

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

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## I. Length of Authorization <sup>Δ 1</sup>

Coverage will be provided for 6 months and may be renewed (unless otherwise specified).

- Neoadjuvant treatment of NSCLC without adjuvant treatment may be authorized for a maximum of three (3) neoadjuvant doses
- Neoadjuvant treatment followed by optional adjuvant treatment of NSCLC may be authorized for a maximum of four (4) neoadjuvant doses and thirteen (13) adjuvant doses.
- Adjuvant treatment of the following indications may be renewed up to a maximum of one (1) year of therapy\*:
  - Cutaneous Melanoma (single agent)
  - Esophageal and Esophagogastric/Gastroesophageal Junction Cancer
  - Urothelial Carcinoma
- The following indications may be renewed up to a maximum of two (2) years of therapy:
  - Esophageal Squamous Cell Carcinoma
  - Esophageal and Esophagogastric/Gastroesophageal Junction Cancer
  - Gastric Cancer
  - Renal Cell Carcinoma (in combination with cabozantinib)
  - 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

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

- 1,200 mg/20,000 units every 4 weeks

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

Coverage 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 (e.g., atezolizumab, pembrolizumab, durvalumab, avelumab, cemiplimab, dostarlimab, nivolumab/relatlimab, retifanlimab, toripalimab, tislelizumab, etc.) unless otherwise specified <sup>Δ</sup> (*Note: Not applicable when used as switch-therapy with intravenous nivolumab*); **AND**
- Therapy will not be used concomitantly with intravenous nivolumab; **AND**
- IV formulation of Opdivo must be used in the following:
  - Patients <80 kg; **OR**
  - Patients requiring 900 mg/15,000 units dose\*; **OR**
  - Patients receiving therapy in combination with ipilimumab; **AND**

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

- Used as a single agent; **AND**
  - Used for 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 patient with unresectable or metastatic disease

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

– High risk for disease recurrence is defined as:

- ypT2-ypT4a or ypN+ for patients who received neoadjuvant cisplatin (excluding prostate with stromal invasion); **OR**
- pT3-pT4a or pN+ for patients who did not receive neoadjuvant cisplatin and are also ineligible for or refused adjuvant cisplatin therapy (excluding ureter or renal pelvis)

#### 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**
    - 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 following treatment with 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 disease following previous treatment with nivolumab and ipilimumab combination therapy; **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 after prior nivolumab/ipilimumab combination therapy; **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) † 1,2,22,23,43,45,46

- 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 Opdivo Qvantig); **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 Opdivo Qvantig 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

§ Genomic Aberration/Mutational Driver Targeted Therapies (Note: not all inclusive, refer to guidelines for appropriate use)			
EGFR exon 19 deletion or exon 21 L858R tumors	EGFR S768I, L861Q, and/or G719X mutation positive tumors	EGFR exon 20 insertion mutation positive tumors	NTRK1/2/3 gene fusion positive tumors
<ul style="list-style-type: none"> <li>– Afatinib</li> <li>– Erlotinib</li> <li>– Dacomitinib</li> <li>– Gefitinib</li> <li>– Osimertinib</li> <li>– Amivantamab</li> </ul>	<ul style="list-style-type: none"> <li>– Afatinib</li> <li>– Erlotinib</li> <li>– Dacomitinib</li> <li>– Gefitinib</li> <li>– Osimertinib</li> <li>– Amivantamab</li> </ul>	<ul style="list-style-type: none"> <li>– Amivantamab</li> </ul>	<ul style="list-style-type: none"> <li>– Larotrectinib</li> <li>– Entrectinib</li> <li>– Repotrectinib</li> </ul>
ALK rearrangement-positive tumors	ROS1 rearrangement-positive tumors	BRAF V600E-mutation positive tumors	ERBB2 (HER2) mutation positive tumors
<ul style="list-style-type: none"> <li>– Alectinib</li> <li>– Brigatinib</li> <li>– Ceritinib</li> <li>– Crizotinib</li> <li>– Lorlatinib</li> </ul>	<ul style="list-style-type: none"> <li>– Ceritinib</li> <li>– Crizotinib</li> <li>– Entrectinib</li> <li>– Lorlatinib</li> <li>– Repotrectinib</li> </ul>	<ul style="list-style-type: none"> <li>– Dabrafenib ± trametinib</li> <li>– Encorafenib + binimetinib</li> <li>– Vemurafenib</li> </ul>	<ul style="list-style-type: none"> <li>– Fam-trastuzumab deruxtecan-nxki</li> <li>– Ado-trastuzumab emtansine</li> </ul>
PD-L1 tumor expression $\geq 1\%$	MET exon-14 skipping mutations	RET rearrangement-positive tumors	KRAS G12C mutation positive tumors
<ul style="list-style-type: none"> <li>– Pembrolizumab</li> <li>– Atezolizumab</li> <li>– Nivolumab + ipilimumab</li> <li>– Cemiplimab</li> <li>– Tremelimumab + durvalumab</li> </ul>	<ul style="list-style-type: none"> <li>– Capmatinib</li> <li>– Crizotinib</li> <li>– Tepotinib</li> </ul>	<ul style="list-style-type: none"> <li>– Selpercatinib</li> <li>– Cabozantinib</li> <li>– Pralsetinib</li> </ul>	<ul style="list-style-type: none"> <li>– Sotorasib</li> <li>– Adagrasib</li> </ul>

## IV. Renewal Criteria <sup>Δ 1,6</sup>

Coverage 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**
- 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.

### NSCLC (neoadjuvant/adjuvant treatment)

- Patient has not exceeded a maximum of twelve (12) months (13 cycles) of therapy

#### <sup>Δ</sup> 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.

## V. Dosage/Administration <sup>Δ 1,14,27,28</sup>

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.</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 40 mg once daily without food, up to a maximum of 2 years of therapy.</li></ul>
Melanoma	<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><i>Note: For adjuvant therapy, treat until disease recurrence or unacceptable toxicity for up to 1 year</i></p>
NSCLC	<b>Neoadjuvant and adjuvant treatment</b>

	<ul style="list-style-type: none"> <li>– * 900 mg/15,000 units with platinum-doublet chemotherapy on the same day every 3 weeks for 3 cycles, then single-agent Opdivo Qvantig 1,200 mg/20,000 units every 4 weeks after surgery for up to 13 cycles.</li> </ul> <p><b>Metastatic non-small cell lung cancer</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>
SCCHN	<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>Urothelial carcinoma</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><i>Note: For adjuvant therapy, treat until disease recurrence or unacceptable toxicity for up to 1 year</i></p> <p><b>First-line unresectable or metastatic urothelial carcinoma</b></p> <ul style="list-style-type: none"> <li>– * 900 mg/15,000 units every 3 weeks with cisplatin and gemcitabine on the same day for up to 6 cycles, then 600 mg/10,000 units every 2 weeks or 1,200 mg/20,000 units every 4 weeks, up to a maximum of 2 years of therapy.</li> </ul>
Colorectal 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.</li> </ul>
Hepatocellular 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.</li> </ul>
Esophageal Squamous Cell 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. <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 fluoropyrimidine- and platinum-containing chemotherapy, up to a maximum of 2 years of therapy.</li> </ul>
Gastric Cancer, GEJ Cancer, and Esophageal Adenocarcinoma	<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, up until a maximum of 2 years of therapy.</li> <li>– * 900 mg/15,000 units every 3 weeks with fluoropyrimidine- and platinum-containing chemotherapy every 3 weeks, up until a maximum of 2 years of therapy.</li> </ul> <p><i>Note: For adjuvant therapy in esophageal and GEJ, treat until disease recurrence or unacceptable toxicity for up to 1 year</i></p>
<p><b>Note:</b></p> <ul style="list-style-type: none"> <li>– * 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:

- J9999 – Not otherwise classified, antineoplastic drugs
- C9399 – Unclassified drugs or biologicals (hospital outpatient use only)

### 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

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## 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
C18.0	Malignant neoplasm of cecum
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
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
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
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
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
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
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
Z85.118	Personal history of other malignant neoplasm of bronchus and lung
Z85.51	Personal history of malignant neoplasm of bladder
Z85.59	Personal history of malignant neoplasm of other urinary tract organ

## 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

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY,	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp
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

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
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	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC