Keytruda® (pembrolizumab)
(Intravenous)

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I. Length of Authorization Δ 1-3,5,6,15-17,50,51,53,57,62,65,68,69,72,73,75-77,82,85-87,95,101,103,117,118,123,124,15e

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

- Adrenal Gland Tumors, Anal Carcinoma, Biliary Tract Cancer (Gallbladder Cancer or Intra-/Extra-Hepatic Cholangiocarcinoma)**, Bladder Cancer/Urothelial Carcinoma, Cervical Cancer, cHL, CNS Cancer, Cutaneous Melanoma (in combination with ipilimumab, Lenvatinib OR trametinib and dabrafenib), cSCC, Endometrial Carcinoma (Uterine Neoplasms), Esophageal and Esophagogastric/Gastroesophageal Junction Cancer (first-line, induction, or subsequent therapy), Gastric Cancer (first-line therapy), HCC, CLL/SLL, MCC, MSI-H/dMMR Cancer**, NSCLC (first-line or subsequent therapy), Penile Cancer, PMBCL, POLE/POLD1 Mutation Cancer, Primary Cutaneous Lymphomas, RCC (first-line therapy), Head and Neck Cancers, SCLC, Thymic Carcinoma, Thyroid Carcinoma (Anaplastic), TMB-H Cancer, TNBC (recurrent unresectable or metastatic disease), Vaginal Cancer, Vulvar Cancer, PM and PeM can be authorized up to a maximum of twenty-four (24) months of therapy.*****
- Neoadjuvant therapy for Biliary Tract Cancer (with or without MSI-H/dMMR) may not be renewed.
- Kaposi Sarcoma may not be renewed.
- Therapy for MSI-H/dMMR Esophageal, Esophagogastric/Gastroesophageal Junction, and Gastric Cancer can be authorized for a maximum of 48 weeks (16 doses) of postoperative therapy after surgery.
- Adjuvant therapy in NSCLC and RCC can be authorized up to a maximum of twelve (12) months of therapy.*****
- Therapy for resectable NSCLC can be authorized for up to a maximum of twelve (12) weeks of neoadjuvant therapy and thirty-nine (39) weeks of adjuvant therapy.*****
- Therapy for Cutaneous Melanoma can be authorized for up to a maximum of 8 weeks of neoadjuvant therapy (3 doses), followed by a maximum of 44 weeks (15 doses) of adjuvant therapy.
- Adjuvant therapy in Cutaneous Melanoma (*if no previous neoadjuvant pembrolizumab was used*) can be authorized up to a maximum of twelve (12) months of therapy.*****
- Neoadjuvant therapy in TNBC can be authorized up to a maximum of twenty-four (24) weeks of therapy.*****
- Adjuvant therapy in TNBC can be authorized up to a maximum of twenty-seven (27) weeks of therapy.*****

********Excluding post-operative therapy for MSI-H/dMMR Esophageal, Esophagogastric/Gastroesophageal Junction, & Gastric Cancer, and Neoadjuvant therapy for Biliary Tract Cancer (with or without MSI-H/dMMR)*

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	2 years	52 doses
3 weeks	24 weeks	8 doses
	27 weeks	9 doses
	1 year	18 doses
	2 years	35 doses
6 weeks	24 weeks	4 doses
	27 weeks	5 doses
	1 year	9 doses
	2 years	18 doses

II. Dosing Limits

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

Indication	Billable Units (BU)	Per unit time (days)
Kaposi Sarcoma, Ovarian, Fallopian Tube, & Primary Peritoneal Cancer, & Soft Tissue Sarcoma	200 BU	21 days
Primary Cutaneous Lymphoma	300 BU	21 days
Anal Carcinoma & POLE/POLD1 Mutation Cancer	600 BU	42 days
CNS Cancer, SCLC, NSCLC	400 BU	42 days
	1200 BU	14 days
All Other Indications	400 BU	42 days

III. Initial Approval Criteria [1,2]

Coverage is provided in 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, unless otherwise specified [Δ]; **AND**

Anal Carcinoma ‡ [2,5,52,92,209e]

- Patient has metastatic squamous cell carcinoma; **AND**
- Used as a single agent as subsequent therapy; **AND**
- Patient has PD-L1 positive tumors

Primary Mediastinal Large B-Cell Lymphoma (PMBCL) † ‡ Φ [1,2,6,34,82]

- Used as a single agent; **AND**
- Patient is at least 6 months of age; **AND**
- Patient has relapsed or refractory disease; **AND**
- Patient does not require urgent cytoreductive therapy; **AND**
  - Used after autologous stem-cell transplant; **OR**
  - Used after 2 or more prior lines of therapy (if ineligible for autologous stem-cell transplant); **OR**
  - Used as second-line therapy **Ω**

Biliary Tract Cancers (Gallbladder Cancer or Intra-/Extra-Hepatic Cholangiocarcinoma) † ‡ Φ [1,2,94,187e]

- Used in combination with gemcitabine and cisplatin; **AND**
  - Patient has unresectable, resected gross residual (R2), or metastatic disease; **AND**
    - Used as primary treatment; **OR**
  - Patient has resectable locoregionally advanced disease *(**NOTE: Only applies to Gallbladder Cancer)*; **AND**
    - Used as neoadjuvant therapy **Ω**; **AND**
      - Patient has incidental finding of suspicious mass during surgery where hepatobiliary surgery expertise is unavailable; **OR**
      - Patient has incidental finding on pathologic review (cystic duct node positive); **OR**
      - Patient has mass on imaging

Urothelial Carcinoma (Bladder Cancer) † ‡ [1,2,8,10,35-37,88,93,99,111,54e-55e,134e,192e]

- Used in combination with enfortumab vedotin; **AND**
  - Used as first-line therapy; **AND**
  - Patient has one of the following diagnoses:
    - Locally advanced or metastatic urothelial carcinoma **†**
    - Muscle invasive bladder cancer with local recurrence or persistent disease in a preserved bladder treated with curative intent **‡**
    - Metastatic or local bladder cancer recurrence post-cystectomy treated with curative intent **‡**
    - Metastatic primary carcinoma of the urethra **‡**
    - Metastatic upper genitourinary (GU) tract tumors **‡**
    - Metastatic urothelial carcinoma of the prostate **‡**; **OR**
- Used as a single agent; **AND**

