229	Squamous cell carcinoma of skin of left ear and external auricular canal
C44.320	Squamous cell carcinoma of skin of unspecified parts of face
C44.321	Squamous cell carcinoma of skin of nose
C44.329	Squamous cell carcinoma of skin of other parts of face

C44.42	Squamous cell carcinoma of skin of scalp and neck
C44.520	Squamous cell carcinoma of anal skin
C44.521	Squamous cell carcinoma of skin of breast
C44.529	Squamous cell carcinoma of skin of other part of trunk
C44.621	Squamous cell carcinoma of skin of unspecified upper limb, including shoulder
C44.622	Squamous cell carcinoma of skin of right upper limb, including shoulder
C44.629	Squamous cell carcinoma of skin of left upper limb, including shoulder
C44.721	Squamous cell carcinoma of skin of unspecified lower limb, including hip
C44.722	Squamous cell carcinoma of skin of right lower limb, including hip
C44.729	Squamous cell carcinoma of skin of left lower limb, including hip
C44.82	Squamous cell carcinoma of overlapping sites of skin
C44.92	Squamous cell carcinoma of skin, unspecified
C45.0	Mesothelioma of pleura
C45.1	Mesothelioma of peritoneum
C45.2	Mesothelioma of pericardium
C45.7	Mesothelioma of other sites
C45.9	Mesothelioma, unspecified
C46.0	Kaposi's sarcoma of skin
C46.1	Kaposi's sarcoma of soft tissue
C46.2	Kaposi's sarcoma of palate
C46.3	Kaposi's sarcoma of lymph nodes
C46.4	Kaposi's sarcoma of gastrointestinal sites
C46.50	Kaposi's sarcoma of unspecified lung
C46.51	Kaposi's sarcoma of right lung
C46.52	Kaposi's sarcoma of left lung
C46.7	Kaposi's sarcoma of other sites
C46.9	Kaposi's sarcoma, unspecified
C47.0	Malignant neoplasm of peripheral nerves of head, face and neck
C47.10	Malignant neoplasm of peripheral nerves of unspecified upper limb, including shoulder
C47.11	Malignant neoplasm of peripheral nerves of right upper limb, including shoulder
C47.12	Malignant neoplasm of peripheral nerves of left upper limb, including shoulder
C47.20	Malignant neoplasm of peripheral nerves of unspecified lower limb, including hip
C47.21	Malignant neoplasm of peripheral nerves of right lower limb, including hip
C47.22	Malignant neoplasm of peripheral nerves of left lower limb, including hip
C47.3	Malignant neoplasm of peripheral nerves of thorax

C47.4	Malignant neoplasm of peripheral nerves of abdomen
C47.5	Malignant neoplasm of peripheral nerves of pelvis
C47.6	Malignant neoplasm of peripheral nerves of trunk, unspecified
C47.8	Malignant neoplasm of overlapping sites of peripheral nerves and autonomic nervous system
C47.9	Malignant neoplasm of peripheral nerves and autonomic nervous system, unspecified
C48.0	Malignant neoplasm of retroperitoneum
C48.1	Malignant neoplasm of specified parts of peritoneum
C48.2	Malignant neoplasm of peritoneum, unspecified
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum
C49.0	Malignant neoplasm of connective and soft tissue of head, face and neck
C49.10	Malignant neoplasm of connective and soft tissue of unspecified upper limb, including shoulder
C49.11	Malignant neoplasm of connective and soft tissue of right upper limb, including shoulder
C49.12	Malignant neoplasm of connective and soft tissue of left upper limb, including shoulder
C49.20	Malignant neoplasm of connective and soft tissue of unspecified lower limb, including hip
C49.21	Malignant neoplasm of connective and soft tissue of right lower limb, including hip
C49.22	Malignant neoplasm of connective and soft tissue of left lower limb, including hip
C49.3	Malignant neoplasm of connective and soft tissue of thorax
C49.4	Malignant neoplasm of connective and soft tissue of abdomen
C49.5	Malignant neoplasm of connective and soft tissue of pelvis
C49.6	Malignant neoplasm of connective and soft tissue of trunk, unspecified
C49.8	Malignant neoplasm of overlapping sites of connective and soft tissue
C49.9	Malignant neoplasm of connective and soft tissue, unspecified
C4A.0	Merkel cell carcinoma of lip
C4A.10	Merkel cell carcinoma of eyelid, including canthus
C4A.111	Merkel cell carcinoma of right upper eyelid, including canthus
C4A.112	Merkel cell carcinoma of right lower eyelid, including canthus
C4A.121	Merkel cell carcinoma of left upper eyelid, including canthus
C4A.122	Merkel cell carcinoma of left lower eyelid, including canthus
C4A.20	Merkel cell carcinoma of unspecified ear and external auricular canal
C4A.21	Merkel cell carcinoma of right ear and external auricular canal
C4A.22	Merkel cell carcinoma of left ear and external auricular canal
C4A.30	Merkel cell carcinoma of unspecified part of face
C4A.31	Merkel cell carcinoma of nose
C4A.39	Merkel cell carcinoma of other parts of face
C4A.4	Merkel cell carcinoma of scalp and neck

C4A.51	Merkel cell carcinoma of anal skin
C4A.52	Merkel cell carcinoma of skin of breast
C4A.59	Merkel cell carcinoma of other part of trunk
C4A.60	Merkel cell carcinoma of unspecified upper limb, including shoulder
C4A.61	Merkel cell carcinoma of right upper limb, including shoulder
C4A.62	Merkel cell carcinoma of left upper limb, including shoulder
C4A.70	Merkel cell carcinoma of unspecified lower limb, including hip
C4A.71	Merkel cell carcinoma of right lower limb, including hip
C4A.72	Merkel cell carcinoma of left lower limb, including hip
C4A.8	Merkel cell carcinoma of overlapping sites
C4A.9	Merkel cell carcinoma, unspecified
C51.0	Malignant neoplasm of labium majus
C51.1	Malignant neoplasm of labium minus
C51.2	Malignant neoplasm of clitoris
C51.8	Malignant neoplasm of overlapping sites of vulva
C51.9	Malignant neoplasm of vulva, unspecified
C52	Malignant neoplasm of vagina
C53.0	Malignant neoplasm of endocervix
C53.1	Malignant neoplasm of exocervix
C53.8	Malignant neoplasm of overlapping sites of cervix uteri
C53.9	Malignant neoplasm of cervix uteri, unspecified
C54.0	Malignant neoplasm of isthmus uteri
C54.1	Malignant neoplasm of endometrium
C54.2	Malignant neoplasm of myometrium
C54.3	Malignant neoplasm of fundus uteri
C54.8	Malignant neoplasm of overlapping sites of corpus uteri
C54.9	Malignant neoplasm of corpus uteri, unspecified
C55	Malignant neoplasm of uterus, part unspecified
C58	Malignant neoplasm of placenta
C61	Malignant neoplasm of prostate
C64.1	Malignant neoplasm of right kidney, except renal pelvis
C64.2	Malignant neoplasm of left kidney, except renal pelvis
C64.9	Malignant neoplasm of unspecified kidney, except renal pelvis
C65.1	Malignant neoplasm of right renal pelvis
C65.2	Malignant neoplasm of left renal pelvis

C65.9	Malignant neoplasm of unspecified renal pelvis
C66.1	Malignant neoplasm of right ureter
C66.2	Malignant neoplasm of left ureter
C66.9	Malignant neoplasm of unspecified ureter
C67.0	Malignant neoplasm of trigone of bladder
C67.1	Malignant neoplasm of dome of bladder
C67.2	Malignant neoplasm of lateral wall of bladder
C67.3	Malignant neoplasm of anterior wall of bladder
C67.4	Malignant neoplasm of posterior wall of bladder
C67.5	Malignant neoplasm of bladder neck
C67.6	Malignant neoplasm of ureteric orifice
C67.7	Malignant neoplasm of urachus
C67.8	Malignant neoplasm of overlapping sites of bladder
C67.9	Malignant neoplasm of bladder, unspecified
C68.0	Malignant neoplasm of urethra
C69.30	Malignant neoplasm of unspecified choroid
C69.31	Malignant neoplasm of right choroid
C69.32	Malignant neoplasm of left choroid
C69.40	Malignant neoplasm of unspecified ciliary body
C69.41	Malignant neoplasm of right ciliary body
C69.42	Malignant neoplasm of left ciliary body
C69.60	Malignant neoplasm of unspecified orbit
C69.61	Malignant neoplasm of right orbit
C69.62	Malignant neoplasm of left orbit
C73	Malignant neoplasm of thyroid gland
C76.0	Malignant neoplasm of head, face and neck
C77.0	Secondary and unspecified malignant neoplasm of lymph nodes of head, face and neck
C78.00	Secondary malignant neoplasm of unspecified lung
C78.01	Secondary malignant neoplasm of right lung
C78.02	Secondary malignant neoplasm of left lung
C78.6	Secondary malignant neoplasm of retroperitoneum and peritoneum
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct
C79.31	Secondary malignant neoplasm of brain
C79.89	Secondary malignant neoplasm of other specified sites
C7A.1	Malignant poorly differentiated neuroendocrine tumors

C7B.1	Secondary Merkel cell carcinoma
D09.0	Carcinoma in situ of bladder
D37.01	Neoplasm of uncertain behavior of lip
D37.02	Neoplasm of uncertain behavior of tongue
D37.05	Neoplasm of uncertain behavior of pharynx
D37.09	Neoplasm of uncertain behavior of other specified sites of the oral cavity
D37.1	Neoplasm of uncertain behavior of stomach
D37.8	Neoplasm of uncertain behavior of other specified digestive organs
D37.9	Neoplasm of uncertain behavior of digestive organ, unspecified
D38.0	Neoplasm of uncertain behavior of larynx
D38.5	Neoplasm of uncertain behavior of other respiratory organs
D38.6	Neoplasm of uncertain behavior of respiratory organ, unspecified
D39.2	Neoplasm of uncertain behavior of placenta
O01.9	Hydatidiform mole, unspecified
Z85.00	Personal history of malignant neoplasm of unspecified digestive organ
Z85.01	Personal history of malignant neoplasm of esophagus
Z85.028	Personal history of other malignant neoplasm of stomach
Z85.068	Personal history of other malignant neoplasm of small intestine
Z85.09	Personal history of malignant neoplasm of other digestive organs
Z85.118	Personal history of other malignant neoplasm of bronchus and lung
Z85.12	Personal history of malignant neoplasm of trachea
Z85.42	Personal history of malignant neoplasm of other parts of uterus
Z85.51	Personal history of malignant neoplasm of bladder
Z85.59	Personal history of malignant neoplasm of other urinary tract organ
Z85.820	Personal history of malignant melanoma of skin
Z85.821	Personal history of Merkel cell carcinoma
Z85.831	Personal history of malignant neoplasm of soft tissue

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents:

<https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

<b>Medicare Part B Administrative Contractor (MAC) Jurisdictions</b>		
<b>Jurisdiction</b>	<b>Applicable State/US Territory</b>	<b>Contractor</b>
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC