Opdivo® (nivolumab)
(Intravenous)

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I. Length of Authorization Δ [1,43,49,50,52,54,65]

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

- Use in the treatment of Classical Hodgkin Lymphoma in combination with brentuximab vedotin can be authorized up to a maximum of twelve (12) weeks of therapy and may NOT be renewed.
- Neoadjuvant treatment of Merkel Cell Carcinoma can be authorized up to a maximum of two (2) doses and may NOT be renewed.
- Neoadjuvant treatment of NSCLC in combination with platinum-doublet chemotherapy may be authorized for a maximum of three (3) cycles and may NOT be renewed.
- Adjuvant treatment of the following indications may be renewed up to a maximum of one (1) year of therapy:
  - Cutaneous Melanoma
  - Esophageal and Esophagogastric/Gastroesophageal Junction Cancer
  - Urothelial Carcinoma
- The following indications may be renewed up to a maximum of two (2) years of therapy:
  - NSCLC (in combination with ipilimumab with or without platinum-doublet chemotherapy)
  - MPM
  - MPeM
  - Vulvar Cancer
  - Renal Cell Carcinoma (in combination with cabozantinib)
  - Gastric Cancer
  - Esophagogastric/Gastroesophageal Junction Cancer or Esophageal Adenocarcinoma (in combination with fluoropyrimidine- and platinum-containing chemotherapy)

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– Cervical Cancer

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Opdivo 40 mg/4 mL single-dose vial: 2 vials per 14 days
- Opdivo 100 mg/10 mL single-dose vial: 3 vials per 14 days
- Opdivo 120 mg/12 mL single-dose vial: 3 vials per 14 days
- Opdivo 240 mg/24 mL single-dose vial: 4 vials per 14 days

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

Indication	Billable Units (BU)	Per unit time (days)
Anal Carcinoma, CNS Metastases, MPM, MPeM, Merkel Cell Carcinoma, MSI-H/dMMR CRC, NSCLC, SCLC, & Small Bowel Adenocarcinoma/Advanced Ampullary Cancer	340 BU	14 days
Cutaneous Melanoma, Esophageal Cancer, Esophagogastric/Gastroesophageal Junction Cancer, Gastric Cancer, Gestational Trophoblastic Neoplasia, HCC, cHL, RCC, SCCHN, Urothelial Carcinoma, Vulvar Cancer, & Cervical Cancer	480 BU	28 days
Uveal Melanoma	1140 BU	14 days
Extranodal NK/ T-Cell Lymphoma	40 BU	14 days
Endometrial Carcinoma	Initial: 340 BU	14 days x 8 doses
	Followed by: 480 BU	28 days

III. Initial Approval Criteria [1]

Coverage is provided for the following conditions:

- Patient is at least 18 years of age (unless otherwise specified); **AND**

Universal Criteria

- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., cemiplimab, avelumab, pembrolizumab, atezolizumab, durvalumab, dostarlimab, etc.), unless otherwise specified [Δ]; **AND**

Cutaneous Melanoma † ‡ Φ [1,2,15-18]

- Used as first-line therapy for unresectable or metastatic* disease; **AND**
  - Used as a single agent or in combination with ipilimumab; **OR**
- Used as initial therapy for limited resectable disease; **AND**
  - Used as a single agent; **AND**
    - Patient has stage III disease with clinical satellite/in-transit metastases; **OR**
    - Patient has local satellite/in-transit recurrence; **OR**
- Used as subsequent therapy for unresectable or metastatic* disease; **AND**
  - Used as re-induction therapy in patients who experienced disease control *(i.e., complete or partial response or stable disease)* and no residual toxicity from prior anti-PD-1

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immunotherapy, but subsequently have disease progression/relapse > 3 months after treatment discontinuation; **AND**

- Used as a single agent or in combination with ipilimumab; **OR**

- Used after disease progression or maximum clinical benefit from BRAF-targeted therapy (e.g., dabrafenib/trametinib, vemurafenib/cobimetinib, encorafenib/binimetinib, etc.); **AND**
  - Used as a single agent or in combination with ipilimumab if anti-PD-1 was not previously used; **OR**
  - Used in combination with ipilimumab for patients who progressed on single agent anti-PD-1 therapy; **OR**

- Used as adjuvant treatment as a single agent; **AND**
  - Patient has lymph node involvement and has undergone complete resection, complete lymph node dissection (CLND), therapeutic lymph node dissection (TLND), or nodal basin ultrasound surveillance; **OR**
  - Patient has satellite/in-transit metastases or recurrence and has no evidence of disease after complete excision; **OR**
  - Patient has undergone TLND and/or complete resection of nodal recurrence; **OR**
  - Patient has undergone complete resection of metastatic disease; **OR**
  - Patient has oligometastatic disease and no evidence of disease following metastasis-directed therapy (i.e., stereotactic ablative therapy or complete resection) or systemic therapy

**Metastatic disease includes stage III unresectable/borderline resectable disease with clinically positive node(s) or clinical satellite/in-transit metastases, as well as unresectable local satellite/in-transit recurrence, unresectable nodal recurrence, and widely disseminated distant metastatic disease.*

Uveal Melanoma ‡ [2,19,20]

- Patient has distant metastatic disease; **AND**
- Used as a single agent or in combination with ipilimumab

Hepatocellular Carcinoma (HCC) † ‡ Φ [1,2,21]

- Used in combination with ipilimumab; **AND**
- Used as subsequent therapy for progressive disease; **AND**
- Patient has Child-Pugh Class A disease; **AND**
  - Patient has unresectable disease and is not a transplant candidate; **OR**
  - Patient has liver-confined disease that is inoperable by performance status, comorbidity, or with minimal or uncertain extrahepatic-disease; **OR**
  - Patient has metastatic disease or extensive liver tumor burden

Non-Small Cell Lung Cancer (NSCLC) † [1,2,22,23,45,46]

- Used for resectable (tumors ≥ 4 cm or node positive) disease; **AND**

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- Used for neoadjuvant therapy in combination with platinum-doublet chemotherapy (e.g., paclitaxel and carboplatin, pemetrexed and either carboplatin or cisplatin, etc.); **OR**

- Used for recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
  - Used as first-line therapy; **AND**
    - Used for one of the following:
      - Patients with a performance status (PS) 0-1 who have tumors that are negative for actionable molecular biomarkers** and PD-L1 expression <1%
      - Patients with a PS 0-1 who are positive for one of the following molecular biomarkers: EGFR exon 20, KRAS G12C, BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, or RET rearrangement
      - PD-L1 expression-positive (PD-L1 ≥1%) tumors, as detected by an FDA or CLIA compliant test❖, that are negative for actionable molecular biomarkers**; **AND**
        - Used in combination with ipilimumab; **OR**
        - Used in combination with ipilimumab and platinum-doublet chemotherapy (e.g., pemetrexed and either carboplatin or cisplatin for nonsquamous cell histology, paclitaxel and carboplatin for squamous cell histology, etc.); **OR**
  - Used as subsequent therapy; **AND**
    - Used as a single agent; **OR**
    - Used for one of the following:
      - Patients with a PS 0-1 who received prior targeted therapy§ for one of the following molecular biomarkers: EGFR S768I, L861Q, and/or G719X, or ROS1 rearrangement
      - Patients with a PS 0-1 who are positive for one of the following molecular biomarkers: BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, or RET rearrangement; **AND**
        - Used in combination with ipilimumab; **OR**
        - Used in combination with ipilimumab, pemetrexed, and either carboplatin or cisplatin for nonsquamous cell histology; **OR**
        - Used in combination with ipilimumab, paclitaxel, and carboplatin for squamous cell histology; **OR**
  - Used as continuation maintenance therapy in combination with ipilimumab; **AND**
    - Patient has achieved a response or stable disease following first-line therapy with nivolumab and ipilimumab with or without chemotherapy

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*** Note: Actionable molecular genomic biomarkers include EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET exon 14 skipping mutation, and RET rearrangement. If there is insufficient tissue to allow testing for all of EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, and RET, repeat biopsy and/or plasma testing should be done. If these are not feasible, treatment is guided by available results and, if unknown, these patients are treated as though they do not have driver oncogenes.*

Renal Cell Carcinoma (RCC) † ‡ [1,2,25,26]

- Used in combination with ipilimumab for clear cell histology; **AND**
  - Used as first-line therapy in patients with advanced, relapsed, or stage IV disease with poor or intermediate risk; **OR**
  - Used as first-line therapy in patients with relapsed or stage IV disease with favorable risk; **OR**
  - Used as subsequent therapy in patients with relapsed or stage IV disease; **OR**
- Used as a single agent; **AND**
  - Used as subsequent therapy in patients with advanced, relapsed, or stage IV disease and clear cell histology; **OR**
  - Patient has relapsed or stage IV disease and non-clear cell histology; **OR**
- Used in combination with cabozantinib (Cabometyx only) for clear cell histology; **AND**
  - Used as first-line therapy for advanced, relapsed, or stage IV disease; **OR**
  - Used as subsequent therapy in patients with relapsed or stage IV disease

Adult Classical Hodgkin Lymphoma (cHL) † ‡ Φ [1,2,27,28]

- Used as a single agent; **AND**
  - Patient has relapsed or progressive disease after autologous hematopoietic stem cell transplantation (HSCT) and brentuximab vedotin; **OR**
  - Used as third-line or subsequent therapy OR as palliative therapy in patients > 60 years of age; **AND**
    - Patient has relapsed or progressive disease after autologous HSCT; **OR**
    - Patient has relapsed or refractory disease and is transplant-ineligible based on comorbidities or failure of second-line chemotherapy; **OR**
    - Patient is post-allogeneic stem-cell transplant; **OR**
- Used in combination with brentuximab vedotin; **AND**
  - Used as subsequent therapy (if not previously used) for relapsed or refractory disease

Pediatric Classical Hodgkin Lymphoma (cHL) ‡ [2,27,28]

- Patient age is 18 years and under*; **AND**
- Patient has relapsed or refractory disease; **AND**
- Used in patients heavily pretreated with platinum or anthracycline-based chemotherapy or if a decrease in cardiac function was observed; **AND**
  - Used as subsequent therapy (if not previously used); **AND**
    - Used as a single agent or in combination with brentuximab vedotin; **OR**
  - Used as re-induction therapy; **AND**

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- Used in combination with brentuximab vedotin; **OR**
- Used in combination with brentuximab vedotin and radiation therapy (ISRT) in highly favorable patients who may avoid autologous stem cell rescue (ASCR) *(i.e., initial stage other than IIIB or IVB, no prior exposure to RT, duration of CR1 >1 year, absence of extranodal disease or B symptoms at relapse)*

** Pediatric Hodgkin Lymphoma may be applicable to adolescent and young adult (AYA) patients up to the age of 39 years.*

Squamous Cell Carcinoma of the Head and Neck (SCCHN) † ‡ [1,2,29]

- Patient has Cancer of the Nasopharynx; **AND**
  - Used in combination with cisplatin and gemcitabine; **AND**
    - Used as first-line therapy for oligometastatic or metastatic disease; **OR**
- Patient has Very Advanced Head and Neck Cancer*****; **AND**
  - Patient has nasopharyngeal cancer; **AND**
    - Used in combination with cisplatin and gemcitabine; **AND**
    - Used for one of the following:
      - Unresectable locoregional recurrence with prior radiation therapy (RT)
      - Unresectable second primary with prior RT
      - Unresectable persistent disease with prior RT
      - Recurrent/persistent disease with distant metastases; **OR**
  - Patient has NON-nasopharyngeal cancer; **AND**
    - Used as a single agent; **AND**
    - Patient has unresectable, recurrent, persistent, or metastatic disease; **AND**
    - Disease has progressed on or after platinum-containing chemotherapy

** Very Advanced Head and Neck Cancer includes: newly diagnosed locally advanced T4b (M0) disease, newly diagnosed unresectable nodal disease, metastatic disease at initial presentation (M1), or recurrent or persistent disease)*

Urothelial Carcinoma (Bladder Cancer) † ‡ [1,2,30,51,62]

- Used as a single agent; **AND**
  - Used for disease that progressed during or following platinum-containing chemotherapy***** OR as second-line treatment after therapy other than a platinum or an immune checkpoint inhibitor; **AND**
    - Patient has one of the following diagnoses:
      - Locally advanced or metastatic urothelial carcinoma; **OR**
      - Muscle invasive bladder cancer with local recurrence or persistent disease in a preserved bladder ‡; **OR**
      - Metastatic or local bladder cancer recurrence post-cystectomy ‡; **OR**
      - Recurrent or metastatic primary carcinoma of the urethra ‡; **AND**

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- Patient does not have recurrence of stage T3-4 disease or palpable inguinal lymph nodes; **OR**

– Metastatic upper genitourinary (GU) tract tumors ‡; **OR**

– Metastatic urothelial carcinoma of the prostate ‡; **OR**

- Used as adjuvant therapy †; **AND**
  - Patient has urothelial carcinoma of the bladder, bulbar urethra, prostate with stromal invasion, ureter, or renal pelvis; **AND**
  - Patient underwent radical surgical resection or partial cystectomy; **AND**
  - Patient is at high risk of disease recurrence**

**** Note:*** [10,51,60]
– *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 carboplatin-ineligible comorbidities).*
▪ *Cisplatin-ineligible comorbidities may include the following: CrCl < 60 mL/min, PS ≥ 2, hearing loss of ≥ 25 decibels (dB) at two contiguous frequencies, grade ≥ 2 peripheral neuropathy, or NYHA class ≥ 3. Carboplatin may be substituted for cisplatin particularly in those patients with a CrCl < 60 mL/min or a PS of 2.*
▪ *Carboplatin-ineligible comorbidities may include the following: CrCl < 30 mL/min, PS > 3, grade > 3 peripheral neuropathy, or NYHA class > 3, etc.*
***** Note:*** [1,62]
– *High risk of disease recurrence is defined as:*
▪ *ypT2-ypT4a or ypN+ for patients who received neoadjuvant cisplatin;* ***OR***
▪ *pT3-pT4a or pN+ for patients who did not receive neoadjuvant cisplatin and are also ineligible for or refused adjuvant cisplatin therapy*

Colorectal Cancer (CRC) † ‡ [1,2,31,32]

- Patient is at least 12 years of age; **AND**
- Patient's disease must be microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); **AND**
- Used as a single agent or in combination with ipilimumab*; **AND**
  - Used for advanced or metastatic disease that progressed following treatment with one of the following:
    - Fluoropyrimidine-, oxaliplatin-, and/or irinotecan-based chemotherapy † ‡; **OR**
    - Non-intensive therapy** ‡; **OR**
  - Used as primary treatment; **AND**
    - Used as neoadjuvant therapy of resectable liver and/or lung metastases; **OR**
    - Used if resection is contraindicated following neoadjuvant therapy for advanced, locally unresectable, or medically inoperable rectal cancer; **OR**
    - Used for unresectable (or medically inoperable) or metastatic disease; **OR**

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- Used for unresectable (or medically inoperable) metastases that remain unresectable after primary systemic therapy ‡

** Single agent nivolumab should be used in patients who are not candidates for intensive therapy.*

*** Except if received previous fluoropyrimidine, with improvement in functional status.*

Merkel Cell Carcinoma ‡ [2,4,33,65]

- Used as a single agent; **AND**
  - Used as neoadjuvant treatment for regional, pathologic N+ disease; **OR**
  - Used for primary or recurrent metastatic disseminated disease

Central Nervous System (CNS) Cancer ‡ [2,5,34,41,42]

- Used in one of the following treatment settings:
  - Used as initial treatment in patients with small asymptomatic brain metastases
  - Used for relapsed limited brain metastases with either stable systemic disease or reasonable systemic treatment options
  - Patient has recurrent limited brain metastases
  - Used for recurrent extensive brain metastases with stable systemic disease or reasonable systemic treatment options; **AND**
- Used as a single-agent or in combination with ipilimumab for the treatment of brain metastases in patients with melanoma; **OR**
- Used as a single-agent for the treatment of brain metastases in patients with PD-L1 positive non-small cell lung cancer (NSCLC)

Anal Carcinoma ‡ [2,6,35]

- Patient has metastatic squamous cell disease; **AND**
- Used as a single agent for subsequent therapy

Gestational Trophoblastic Neoplasia ‡ [2,36]

- Used as single-agent therapy for multiagent chemotherapy-resistant disease; **AND**
  - Patient has intermediate placental site trophoblastic tumor (PSTT) or epithelioid trophoblastic tumor (ETT); **AND**
    - Patient has recurrent or progressive disease; **AND**
    - Patient was previously treated with a platinum-based regimen; **OR**
  - Patient has high risk disease (i.e., ≥7 Prognostic score or stage IV disease)

Malignant Pleural Mesothelioma (MPM) † ‡ Φ [2,37,38,47,64]

- Used as a single agent or in combination with ipilimumab as subsequent therapy (if not administered first-line); **OR**
- Used in combination with ipilimumab as first-line therapy; **AND**
  - Patient has stage IIIB or IV disease; **OR**
  - Patient has sarcomatoid or biphasic histology; **OR**
  - Disease is medically inoperable or unresectable

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**Note: May also be used for pericardial mesothelioma and tunica vaginalis testis mesothelioma.*

Malignant Peritoneal Mesothelioma (MPeM) ‡ [2,64]

- Used as a single agent or in combination with ipilimumab as subsequent therapy (if not administered first-line); **OR**
- Used in combination with ipilimumab as first-line therapy; **AND**
  - Patient has diffuse disease; **OR**
  - Patient has recurrent benign multicystic or well-differentiated papillary disease

**Note: May also be used for pericardial mesothelioma and tunica vaginalis testis mesothelioma.*

Small Bowel Adenocarcinoma/Advanced Ampullary Cancer ‡ [2,31,39]

- Patient has advanced or metastatic disease that is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); **AND**
- Used as a single agent or in combination with ipilimumab; **AND**
  - Used as initial therapy; **OR**
  - Used as subsequent therapy for patients with no prior oxaliplatin exposure in the adjuvant treatment setting and no contraindication to oxaliplatin therapy

Extranodal NK/T-Cell Lymphomas ‡ [2,40]

- Used as a single agent for relapsed or refractory disease; **AND**
- Used following additional therapy with an alternative asparaginase-based chemotherapy regimen not previously used; **AND**
- Participation in a clinical trial is unavailable

Esophageal Cancer † ‡ Φ [1,2,44,52,56]

- Patient is not a surgical candidate or has unresectable, advanced, recurrent, or metastatic disease; **AND**
  - Patient has squamous cell carcinoma (SCC) †; **AND**
    - Used as a single agent for subsequent therapy; **OR**
  - Patient has adenocarcinoma; **AND**
    - Used as first-line therapy in combination with fluoropyrimidine- and platinum-containing chemotherapy; **OR**
- Used as adjuvant treatment of completely resected disease †; **AND**
  - Used as a single agent in patients with residual disease following neoadjuvant chemoradiotherapy (CRT)

Esophagogastric/Gastroesophageal Junction Cancer † ‡ Φ [1,2,52,56]

- Patient is not a surgical candidate or has unresectable, advanced, recurrent, or metastatic disease; **AND**
  - Used as first-line therapy in combination with fluoropyrimidine- and platinum-containing chemotherapy; **OR**
- Used as adjuvant treatment of completely resected disease †; **AND**

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- Used as a single agent in patients with residual disease following neoadjuvant chemoradiotherapy (CRT)

Gastric Cancer † ‡ Φ [1,2,53,56]

- Patient is not a surgical candidate or has unresectable, advanced, recurrent, or metastatic disease; **AND**
  - Used as first-line therapy in combination with fluoropyrimidine- and platinum-containing chemotherapy

Endometrial Carcinoma (Uterine Neoplasms) ‡ [2,48]

- Used as a single agent; **AND**
- Used as second-line therapy for microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) recurrent or metastatic disease

Vulvar Cancer (Squamous Cell Carcinoma) ‡ [2,49]

- Used as a single agent; **AND**
- Used as second-line therapy for HPV-related advanced, recurrent, or metastatic disease

Small Cell Lung Cancer (SCLC) ‡ [2,24,61]

- Used as subsequent systemic therapy as a single agent; **AND**
  - Disease has relapsed following a complete or partial response or stable disease with primary treatment (*excluding use in patients who progressed on maintenance atezolizumab or durvalumab at time of relapse*); **OR**
  - Used for primary progressive disease

Cervical Cancer ‡ [2,49,63]

- Used as subsequent therapy as a single agent; **AND**
- Patient has persistent, recurrent, or metastatic disease; **AND**
- Tumor expresses PD-L1 (e.g., CPS ≥1) as determined by an FDA-approved or CLIA-compliant test❖

❖ *If confirmed using an immunotherapy assay-http://www.fda.gov/CompanionDiagnostics*

† FDA Approved Indication(s); ‡ Compendia recommended indication(s); Φ Orphan Drug

Genomic Aberration/Mutational Driver Targeted Therapies (Note: *not all inclusive, refer to guidelines for appropriate use*) §				
Sensitizing *EGFR* mutation-positive tumors	*ALK* rearrangement-positive tumors	*ROS1* rearrangement-positive tumors	*BRAF* V600E-mutation positive tumors	*NTRK* gene fusion positive tumors
– Afatinib – Erlotinib – Dacomitinib – Gefitinib – Osimertinib – Amivantamab *(exon-20 insertion)* – Mobocertinib *(exon-20 insertion)*	– Alectinib – Brigatinib – Ceritinib – Crizotinib – Lorlatinib	– Ceritinib – Crizotinib – Entrectinib – Lorlatinib	– Dabrafenib ± trametinib – Vemurafenib	– Larotrectinib – Entrectinib
PD-L1 tumor expression ≥1%	PD-L1 tumor expression ≥50%	*MET* exon-14 skipping mutations	*RET* rearrangement-positive tumors	KRAS G12C mutation positive tumors

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– Pembrolizumab – Atezolizumab – Nivolumab + ipilimumab	– Pembrolizumab – Atezolizumab – Nivolumab + ipilimumab – Cemiplimab	– Capmatinib – Crizotinib – Tepotinib	– Selpercatinib – Cabozantinib – Pralsetinib	– Sotorasib

IV. Renewal Criteria Δ 1,2,4-6,15-42,43,49,50,52,54

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion-related reactions, complications of allogeneic hematopoietic stem cell transplantation (HSCT), severe immune-mediated adverse reactions (i.e., pneumonitis, colitis, hepatitis, endocrinopathies, nephritis/renal dysfunction, adverse skin reactions/rash, etc.), hepatotoxicity when taken with cabozantinib, etc.; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**

Cutaneous Melanoma (adjuvant therapy)

- Patient has not exceeded a maximum of one (1) year of therapy

Cutaneous Melanoma (re-induction therapy)

- *Refer to Section III for criteria (see Cutaneous Melanoma – Used for retreatment of disease as re-induction)*

Non-Small Cell Lung Cancer (neoadjuvant therapy in combination with platinum-doublet chemotherapy)

- Patient has not exceeded a maximum of three (3) cycles

Non-Small Cell Lung Cancer (in combination with ipilimumab with or without platinum-doublet chemotherapy)

- Patient has not exceeded a maximum of two (2) years of therapy

Non-Small Cell Lung Cancer (maintenance therapy)

- *Refer to Section III for criteria*

Malignant Pleural Mesothelioma and Malignant Peritoneal Mesothelioma

- Patient has not exceeded a maximum of two (2) years of therapy

Vulvar Cancer

- Patient has not exceeded a maximum of two (2) years of therapy

Cervical Cancer

- Patient has not exceeded a maximum of two (2) years of therapy

Renal Cell Carcinoma (in combination with cabozantinib)

- Patient has not exceeded a maximum of two (2) years of therapy

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Urothelial Carcinoma (adjuvant therapy)

- Patient has not exceeded a maximum of one (1) year of therapy

Esophageal and Esophagogastric/Gastroesophageal Junction Cancer (adjuvant therapy)

- Patient has not exceeded a maximum of one (1) year of therapy

Gastric Cancer, Esophagogastric/Gastroesophageal Junction Cancer, and Esophageal Adenocarcinoma (in combination with fluoropyrimidine- and platinum-containing chemotherapy)

- Patient has not exceeded a maximum of two (2) years of therapy

Classical Hodgkin Lymphoma (in combination with brentuximab vedotin)

- Patient has not exceeded a maximum of twelve (12) weeks of therapy

Merkel Cell Carcinoma (neoadjuvant therapy)

- Patient has not exceeded a maximum of two (2) doses

Δ Notes:

- Patients responding to therapy who relapse ≥ 6 months after discontinuation due to duration (i.e., receipt of 24 months of therapy) are eligible to re-initiate PD-directed therapy.
- Patients who complete adjuvant therapy and progress ≥ 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 Δ [1,4-6,24,31-42,48-50,54,58,59,61,65]

Indication	Dose
Merkel Cell Carcinoma	Neoadjuvant treatment: • Administer 240 mg intravenously every 2 weeks (days 1 and 15) for a total of 2 doses Primary or recurrent metastatic disease: • Administer 240 mg intravenously every 2 weeks or 3 mg/kg intravenously every 2 weeks until disease progression or unacceptable toxicity
Anal Cancer	Administer 240 mg intravenously every 2 weeks, 480 mg intravenously every 4 weeks, or 3 mg/kg intravenously every 2 weeks until disease progression or unacceptable toxicity
Cutaneous Melanoma	Single agent *(excluding adjuvant therapy)*: • Administer 240 mg intravenously every 2 weeks or 480 mg intravenously every 4 weeks until disease progression or unacceptable toxicity In combination with ipilimumab *(excluding adjuvant therapy)*: • Administer 1 mg/kg intravenously, with ipilimumab on the same day, every 3 weeks for 4 doses, then follow with single agent regimen Adjuvant treatment:

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	• Administer 240 mg intravenously every 2 weeks or 480 mg intravenously every 4 weeks until disease recurrence or unacceptable toxicity for up to 1 year
Uveal Melanoma	Single agent: • Administer up to 10 mg/kg intravenously every 2 weeks until disease progression or unacceptable toxicity In combination with ipilimumab: • Administer 1 mg/kg intravenously, with ipilimumab on the same day, every 3 weeks for 4 doses, then 3 mg/kg intravenously every 2 weeks until disease progression or unacceptable toxicity
NSCLC	Neoadjuvant treatment in combination with platinum-doublet chemotherapy: • Administer 360 mg intravenously with platinum-doublet chemotherapy every 3 weeks for 3 cycles. Single agent: • Administer 240 mg intravenously every 2 weeks or 480 mg intravenously every 4 weeks until disease progression or unacceptable toxicity In combination with ipilimumab: • Administer 3 mg/kg intravenously every 2 weeks, with ipilimumab every 6 weeks, until disease progression or unacceptable toxicity for up to 2 years In combination with ipilimumab and platinum-doublet chemotherapy: • Administer 360 mg intravenously every 3 weeks, with ipilimumab every 6 weeks and histology-based platinum-doublet chemotherapy every 3 weeks for 2 cycles, then continue 360 mg every 3 weeks until disease progression or unacceptable toxicity for up to 2 years
SCCHN & Gestational Trophoblastic Neoplasia (GTN)	Administer 240 mg intravenously every 2 weeks or 480 mg intravenously every 4 weeks until disease progression or unacceptable toxicity
Urothelial Carcinoma (Bladder Cancer)	Second-line or subsequent treatment: • Administer 240 mg intravenously every 2 weeks or 480 mg intravenously every 4 weeks until disease progression or unacceptable toxicity Adjuvant treatment: • Administer 240 mg intravenously every 2 weeks or 480 mg intravenously every 4 weeks until disease recurrence or unacceptable toxicity for up to 1 year
cHL	Single agent: • Administer 240 mg intravenously every 2 weeks or 480 mg intravenously every 4 weeks until disease progression or unacceptable toxicity In combination with brentuximab vedotin • Administer 3 mg/kg intravenously every 3 weeks for up to 12 weeks (4 cycles)
MSI-H/dMMR CRC	Adult patients and for pediatric patients ≥ 12 years and ≥ 40 kg: • **As a single agent:** Administer 3 mg/kg intravenously every 2 weeks, or 240 mg intravenously every 2 weeks, or 480 mg intravenously every 4 weeks until disease progression or unacceptable toxicity • **In combination with ipilimumab:**

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	Primary treatment ○ Administer 3 mg/kg intravenously every 2 weeks, with ipilimumab every 6 weeks, until disease progression or unacceptable toxicity Disease progression or for disease that remains unresectable after primary treatment ○ Administer 3 mg/kg intravenously, with ipilimumab on the same day, every 3 weeks for 4 doses, then follow with the single agent regimen Pediatric patients ≥ 12 years and < 40 kg: • **As a single agent:** Administer 3 mg/kg intravenously every 2 weeks until disease progression or unacceptable toxicity • **In combination with ipilimumab:** Primary treatment ○ Administer 3 mg/kg intravenously every 2 weeks, with ipilimumab every 6 weeks, until disease progression or unacceptable toxicity Disease progression or for disease that remains unresectable after primary treatment ○ Administer 3 mg/kg intravenously, with ipilimumab on the same day, every 3 weeks for 4 doses, then follow with the single agent regimen
Renal Cell Carcinoma (RCC)	Single agent: • Administer 240 mg intravenously every 2 weeks or 480 mg intravenously every 4 weeks until disease progression or unacceptable toxicity In combination with ipilimumab: • Administer 3 mg/kg intravenously, with ipilimumab on the same day, every 3 weeks for 4 doses, then follow with single agent regimen In combination with cabozantinib (Cabometyx): • Administer 240 mg intravenously every 2 weeks or 480 mg intravenously every 4 weeks until disease progression or unacceptable toxicity for up to 2 years
Hepatocellular Carcinoma (HCC)	In combination with ipilimumab: • Administer 1 mg/kg intravenously, with ipilimumab on the same day, every 3 weeks for 4 doses, then 240 mg intravenously every 2 weeks or 480 mg intravenously every 4 weeks until disease progression or unacceptable toxicity
Malignant Pleural Mesothelioma (MPM) & Malignant Peritoneal Mesothelioma (MPeM)	Single agent: • Administer 3 mg/kg intravenously every 2 weeks until disease progression or unacceptable toxicity for up to 2 years In combination with ipilimumab: • Subsequent Therapy – Administer 3 mg/kg intravenously every 2 weeks, with ipilimumab every 6 weeks, until disease progression or unacceptable toxicity for up to 2 years; **OR**

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	– Administer 240 mg intravenously every 2 weeks, with ipilimumab every 6 weeks (ipilimumab given for a total of 4 doses), until disease progression or unacceptable toxicity for up to 2 years • Initial Therapy – Administer 360 mg intravenously every 3 weeks or 3 mg/kg every 2 weeks, with ipilimumab every 6 weeks, until disease progression or unacceptable toxicity for up to 2 years
CNS Metastases from Melanoma	Single agent: • Administer 3 mg/kg intravenously every 2 weeks until disease progression or unacceptable toxicity In combination with ipilimumab: • Administer 1 mg/kg intravenously, with ipilimumab on the same day, every 3 weeks for 4 doses, then 3 mg/kg intravenously every 2 weeks until disease progression or unacceptable toxicity
CNS Metastases from NSCLC	Administer 3 mg/kg intravenously every 2 weeks until disease progression or unacceptable toxicity
Small Bowel Adenocarcinoma/ Advanced Ampullary Cancer	Single agent: • Administer 3 mg/kg intravenously every 2 weeks, or 240 mg intravenously every 2 weeks, or 480 mg intravenously every 4 weeks until disease progression or unacceptable toxicity In combination with ipilimumab: • Administer 3 mg/kg intravenously, with ipilimumab on the same day, every 3 weeks for 4 doses, then 3 mg/kg or 240 mg intravenously every 2 weeks until disease progression or unacceptable toxicity
Esophageal and Esophagogastric/ Gastroesophageal Junction Cancer	Esophageal Squamous Cell Carcinoma: • Administer 240 mg intravenously every 2 weeks or 480 mg intravenously every 4 weeks until disease progression or unacceptable toxicity Single agent for adjuvant therapy: • Administer 240 mg intravenously every 2 weeks or 480 mg intravenously every 4 weeks for up to 1 year In combination with fluoropyrimidine- and platinum-containing chemotherapy: • Administer 240 mg intravenously every 2 weeks or 360 mg intravenously every 3 weeks until disease progression or unacceptable toxicity for up to 2 years
Gastric Cancer	Administer 240 mg intravenously every 2 weeks or 360 mg intravenously every 3 weeks until disease progression or unacceptable toxicity for up to 2 years
Extranodal NK/T-Cell Lymphoma	Administer 40 mg intravenously every 2 weeks until disease progression or unacceptable toxicity
Endometrial Carcinoma	Administer 3 mg/kg intravenously every 2 weeks for 8 doses, then 480 mg intravenously every 4 weeks until disease progression or unacceptable toxicity
Vulvar Cancer & Cervical Cancer	Administer 240 mg intravenously every 2 weeks until disease progression or unacceptable toxicity for up to 2 years

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SCLC	Administer 3 mg/kg intravenously every 2 weeks until disease progression or unacceptable toxicity

Dosing should be calculated using actual body weight and not flat dosing (as applicable) based on the following:

Weight ≥ 74 kg:

- Standard dose 480 mg IV every 4 weeks

Weight is 67 kg to 73 kg:

- Use 440 mg IV every 4 weeks

Weight is ≤ 66kg:

- Use 400 mg IV every 4 weeks

-OR-

Weight > 67 kg:

- Standard dose 240 mg IV every 2 weeks

Weight is 53 kg to 67 kg:

- Use 200 mg IV every 2 weeks

Weight is < 53kg:

- Use 160 mg IV every 2 weeks

Note: This information is not meant to replace clinical decision making when initiating or modifying medication therapy and should only be used as a guide. Patient-specific variables should be taken into account.

VI. Billing Code/Availability Information

HCPCS Code:

- J9299 – Injection, nivolumab, 1 mg; 1 billable unit = 1 mg

NDC(s):

- Opdivo 40 mg/4 mL single-dose vial: 00003-3772-xx
- Opdivo 100 mg/10 mL single-dose vial: 00003-3774-xx
- Opdivo 120 mg/12 mL single-dose vial: 00003-3756-xx
- Opdivo 240 mg/24 mL single-dose vial: 00003-3734-xx

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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

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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

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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

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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
C43.10	Malignant melanoma of unspecified eyelid, including canthus
C43.11	Malignant melanoma of right eyelid, including canthus
C43.12	Malignant melanoma of left eyelid, including canthus
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

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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
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
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

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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
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
C63.2	Malignant neoplasm of scrotum
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

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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
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
C79.51	Secondary malignant neoplasm of bone
C79.52	Secondary malignant neoplasm of bone marrow
C7A.1	Malignant poorly differentiated neuroendocrine tumors
C7B.1	Secondary Merkel cell carcinoma
C81.10	Nodular sclerosis Hodgkin lymphoma, unspecified site
C81.11	Nodular sclerosis Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.12	Nodular sclerosis Hodgkin lymphoma, intrathoracic lymph nodes
C81.13	Nodular sclerosis Hodgkin lymphoma, intra-abdominal lymph nodes
C81.14	Nodular sclerosis Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.15	Nodular sclerosis Hodgkin lymphoma, lymph nodes of inguinal region and lower limb

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C81.16	Nodular sclerosis Hodgkin lymphoma, intrapelvic lymph nodes
C81.17	Nodular sclerosis Hodgkin lymphoma, spleen
C81.18	Nodular sclerosis Hodgkin lymphoma, lymph nodes of multiple sites
C81.19	Nodular sclerosis Hodgkin lymphoma, extranodal and solid organ sites
C81.20	Mixed cellularity Hodgkin lymphoma, unspecified site
C81.21	Mixed cellularity Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.22	Mixed cellularity Hodgkin lymphoma, intrathoracic lymph nodes
C81.23	Mixed cellularity Hodgkin lymphoma, intra-abdominal lymph nodes
C81.24	Mixed cellularity Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.25	Mixed cellularity Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.26	Mixed cellularity Hodgkin lymphoma, intrapelvic lymph nodes
C81.27	Mixed cellularity Hodgkin lymphoma, spleen
C81.28	Mixed cellularity Hodgkin lymphoma, lymph nodes of multiple sites
C81.29	Mixed cellularity Hodgkin lymphoma, extranodal and solid organ sites
C81.30	Lymphocyte depleted Hodgkin lymphoma, unspecified site
C81.31	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.32	Lymphocyte depleted Hodgkin lymphoma, intrathoracic lymph nodes
C81.33	Lymphocyte depleted Hodgkin lymphoma, intra-abdominal lymph nodes
C81.34	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.35	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.36	Lymphocyte depleted Hodgkin lymphoma, intrapelvic lymph nodes
C81.37	Lymphocyte depleted Hodgkin lymphoma, spleen
C81.38	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of multiple sites
C81.39	Lymphocyte depleted Hodgkin lymphoma, extranodal and solid organ sites
C81.40	Lymphocyte-rich Hodgkin lymphoma, unspecified site
C81.41	Lymphocyte-rich Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.42	Lymphocyte-rich Hodgkin lymphoma, intrathoracic lymph nodes
C81.43	Lymphocyte-rich Hodgkin lymphoma, intra-abdominal lymph nodes
C81.44	Lymphocyte-rich Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.45	Lymphocyte-rich Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.46	Lymphocyte-rich Hodgkin lymphoma, intrapelvic lymph nodes
C81.47	Lymphocyte-rich Hodgkin lymphoma, spleen
C81.48	Lymphocyte-rich Hodgkin lymphoma, lymph nodes of multiple sites
C81.49	Lymphocyte-rich Hodgkin lymphoma, extranodal and solid organ sites
C81.70	Other Hodgkin lymphoma unspecified site
C81.71	Other Hodgkin lymphoma lymph nodes of head, face, and neck

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C81.72	Other Hodgkin lymphoma intrathoracic lymph nodes
C81.73	Other Hodgkin lymphoma intra-abdominal lymph nodes
C81.74	Other Hodgkin lymphoma lymph nodes of axilla and upper limb
C81.75	Other Hodgkin lymphoma lymph nodes of inguinal region and lower limb
C81.76	Other Hodgkin lymphoma intrapelvic lymph nodes
C81.77	Other Hodgkin lymphoma spleen
C81.78	Other Hodgkin lymphoma lymph nodes of multiple sites
C81.79	Other Hodgkin lymphoma extranodal and solid organ sites
C81.90	Hodgkin lymphoma, unspecified site
C81.91	Hodgkin lymphoma, unspecified lymph nodes of head, face, and neck
C81.92	Hodgkin lymphoma, unspecified intrathoracic lymph nodes
C81.93	Hodgkin lymphoma, unspecified intra-abdominal lymph nodes
C81.94	Hodgkin lymphoma, unspecified lymph nodes of axilla and upper limb
C81.95	Hodgkin lymphoma, unspecified lymph nodes of inguinal region and lower limb
C81.96	Hodgkin lymphoma, unspecified intrapelvic lymph nodes
C81.97	Hodgkin lymphoma, unspecified spleen
C81.98	Hodgkin lymphoma, unspecified lymph nodes of multiple sites
C81.99	Hodgkin lymphoma, unspecified extranodal and solid organ sites
C84.90	Mature T/NK-cell lymphomas, unspecified, unspecified site
C84.91	Mature T/NK-cell lymphomas, unspecified, lymph nodes of head, face, and neck
C84.92	Mature T/NK-cell lymphomas, unspecified, intrathoracic lymph nodes
C84.93	Mature T/NK-cell lymphomas, unspecified, intra-abdominal lymph nodes
C84.94	Mature T/NK-cell lymphomas, unspecified, lymph nodes of axilla and upper limb
C84.95	Mature T/NK-cell lymphomas, unspecified, lymph nodes of inguinal region and lower limb
C84.96	Mature T/NK-cell lymphomas, unspecified, intrapelvic lymph nodes
C84.97	Mature T/NK-cell lymphomas, unspecified, spleen
C84.98	Mature T/NK-cell lymphomas, unspecified, lymph nodes of multiple sites
C84.99	Mature T/NK-cell lymphomas, unspecified, extranodal and solid organ sites
C84.Z0	Other mature T/NK-cell lymphomas, unspecified site
C84.Z1	Other mature T/NK-cell lymphomas, lymph nodes of head, face, and neck
C84.Z2	Other mature T/NK-cell lymphomas, intrathoracic lymph nodes
C84.Z3	Other mature T/NK-cell lymphomas, intra-abdominal lymph nodes
C84.Z4	Other mature T/NK-cell lymphomas, lymph nodes of axilla and upper limb
C84.Z5	Other mature T/NK-cell lymphomas, lymph nodes of inguinal region and lower limb
C84.Z6	Other mature T/NK-cell lymphomas, intrapelvic lymph nodes
C84.Z7	Other mature T/NK-cell lymphomas, spleen

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C84.Z8	Other mature T/NK-cell lymphomas, lymph nodes of multiple sites
C84.Z9	Other mature T/NK-cell lymphomas, extranodal and solid organ sites
C86.0	Extranodal NK/T-cell lymphoma, nasal type
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
Z85.038	Personal history of other malignant neoplasm of large intestine
Z85.068	Personal history of other malignant neoplasm of small intestine
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
Z85.71	Personal history of Hodgkin lymphoma
Z85.820	Personal history of malignant melanoma of skin

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

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 Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered at the discretion of the health plan.

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

Jurisdiction(s): 6, K	**NCD/LCD/LCA Document (s):** A54862

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https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a54862&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP

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, 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, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
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

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