- Patient has Bacillus Calmette-Guerin (BCG)-unresponsive**, high-risk, non-muscle invasive bladder cancer (NMIBC) defined as one of the following †:
  - Persistent disease despite adequate BCG therapy
  - Disease recurrence after an initial tumor free state following an adequate BCG course of therapy
  - T1 disease following a single induction course of BCG therapy; **AND**
  - Patient has carcinoma in situ (CIS); **AND**
  - Patient is ineligible for or has elected not to undergo cystectomy; **OR**
- Patient has one of the following diagnoses:
  - Locally advanced or metastatic urothelial carcinoma †
  - Muscle invasive bladder cancer with local recurrence or persistent disease in a preserved bladder treated with curative intent ‡
  - Metastatic or local bladder cancer recurrence post-cystectomy treated with curative intent ‡
  - Recurrent or metastatic primary carcinoma of the urethra *(excluding recurrence of stage T3-4 disease or palpable inguinal lymph nodes)* ‡
  - Primary carcinoma of the urethra that is stage T3-4 cN1-2 OR cN1-2 with palpable inguinal lymph nodes *(first-line therapy only)* ‡
  - Metastatic upper genitourinary (GU) tract tumors ‡
  - Metastatic urothelial carcinoma of the prostate ‡; **AND**
  - Used for disease that progressed during or following platinum-containing chemotherapy*; **OR**
  - Used as second-line treatment after chemotherapy other than a platinum Ω; **OR**
  - Used as first-line therapy in cisplatin-ineligible patients*; **AND**
    - Patient is not eligible for any platinum-containing chemotherapy (i.e., both cisplatin and carboplatin-ineligible)*

Note: [10,71,79]

- *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.*

******** *Adequate BCG therapy is defined as administration of at least five of six doses of an initial induction course AND at least two of three doses of maintenance therapy or at least two of six doses of a second induction course.*

Triple-Negative Breast Cancer (TNBC) † ‡ Ψ [1,2,69]

- Used as first-line therapy for recurrent unresectable or metastatic disease OR inflammatory breast cancer **Ω** with no response to preoperative systemic therapy; **AND**
  - Used in combination with albumin-bound paclitaxel, paclitaxel, or gemcitabine with carboplatin; **AND**
  - Tumor expresses PD-L1 (combined positive score [CPS] ≥10) as determined by an FDA-approved or CLIA-compliant test❖; **OR**
- Patient has cN+ and M0 disease, cT1c and cN0 disease, stage II-III disease, OR inflammatory breast cancer **Ω**; **AND**
  - Used as neoadjuvant/preoperative therapy in combination with carboplatin and docetaxel; **OR**
  - Used as neoadjuvant/preoperative therapy in combination with carboplatin and paclitaxel, then in combination with cyclophosphamide and either doxorubicin or epirubicin; **OR**
  - Used as adjuvant therapy as a single agent following use as neoadjuvant/preoperative therapy in combination with chemotherapy

**There are no data on sequencing or combining adjuvant pembrolizumab with capecitabine or olaparib in patients who meet criteria for treatment with one or more of these agents. However, their sequential/combined use may be considered given high-risk of recurrence in patients with residual disease*

Adult Central Nervous System (CNS) Cancer ‡ [2,47,49,50]

- Used as a single agent; **AND**
- Primary tumor is due to BRAF non-specific melanoma or PD-L1 positive (TPS ≥1%) non-small cell lung cancer (NSCLC); **AND**
  - Used as initial treatment in patients with small asymptomatic brain metastases; **OR**
  - Used for relapsed limited brain metastases with either stable systemic disease or reasonable systemic treatment options; **OR**
  - Used for recurrent limited brain metastases; **OR**
  - Used for recurrent extensive brain metastases with stable systemic disease or reasonable systemic treatment options

Pediatric Central Nervous System (CNS) Cancers ‡ Ω [2,81]

- Patient is ≤ 21 years of age, unless otherwise specified; **AND**
- Patient has hypermutant diffuse high-grade glioma; **AND**
  - Used for recurrent or progressive disease as a single agent *(excluding oligodendroglioma, IDH-mutant and 1p/19q co-deleted or astrocytoma IDH-mutant)*; **OR**

- Used as adjuvant therapy *(excluding diffuse midline glioma, H3 K27-altered or pontine location)*; **AND**
  - Patient is < 3 years of age and used as a single agent; **OR**
  - Patient is ≥ 3 years of age and used following standard brain radiation therapy (RT) with or without concurrent temozolomide

Cervical Cancer † ‡ [1,2,42,70,100]

- Patient has FIGO 2014 Stage III-IVA disease; **AND**
  - Used in combination with platinum-containing chemoradiotherapy (CRT); **OR**
- Tumor expresses PD-L1 (CPS ≥1) as determined by an FDA-approved or CLIA-compliant test❖; **AND**
  - Used as a single agent OR in combination with tisotumab vedotin-tftv; **AND**
    - Used as subsequent therapy for recurrent or metastatic disease; **OR**
  - Used in combination with cisplatin or carboplatin AND paclitaxel (with or without bevacizumab)^; **AND**
    - Patient has persistent, recurrent, or metastatic disease; **AND**
    - Disease is not amenable to curative treatment (i.e., surgery and/or radiation); **AND**
      - Used as first-line therapy; **OR**
      - Used as second-line or subsequent therapy (if not used previously as first-line therapy) **Ω**

^*Pembrolizumab may be continued as maintenance therapy*

Esophageal Cancer and Esophagogastric/Gastroesophageal Junction Cancer † ‡ Φ [1,2,39-41,66,67,95,98,101]

- Patient is medically fit and planned for esophagectomy **Ω**; **AND**
  - Used as induction systemic therapy for relieving dysphagia; **AND**
  - Patient has squamous cell carcinoma; **AND**
  - Patient has cT2, N0 (high-risk lesions: lymphovascular invasion, ≥ 3 cm, poorly differentiated), cT1b-cT2, N+ or cT3-cT4a, Any N disease; **AND**
  - Tumor expresses PD-L1 (CPS ≥ 1) as determined by an FDA-approved or CLIA compliant test❖; **AND**
  - Used in combination with platinum- and fluoropyrimidine-based chemotherapy; **OR**
- Patient is not a surgical candidate or has unresectable locally advanced, recurrent, or metastatic disease; **AND**
  - Used as first-line therapy; **AND**
    - Patient has HER2-positive adenocarcinoma; **AND**
      - Used in combination with trastuzumab AND fluorouracil or capecitabine AND oxaliplatin or cisplatin; **AND**

        - Tumor expresses PD-L1 (CPS ≥ 1) as determined by an FDA-approved or CLIA compliant test❖; **OR**
    - Patient has HER2-negative adenocarcinoma; **AND**
        - Used in combination with oxaliplatin or cisplatin AND either fluorouracil or capecitabine; **AND**
        - Tumor expresses PD-L1 (CPS ≥ 1) as determined by an FDA-approved or CLIA compliant test❖; **OR**
    - Patient has squamous cell carcinoma; **AND**
        - Used in combination with oxaliplatin or cisplatin AND either fluorouracil or capecitabine; **AND**
        - Tumor expresses PD-L1 (CPS ≥ 10) as determined by an FDA-approved or CLIA compliant test❖; **OR**
- Used as subsequent therapy; **AND**
    - Used as a single agent; **AND**
    - Patient has squamous cell carcinoma **†**; **AND**
    - Tumor expresses PD-L1 (CPS ≥ 10) as determined by an FDA-approved or CLIA compliant test❖; **AND**
    - Patients with HER2-positive disease must have previously received HER2-directed therapy (e.g., trastuzumab, etc.), unless contraindicated

Gastric Cancer † ‡ Φ [1,2,39,67,95,98,103]

- Patient is not a surgical candidate or has unresectable locally advanced, recurrent, or metastatic disease; **AND**
- Used as first-line therapy; **AND**
    - Patient has HER2-positive adenocarcinoma; **AND**
        - Used in combination with trastuzumab AND fluorouracil or capecitabine AND oxaliplatin or cisplatin; **AND**
        - Tumor expresses PD-L1 (CPS ≥ 1) as determined by an FDA-approved or CLIA compliant test❖; **OR**
    - Patient has HER2-negative adenocarcinoma; **AND**
        - Used in combination with oxaliplatin or cisplatin AND either fluorouracil or capecitabine; **AND**
        - Tumor expresses PD-L1 (CPS ≥ 1) as determined by an FDA-approved or CLIA compliant test❖

Head and Neck Cancers † ‡ [1,2,31,32,106,125,42e,188e]

- Patient has salivary gland tumors **Ω**; **AND**
    - Used as a single agent; **AND**

- Tumor expresses PD-L1 (CPS ≥1) as determined by an FDA-approved or CLIA-compliant test❖; **AND**
- Patient has recurrent disease with one of the following:
  - Distant metastases; **OR**
  - Unresectable locoregional recurrence with prior radiation therapy (RT); **OR**
  - Unresectable second primary with prior RT; **OR**

- Patient has Very Advanced Head and Neck Cancer*****; **AND**
  - Patient has NON-nasopharyngeal cancer; **AND**
    - Patient is unfit for surgery **Ω** or has T4b, N0-3, M0 disease **Ω**; **AND**
      - Used as a single agent as first-line therapy in patients with a performance status (PS) 3; **AND**
      - Tumor expresses PD-L1 (CPS ≥1) as determined by an FDA-approved or CLIA-compliant test❖; **OR**
    - Patient has unresectable, recurrent, persistent, or metastatic disease*;* **AND**
      - Used as a single agent; **AND**
        - Tumor expresses PD-L1 (CPS ≥1) as determined by an FDA-approved or CLIA-compliant test❖; **AND**
          - Used as first-line therapy **†**; **OR**
          - Used as subsequent therapy for disease that has progressed on or after platinum-containing chemotherapy; **OR**
      - Used in combination with cetuximab; **AND**
        - Patient has a performance status 0-1; **AND**
        - Patient has platinum-resistant disease or is platinum-ineligible; **OR**
      - Used in combination with carboplatin or cisplatin AND either fluorouracil, docetaxel, paclitaxel; **AND**
        - Patient has a performance status 0-1; **AND**
        - Used as first-line therapy

****** *Very Advanced Head and Neck Cancer includes: Newly diagnosed locally advanced T4b (M0) disease; newly diagnosed unresectable regional nodal disease (typically N3); metastatic disease at initial presentation (M1); or recurrent or persistent disease.*

Hepatocellular Carcinoma (HCC) † ‡ Φ [1,2,43,107]

- Used as a single agent; **AND**
  - Disease is secondary to hepatitis B **†**; **AND**
    - Patient has received prior systemic therapy other than a PD-1/PD-L1- containing regimen; **OR**
  - Used as subsequent therapy for progressive disease **‡**; **AND**

- Patient has liver-confined, unresectable disease and deemed ineligible for transplant; **OR**
- Patient has extrahepatic/metastatic disease and deemed ineligible for resection, transplant, or locoregional therapy

Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) ‡ [2]

- Used for histologic (Richter) transformation to diffuse large B-cell lymphoma; **AND**
- Used as a single agent or in combination with ibrutinib; **AND**
  - Patient is positive for del(17p)/TP53 mutation; **OR**
  - Patient is chemotherapy refractory or is unable to receive chemoimmunotherapy

Adult Classical Hodgkin Lymphoma (cHL) † ‡ Φ [1,2,33,61,96,97]

- Patient has relapsed or refractory disease; **AND**
  - Used as a single agent; **OR**
  - Used in combination with GVD (gemcitabine, vinorelbine, liposomal doxorubicin) or ICE (ifosfamide, carboplatin, etoposide); **AND**
    - Patient is ≤ 60 years of age; **OR**
- Used as primary therapy **Ω**; **AND**
  - Patient is not a candidate for anthracycline therapy; **AND**
  - Used as a single agent with involved-site radiation therapy (IRST); **AND**
  - Patient has contraindications to brentuximab vedotin

Pediatric Classical Hodgkin Lymphoma † ‡ Φ [1,2,33,61]

- Patient is at least 6 months of age*; **AND**
- Used as a single agent; **AND**
  - Patient has refractory disease †; **OR**
  - Patient has relapsed disease; **AND**
    - Used after two (2) or more prior lines of therapy †; **OR**
    - Used as subsequent therapy in patients heavily pretreated with platinum or anthracycline-based chemotherapy ‡; **OR**
    - Used as subsequent therapy in patients with an observed decrease in cardiac function ‡

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

Kaposi Sarcoma ‡ [2,85,86]

- Used as a single agent as subsequent therapy; **AND**
- Used for relapsed/refractory advanced cutaneous, oral, visceral, or nodal disease; **AND**
- Disease has progressed on or has not responded to first-line systemic therapy; **AND**

- Disease has progressed on alternate first-line systemic therapy; **AND**
- Patient does not have multicentric Castleman disease (MCD) or KSHV–associated inflammatory cytokine syndrome (KICS)

Renal Cell Carcinoma (RCC) † ‡ [1,2,45,74-76]

- Patient has clear cell histology; **AND**
  - Used in combination with axitinib or lenvatinib; **AND**
    - Used as first-line therapy for advanced, relapsed, or stage IV disease; **OR**
  - Used as a single agent; **AND**
    - Used as adjuvant therapy **†**; **AND**
      - Patient has undergone a nephrectomy prior to receiving treatment; **AND**
        - Patient has stage II disease with grade 4 tumors (with or without sarcomatoid features); **OR**
        - Patient has stage III disease; **OR**
        - Patient has resectable stage IV (T4, M0) disease; **OR**
      - Patient has undergone a metastasectomy with complete resection of disease within one year of nephrectomy for relapsed or stage IV disease; **OR**
- Patient has non-clear cell histology; **AND**
  - Used as a single agent; **AND**
    - Used as first line therapy for relapsed or stage IV (M1 or unresectable T4, M0) disease **‡**; **OR**
  - Used in combination with lenvatinib; **AND**
    - Used as first line therapy for advanced, relapsed, or stage IV disease

Peritoneal Mesothelioma (PeM)* ‡ [2]

- Used in combination with pemetrexed AND either cisplatin or carboplatin as first-line therapy; **AND**
  - Used as adjuvant treatment for medically operable disease following cytoreductive surgery (CRS) and hyperthermic intraperitoneal chemotherapy (HIPEC) **Ω**; **AND**
    - Patient has surgical or pathologic high-risk features**; **OR**
  - Patient has medically inoperable disease and/or complete cytoreduction not achievable, or presence of any high-risk features**; **OR**
  - Patient has disease progression following CRS + HIPEC if no prior adjuvant systemic therapy was given

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

*** High-risk features include: biphasic/sarcomatoid histology, nodal metastasis, Ki-67 >9%, thrombocytosis, PS=2, bicavitary disease, high disease burden/incomplete cytoreduction (Peritoneal Cancer Index [PCI] >17, completeness of cytoreduction (cc) score >1)*

Pleural Mesothelioma (PM)* † ‡ [1,2]

- Used in combination with pemetrexed AND either cisplatin or carboplatin ; **AND**
  - Used as first line therapy; **AND**
    - Patient has unresectable advanced or metastatic disease; **OR**
  - Used as induction therapy prior to surgical exploration; **AND**
    - Patient has clinical stage I disease and epithelioid histology

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

Cutaneous Melanoma † ‡ Φ [1,2,22-24,65,68,87,112,15e]

- Used as first-line therapy as a single agent for unresectable or metastatic***** disease; **OR**
- Used as subsequent therapy; **AND**
  - Used as a single agent for unresectable or metastatic disease **†**; **OR**
  - Used for disease progression following treatment with anti-PD-1/PD-L1-based therapy, including in combination with anti-CTLA-4 (e.g., ipilimumab) for ≥2 doses; **AND**
    - Used in combination with lenvatinib for metastatic or unresectable disease **Ω**; **OR**
  - Used for disease progression, intolerance, and/or projected risk of progression with BRAF-targeted therapy; **AND**
    - Used in combination with trametinib and dabrafenib for metastatic or unresectable disease **Ω**; **AND**
      - Patient has BRAF V600 activating mutation positive disease; **OR**
    - Used in combination with ipilimumab for metastatic* or unresectable disease; **AND**
      - Used after progression on anti-PD-1 therapy; **OR**
  - Used as re-induction therapy; **AND**
    - Patient experienced disease control *(i.e., complete response, partial response, or stable disease)* and no residual toxicity from prior therapy, but subsequently have disease progression/relapse > 3 months after treatment discontinuation; **AND**
      - Used as a single agent if patient received prior pembrolizumab; **OR**
      - Used in combination with ipilimumab if patient received prior combination ipilimumab/anti-PD-1 therapy **Ω**; **OR**
      - Used in combination with trametinib and dabrafenib if patient received prior combination BRAF/MEK + PD(L)-1 checkpoint inhibitor therapy **Ω**; **AND**
        - Patient has BRAF V600 activating mutation positive disease; **OR**
- Used as a single agent for neoadjuvant treatment; **AND**
  - Patient has stage III disease; **AND**
    - Used as primary treatment for clinically positive, resectable nodal disease; **OR**
    - Used for limited resectable disease with clinical satellite/in-transit metastases; **OR**
  - Patient has limited resectable local satellite/in-transit recurrence; **OR**

- Patient has resectable disease limited to nodal recurrence; **OR**

- Used as a single agent for adjuvant treatment; **AND**
  - Patient has stage IIB or IIC melanoma following complete resection **†**; **AND**
    - Patient is at least 12 years of age; **OR**
  - Patient has stage III disease; **AND**
    - Used following complete resection **†**; **AND**
      - Patient is at least 12 years of age; **OR**
    - Patient has resected sentinel node positive disease either during radiographic surveillance OR after complete lymph node dissection (CLND); **OR**
    - Patient has clinically positive node(s) following wide excision of the primary tumor and therapeutic lymph node dissection (TLND); **OR**
    - Patient has clinical satellite/in-transit metastases and has no evidence of disease (NED) after complete excision to clear margins; **OR**
  - Patient has local satellite/in-transit recurrence and has NED after complete excision to clear margins; **OR**
  - Patient has resectable disease limited to nodal recurrence following excision and complete TLND; **OR**
  - Patient has oligometastatic disease and NED after receiving metastasis-directed therapy (i.e., complete resection, stereotactic ablative therapy, or T-VEC/intralesional therapy) or systemic therapy followed by resection

***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.*

Merkel Cell Carcinoma (MCC) † ‡ Φ [1,2,9,44,22e]

- Patient is at least 6 months of age; **AND**
- Used as a single agent; **AND**
  - Patient has primary locally advanced disease **‡ Ω**; **AND**
    - Both curative surgery and curative radiation therapy are not feasible; **OR**
  - Patient has recurrent locally advanced disease; **AND**
    - Both curative surgery and curative radiation therapy are not feasible; **OR**
    - Patient has progressed on neoadjuvant nivolumab **Ω**; **OR**
  - Patient has M1 disseminated disease **†**; **OR**
  - Patient has recurrent regional disease **‡**; **AND**
    - Both curative surgery and curative radiation therapy are not feasible; **OR**
  - Patient has primary regional disease **‡ Ω**; **AND**
    - Both curative surgery and curative radiation therapy are not feasible

Adrenal Gland Tumors ‡ [2,62,63,77,128e,129e,203e]

- Patient has locoregional unresectable or metastatic adrenocortical carcinoma (ACC); **AND**
- Used as a single agent

Non-Small Cell Lung Cancer (NSCLC) † ‡ [1,2,11,25-29,84,120e,133e,136e,196e]

- Used for stage III disease **†**; **AND**
  - Used as first-line therapy as a single-agent in patients who are not candidates for surgical resection or definitive chemoradiation; **AND**
  - Used in patients with tumors expressing PD-L1 (TPS ≥1%) as determined by an FDA-approved or CLIA compliant test❖ and with no EGFR or ALK genomic tumor aberrations; **OR**
- Used as neoadjuvant therapy **†**; **AND**
  - Patient has resectable disease (tumors ≥4 cm or node positive); **AND**
  - Used in combination with platinum-containing chemotherapy, and then continued as a single agent as adjuvant treatment after surgery; **OR**
- Used as adjuvant therapy; **AND**
  - Used as a single agent; **AND**
    - Used following resection and previous adjuvant platinum-based chemotherapy; **AND**
      - Patient has stage IB (T2a ≥4 cm), II, or IIIA disease **†**; **OR**
      - Patient has stage IIIB (T3-4, N2) disease **Ω**; **AND**
        - Disease is negative for EGFR exon 19 deletion or exon 21 L858R mutations, or ALK rearrangements; **OR**
    - Used following previous neoadjuvant pembrolizumab plus chemotherapy and resection; **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 who have tumors that are negative for actionable molecular biomarkers***¥**
      - Patients who are positive for one of the following molecular biomarkers: EGFR exon 20, BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, ERBB2 (HER2), or NRG1 gene fusion; **AND**
    - Used in combination with pemetrexed AND either carboplatin or cisplatin for non-squamous cell histology; **OR**
    - Used in combination with carboplatin AND either paclitaxel or albumin-bound paclitaxel for squamous cell histology; **OR**

        - Used as a single agent *(for PD-L1 expression-positive tumors ONLY)* **†**; **OR**
    - Used as subsequent therapy; **AND**
        - Used in patients with tumors expressing PD-L1 (TPS ≥1%) as determined by an FDA-approved or CLIA compliant test❖ in patients with disease progression on or after platinum-containing chemotherapy (patients with EGFR or ALK genomic tumor aberrations should also have disease progression on FDA-approved therapy**§**); **AND**
            - Used as a single agent; **OR**
        - Used for one of the following:
            - Patients who are positive for one of the following molecular biomarkers***** and have received prior targeted therapy**§**: EGFR S768I, L861Q and/or G719X mutation
            - Patients who are positive for one of the following molecular biomarkers*****: BRAF V600E, NTRK1/2/3 gene fusion, or MET exon 14 skipping; **AND**
            - Used in combination with carboplatin AND either paclitaxel or albumin-bound paclitaxel for squamous cell histology; **OR**
            - Used in combination with pemetrexed AND either carboplatin or cisplatin for non-squamous cell histology; **OR**
    - Used as continuation maintenance therapy in patients who have achieved tumor response or stable disease following initial systemic therapy; **AND**
        - Used in combination with pemetrexed following a first-line pembrolizumab/pemetrexed/(carboplatin or cisplatin) regimen for non-squamous cell histology; **OR**
        - Used as a single agent following a first-line pembrolizumab/carboplatin/(paclitaxel or albumin-bound paclitaxel) regimen for squamous cell histology; **OR**
        - Used as a single agent following a first-line pembrolizumab monotherapy regimen

*******Note: Actionable molecular genomic biomarkers include EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, RET, NRG1, and ERBB2 (HER2). Complete genotyping for EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, RET, NRG1, and ERBB2 (HER2), via biopsy and/or plasma testing. If a clinically actionable marker is found, it is reasonable to start therapy based on the identified marker. Treatment is guided by available results and, if unknown, these patients are treated as though they do not have driver oncogenes.*
¥ *May also be used for patients with KRAS G12C mutation positive tumors.*
§ *Genomic Aberration/Mutational Driver Targeted Therapies: Refer to guidelines for appropriate use.*

Ovarian, Fallopian Tube, and Primary Peritoneal Cancer ‡ [2,104,105,197e,198e,204e,205e]

- Patient has epithelial***** ovarian, fallopian tube, or primary peritoneal cancer; **AND**
- Used in combination with oral cyclophosphamide and bevacizumab; **AND**
- Patient has platinum-resistant disease; **AND**
    - Patient has persistent or recurrent disease; **AND**

        - Patient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 without radiographic evidence of disease); **OR**
    - Patient has recurrent disease *(low-grade serous carcinoma only)*

***** *Epithelial subtypes include serous, endometrioid, carcinosarcoma (malignant mixed Müllerian tumors [MMMTs] of the ovary), clear cell, mucinous, and borderline epithelial tumors (also known as low malignant potential [LMP] tumors).*

Penile Cancer ‡ [2,124]

- Used in combination with fluorouracil and either cisplatin or carboplatin, followed by single agent maintenance therapy; **AND**
- Used as first-line chemotherapy; **AND**
- Patient has penile squamous cell carcinoma; **AND**
    - Patient has metastatic disease; **OR**
    - Patient has local recurrence in the inguinal region and received prior inguinal lymphadenectomy or radiotherapy

Primary Cutaneous Lymphomas ‡ [2,15,102e,104e,117e]

- Used as a single agent systemic therapy; **AND**
- Patient has Mycosis Fungoides/Sezary Syndrome; **AND**
    - Used as subsequent therapy for relapsed or persistent disease; **AND**
        - Patient has one of the following:
            - Stage III Mycosis Fungoides
            - Stage IV Sezary Syndrome; **OR**
    - Used as subsequent therapy for disease refractory to multiple previous therapies *(excluding use in patients with stage IA Mycosis Fungoides)*

Small Cell Lung Cancer (SCLC) ‡ Φ [2,72,73,93e,252e]

- Used as subsequent therapy as a single agent; **AND**
- Patient has had a chemotherapy-free interval of ≤ 6 months; **AND**
- Used for one of the following:
    - Patient has relapsed disease following a complete or partial response or stable disease with primary treatment
    - Patient has primary progressive disease

Soft Tissue Sarcoma ‡ [2,56,83,89.90]

- Used in combination with axitinib; **AND**
    - Patient has alveolar soft part sarcoma (ASPS); **OR**
- Used as a single agent; **AND**

- Patient has myxofibrosarcoma **Ω**, undifferentiated pleomorphic sarcoma (UPS), dedifferentiated liposarcoma **Ω**, or undifferentiated sarcomas **Ω**; **AND**
  - Used as subsequent therapy for advanced/metastatic disease with disseminated metastases *(Note: only applies to Extremity/Body Wall, Head/Neck*****)*; **OR**
  - Used as alternative systemic therapy for unresectable or progressive disease after initial therapy for unresectable localized disease *(Note: only applies to Retroperitoneal/Intra-Abdominal******)*; **OR**
  - Used as subsequent therapy for stage IV disease with disseminated metastases *(Note: only applies to Retroperitoneal/Intra-Abdominal******)*; **OR**
- Patient has pleomorphic rhabdomyosarcoma **Ω**; **AND**
  - Used as subsequent therapy for advanced/metastatic disease

***For atypical lipomatous tumor/well-differentiated liposarcoma (ALT/WDLPS) of the extremity, abdominal wall, trunk that was initially diagnosed as ALT/WDLPS and shows evidence of de-differentiation, treat as other soft tissue sarcomas.*

****For well-differentiated liposarcoma (WDLPS-retroperitoneum, paratesticular) with or without evidence of de-differentiation, treat as other soft tissue sarcomas.*

Cutaneous Squamous Cell Carcinoma (cSCC) † ‡ [1,2,58,125e]

- Used as a single agent; **AND**
- Patient has locally advanced, recurrent or metastatic disease that is not curable by surgery or radiation

Thymic Carcinoma ‡ [2,16,17]

- Used as a single agent; **AND**
  - Patient is unable to tolerate first-line combination regimens **Ω**; **AND**
    - Used as preoperative systemic therapy for surgically resectable disease if R0 resection is considered uncertain; **OR**
    - Used as postoperative treatment after R1 (microscopic residual tumor) or R2 (macroscopic residual tumor) resection; **OR**
    - Used as first-line therapy for recurrent, advanced, or metastatic disease; **OR**
  - Used as second-line therapy; **AND**
    - Patient has unresectable or metastatic disease

Thyroid Carcinoma (Anaplastic Carcinoma) ‡ [2,108,109,206e]

- Used in combination with lenvatinib; **AND**
- Patient has stage IVC disease; **AND**
  - Used as aggressive first-line therapy; **OR**
  - Used as second-line therapy

Endometrial Carcinoma (Uterine Neoplasms) † ‡ [1,2,46,80,91,255e]

- Used in combination with lenvatinib; **AND**
  - Disease is mismatch repair proficient (pMMR) or NOT microsatellite instability-high (MSI-H) as determined by an FDA-approved or CLIA-compliant test❖; **AND**
  - Patient received prior platinum-based therapy in any setting (including neoadjuvant or adjuvant therapy); **AND**
    - Used as first-line therapy for recurrent disease *(excluding use in patients with isolated metastases)*; **OR**
    - Used as subsequent therapy for advanced, recurrent, or metastatic disease; **OR**
- Used in combination with carboplatin and paclitaxel, followed by single agent maintenance therapy; **AND**
  - Used as primary treatment for patients with advanced stage III-IV tumors *(excluding use in patients with carcinosarcoma)*♦ **‡**; **OR**
  - Used as adjuvant therapy for patients with stage III-IV endometrioid adenocarcinoma♦ **‡ Ω**; **OR**
  - Used as first-line therapy for recurrent disease **‡**; **AND**
    - Patient does not have isolated metastases; **OR**
  - Used as subsequent therapy for recurrent disease **‡ Ω**; **OR**
- Used as a single agent as maintenance therapy following treatment with pembrolizumab in combination with carboplatin and paclitaxel

♦*Note: For patients not meeting the eligibility criteria for NRG-GY018, carboplatin/paclitaxel + pembrolizumab should be considered for stage III-IV dMMR tumors.*

Vaginal Cancer ‡ Ω [2,70]

- Tumor expresses PD-L1 (CPS ≥1) as determined by an FDA-approved or CLIA-compliant test❖; **AND**
- Patient has recurrent or metastatic disease; **AND**
  - Used as a single agent as subsequent therapy; **OR**
  - Used in combination with cisplatin or carboplatin, paclitaxel, and with or without bevacizumab; **AND**
    - Used as first-line therapy; **AND**
      - ➢ Disease is not amenable to curative treatment (i.e., surgery and/or radiation); **OR**
    - Used as subsequent therapy (if not previously used as first-line)

Vulvar Cancer ‡ Ω [2,51,57]

- Patient has advanced, recurrent, or metastatic disease; **AND**
  - Used as a single agent; **AND**

        - Tumor expresses PD-L1 (CPS ≥1) as determined by an FDA-approved or CLIA-compliant test❖; **AND**
        - Used as subsequent therapy for disease progression on or after chemotherapy; **OR**
    - Used in combination with paclitaxel and either cisplatin or carboplatin with or without bevacizumab^; **AND**
        - Disease is not amenable to curative treatment (i.e., surgery and/or radiation); **AND**
            - Used as first-line therapy; **OR**
            - Used as subsequent therapy (if not previously used)

^*Pembrolizumab and bevacizumab may be continued as a maintenance therapy*

Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Cancer † ‡
1,2,4,38,51,110,113-115

- Patient is at least 6 months of age; **AND**
- Patient has microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by an FDA-approved or CLIA compliant test❖; **AND**
- Patient has unresectable or medically inoperable, advanced, recurrent, persistent, or metastatic solid tumors; **AND**
    - Used as a single agent; **AND**
        - Used for disease progression following prior treatment **†**; **AND**
            - Patient has Colorectal Cancer and was previously treated with a fluoropyrimidine AND either oxaliplatin or irinotecan, unless contraindicated; **OR**
            - Patient has no satisfactory alternative treatment options; **OR**
        - Used as initial therapy **† ‡**; **AND**
            - Patient has one of the following cancers:
                - Ampullary Adenocarcinoma **Ω**
                - Biliary Tract Cancers (Gallbladder Cancer, Intra-/Extra-hepatic Cholangiocarcinoma) **Ω**
                - Appendiceal Adenocarcinoma – Colon Cancer **Ω**
                - Colorectal Cancer
                - Esophageal or Esophagogastric/Gastroesophageal Junction adenocarcinoma or squamous cell carcinoma (**Ω** for squamous cell carcinoma only)
                - Gastric Cancer
                - Salivary Gland Tumors **Ω**
                - Very Advanced Head and Neck Cancers (non-nasopharyngeal type) **Ω**
                - Occult Primary/Cancer of Unknown Primary (CUP) **Ω**
                - Pancreatic Adenocarcinoma **Ω**
                - Small Bowel Adenocarcinoma **Ω**

        - Endometrial Carcinoma (Uterine Neoplasms) **Ω** *(excluding patients with isolated metastases)*; **OR**
    - Used as induction systemic therapy to relieve dysphagia **‡ Ω**; **AND**
        - Patient has Esophageal or Esophagogastric/Gastroesophageal Junction squamous cell carcinoma; **AND**
        - Patient is medically fit and planned for esophagectomy with cT2, N0 (high-risk lesions: lymphovascular invasion, ≥ 3cm, poorly differentiated), cT1b-cT2, N+ or cT3-cT4a, Any N disease; **OR**
    - Used as neoadjuvant therapy **‡**; **AND**
        - Patient has one of the following cancers:
            - Colorectal Cancer
            - Appendiceal Adenocarcinoma – Colon Cancer **Ω**
            - Esophageal **Ω** or Esophagogastric/Gastroesophageal Junction Adenocarcinoma **Ω**
            - Gastric Cancer **Ω**
            - Biliary Tract Cancers **Ω** (Gallbladder Cancer only) (*excluding patients with disease presenting as jaundice*); **OR**
    - Used as postoperative management following R0 resection **‡ Ω**; **AND**
        - Patient has received preoperative therapy with pembrolizumab; **AND**
            - Patient has Esophageal or Esophagogastric/Gastroesophageal Junction Adenocarcinoma; **OR**
        - Patient has received systemic therapy; **AND**
            - Patient has Gastric Cancer; **OR**
- Used in combination with oxaliplatin AND either fluorouracil or capecitabine; **AND**
    - Patient has Esophageal or Esophagogastric/Gastroesophageal Junction Cancer; **AND**
        - Used as first-line therapy; **AND**
            - Patient has adenocarcinoma or squamous cell carcinoma (**Ω** for squamous cell carcinoma only); **OR**
        - Used as induction systemic therapy to relieve dysphagia **Ω**; **AND**
            - Patient has squamous cell carcinoma; **AND**
            - Patient is medically fit and planned for esophagectomy with cT2, N0 (high-risk lesions: lymphovascular invasion, ≥ 3cm, poorly differentiated), cT1b-cT2, N+ or cT3-cT4a, Any N disease; **OR**
    - Patient has Gastric Cancer; **AND**
        - Used as first-line therapy

Polymerase Epsilon/Delta (POLE/POLD1) Mutation Cancer ‡ Ω [2,113-115]

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

- Patient has disease with ultra-hypermutated phenotype (e.g., TMB > 50 mut/Mb); **AND**
  - Patient has Colon Cancer or Rectal Cancer; **AND**
    - Used for locally unresectable or medically inoperable, advanced, or metastatic disease; **OR**
  - Patient has Appendiceal Adenocarcinoma; **AND**
    - Patient has advanced or metastatic disease; **OR**
  - Patient has Small Bowel Adenocarcinoma; **AND**
    - Patient has advanced or metastatic disease; **OR**
    - Patient has locally unresectable or medically inoperable disease; **AND**
      - Used as primary treatment

Tumor Mutational Burden-High (TMB-H) Cancer † ‡ [1,2,57]

- Patient is at least 6 months of age; **AND**
- Patient has tumor mutational burden-high (TMB-H) [≥ 10 mutations/megabase (mut/Mb)] solid tumors, as determined by an FDA-approved or CLIA-compliant test❖; **AND**
- Used as a single agent; **AND**
- Pediatric patients must not have a diagnosis of TMB-H central nervous system cancer; **AND**
- Patient has unresectable or medically inoperable, advanced, recurrent, persistent, or metastatic solid tumors; **AND**
  - Used for disease progression following prior treatment **†**; **AND**
    - Patient has no satisfactory alternative treatment options; **OR**
  - Used as initial therapy **‡ Ω**; **AND**
    - Patient has one of the following cancers:
      - Ampullary Adenocarcinoma
      - Salivary Gland Tumors
      - Very Advanced Head and Neck Cancers (non-nasopharyngeal type)
      - Occult Primary/Cancer of Unknown Primary (CUP)
      - Pancreatic Adenocarcinoma
      - Medullary Thyroid Carcinoma
      - Follicular, Oncocytic, or Papillary Thyroid Carcinoma (*only applicable to patients not amenable to radioactive iodine therapy*)
      - Endometrial Carcinoma (Uterine Neoplasms) (*excluding patients with isolated metastases*)

Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.

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

Ω *Please note that the supporting data for this indication has been assessed and deemed to be of insufficient quality based on the review conducted for the Enhanced Oncology Value (EOV) program. However, due to the absence of viable alternative treatment options, this indication will be retained in our policy and evaluated on a case-by-case basis.*

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

Ψ ER Scoring Interpretation *(following ER testing by validated IHC assay)* [116]	
Results	**Interpretation**
– 0% – <1% of nuclei stain	– ER-negative
– 1%–10% of nuclei stain	– ER-low–positive*
– >10% of nuclei stain	– ER-positive
**Note: Invasive cancers with between 1%–10% ER positivity are considered ER-low–positive. However, this group is noted to be heterogeneous and the biologic behavior of ER-low–positive cancers may be more similar to ER-negative cancers. This should be considered in decision making for other adjuvant therapy and overall treatment pathway.*	

IV. Renewal Criteria Δ [1-3,5,6,15-17,50,51,53,57,62,65,68,69,70,72,73,75-77,82,85-87,95,101,103,109,112,117-124,15e]

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria 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: severe infusion-related reactions, severe immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis with renal dysfunction, dermatologic adverse reactions/rash, etc.), hepatotoxicity when used in combination with axitinib, complications of allogeneic hematopoietic stem cell transplantation (HSCT), etc.

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 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 beyond the 24-month limit without interruption or discontinuation.
- 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.
- Patients diagnosed with Renal Cell Carcinoma with clear cell histology who have received previous immuno-oncology therapy may be eligible for treatment with pembrolizumab as subsequent therapy and will be evaluated on a case-by-case basis.

V. Dosage/Administration Δ 1-6,8,12,13,15-17,22-48,50-57,62,65,68,70,72,73,75-77,82,83,85-87,91,92,95,101,103-106,109,112,117-124,126,127,15e

Indication	Dose
Bladder Cancer/Urothelial Carcinoma, Cervical, CLL/SLL, Vaginal, cSCC, Endometrial Carcinoma/Uterine Neoplasms *(excluding MSI-H/dMMR)*, HCC, Penile Cancer, Thyroid Carcinoma (Anaplastic), Head and Neck Cancers, Adrenal Gland Tumors, Thymic Carcinoma, Vulvar Cancer, PM & PeM	200 mg intravenously every 3 weeks or 400 mg intravenously every 6 weeks up to a maximum of 24 months in patients without disease progression or unacceptable toxicity **NMIBC treatment may continue up to a maximum of 24 months in patients without persistent or recurrent high-risk disease, disease progression, or unacceptable toxicity.*
Biliary Tract Cancers	Neoadjuvant therapy: 200 mg intravenously every 3 weeks or 400 mg intravenously every 6 weeks up to a maximum of 6 months in patients without disease progression or unacceptable toxicity All other treatment settings: 200 mg intravenously every 3 weeks or 400 mg intravenously every 6 weeks up to a maximum of 24 months in patients without disease progression or unacceptable toxicity
Esophageal and Esophagogastric/ Gastroesophageal Junction Cancer	First-line, induction, or subsequent therapy: 200 mg intravenously every 3 weeks or 400 mg intravenously every 6 weeks up to a maximum of 24 months in patients without disease progression or unacceptable toxicity Neoadjuvant therapy *(MSI-H/dMMR disease ONLY)*: 200 mg intravenously every 3 weeks for at least 12 weeks, followed by surgery and then post-operative therapy *(See below)* Post-operative therapy *(MSI-H/dMMR disease ONLY)*:

	200 mg intravenously every 3 weeks for 48 weeks (16 cycles)
Gastric Cancer	First-line therapy: 200 mg intravenously every 3 weeks or 400 mg intravenously every 6 weeks up to a maximum of 24 months in patients without disease progression or unacceptable toxicity Neoadjuvant therapy *(MSI-H/dMMR disease ONLY)*: 200 mg intravenously every 3 weeks for at least 12 weeks, followed by surgery and then post-operative therapy *(See below)* Post-operative therapy *(MSI-H/dMMR disease ONLY)*: 200 mg intravenously every 3 weeks for 48 weeks (16 cycles)
NSCLC	First-line, subsequent, or continuation maintenance therapy: 200 mg intravenously every 3 weeks or 400 mg intravenously every 6 weeks up to a maximum of 24 months in patients without disease progression or unacceptable toxicity Adjuvant treatment of resected NSCLC: 200 mg intravenously every 3 weeks or 400 mg intravenously every 6 weeks up to a maximum of 12 months in patients without disease recurrence or unacceptable toxicity Neoadjuvant and adjuvant treatment of resectable NSCLC: • Neoadjuvant therapy: 200 mg intravenously every 3 weeks or 400 mg intravenously every 6 weeks in combination with chemotherapy for 12 weeks or until disease progression that precludes definitive surgery or unacceptable toxicity • Adjuvant therapy: 200 mg intravenously every 3 weeks or 400 mg intravenously every 6 weeks as a single agent after surgery for 39 weeks or until disease recurrence or unacceptable toxicity
RCC	First-line therapy: 200 mg intravenously every 3 weeks or 400 mg intravenously every 6 weeks up to a maximum of 24 months in patients without disease progression or unacceptable toxicity Adjuvant therapy: 200 mg intravenously every 3 weeks or 400 mg intravenously every 6 weeks up to a maximum of 12 months in patients without disease recurrence or unacceptable toxicity
TNBC	Recurrent unresectable or metastatic disease: 200 mg intravenously every 3 weeks or 400 mg intravenously every 6 weeks up to a maximum of 24 months in patients without disease progression or unacceptable toxicity Neoadjuvant therapy: 200 mg intravenously every 3 weeks or 400 mg intravenously every 6 weeks up to a maximum of 24 weeks in patients without disease

	progression or unacceptable toxicity (up to 8 doses of 200 mg every 3 weeks or 4 doses of 400 mg every 6 weeks) Adjuvant therapy*****: 200 mg intravenously every 3 weeks or 400 mg intravenously every 6 weeks up to a maximum of 27 weeks in patients without disease recurrence or unacceptable toxicity (up to 9 doses of 200 mg every 3 weeks or 5 doses of 400 mg every 6 weeks) ** Patients who experience disease progression or unacceptable toxicity related to KEYTRUDA with neoadjuvant treatment in combination with chemotherapy should not receive adjuvant single agent KEYTRUDA.*
Cutaneous Melanoma	Single-agent therapy *(excluding neoadjuvant and adjuvant treatment)*: 200 mg intravenously every 3 weeks or 400 mg intravenously every 6 weeks until disease progression or unacceptable toxicity In combination with ipilimumab, lenvatinib, OR trametinib and dabrafenib: 200 mg intravenously every 3 weeks or 400 mg every 6 weeks up to a maximum of 24 months in patients without disease progression or unacceptable toxicity Neoadjuvant and adjuvant treatment: • 200 mg intravenously every 3 weeks for 3 doses in the neoadjuvant setting, followed by surgery and then adjuvant treatment (see below) • 200 mg intravenously every 3 weeks for 15 doses in the adjuvant setting in patients without disease progression or unacceptable toxicity Adjuvant treatment (*if no neoadjuvant pembrolizumab was used*): • Adults: 200 mg intravenously every 3 weeks or 400 mg intravenously every 6 weeks up to a maximum of 12 months in patients without disease recurrence or unacceptable toxicity • Pediatrics: 2 mg/kg (up to 200 mg) intravenously every 3 weeks up to a maximum of 12 months in patients without disease recurrence or unacceptable toxicity
cHL, MCC, MSI-H/dMMR Cancer*, PMBCL, & TMB-H Cancer ***Excluding the following MSI-H/dMMR indications: neoadjuvant and post-operative therapy for Esophageal, Esophagogastric/Gastroesophageal Junction Cancer, neoadjuvant, and post-operative therapy for Gastric Cancer; and neoadjuvant therapy for Biliary Tract Cancer.*	Adults: 200 mg intravenously every 3 weeks or 400 mg intravenously every 6 weeks up to a maximum of 24 months in patients without disease progression or unacceptable toxicity Pediatrics: 2 mg/kg (up to 200 mg) intravenously every 3 weeks up to a maximum of 24 months in patients without disease progression or unacceptable toxicity
CNS Cancer	Adults:

	10 mg/kg intravenously every 2 weeks for up to 24 months in patients without disease progression or unacceptable toxicity Pediatrics: 2 mg/kg (up to 200 mg) intravenously every 3 weeks for up to 24 months in patients without disease progression or unacceptable toxicity
Primary Cutaneous Lymphomas	2 mg/kg intravenously every 3 weeks up to a maximum of 24 months in patients without disease progression or unacceptable toxicity
Ovarian, Fallopian Tube, and Primary Peritoneal Cancer, & Soft Tissue Sarcoma	200 mg intravenously every 3 weeks until disease progression or unacceptable toxicity
Anal Carcinoma and POLE/POLD1 Mutation Cancer	200 mg intravenously every 3 weeks or 400 mg intravenously every 6 weeks or 2 mg/kg intravenously every 3 weeks, up to a maximum of 24 months in patients without disease progression or unacceptable toxicity
Small Cell Lung Cancer (SCLC)	10 mg/kg intravenously every 2 weeks or 200 mg intravenously every 3 weeks, up to a maximum of 24 months in patients without disease progression or unacceptable toxicity
Kaposi Sarcoma	200 mg intravenously every 3 weeks, up to a maximum of 6 months in patients without unacceptable toxicity

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

Weight ≤ 55 kg:

- Use 100 mg IV (2 mg/kg) every 21 days; **OR**
- Use 200 mg IV (4 mg/kg) every 42 days

Weight is ≤ 82.5 kg:

- Use 300 mg IV (4 mg/kg) every 42 days

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:

- J9271 – Injection, pembrolizumab, 1 mg; 1 billable unit = 1 mg

NDC:

- Keytruda 100 mg/4 mL single-dose vial: 00006-3026-xx

VII. References (STANDARD)

1. Keytruda [package insert]. Rahway, NJ; Merck & Co, Inc; March 2025. Accessed April 2025.

2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) pembrolizumab. 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 April 2025.
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10. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Bladder Cancer. Version 1.2025. 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 April 2025.
11. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Non-Small Cell Lung Cancer. Version 3.2025. 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

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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

ICD-10	ICD-10 Description
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
C07	Malignant neoplasm of parotid gland
C08.0	Malignant neoplasm of submandibular gland
C08.1	Malignant neoplasm of sublingual gland
C08.9	Malignant neoplasm of major salivary gland, 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
C12	Malignant neoplasm of pyriform sinus

ICD-10	ICD-10 Description
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

ICD-10	ICD-10 Description
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
C22.1	Intrahepatic bile duct carcinoma
C22.8	Malignant neoplasm of liver, primary, unspecified as to type
C22.9	Malignant neoplasm of liver, not specified as primary or secondary
C23	Malignant neoplasm of gallbladder
C24.0	Malignant neoplasm of extrahepatic bile duct
C24.1	Malignant neoplasm of ampulla of Vater
C24.8	Malignant neoplasm of overlapping sites of biliary tract
C24.9	Malignant neoplasm of biliary tract, unspecified
C25.0	Malignant neoplasm of head of pancreas
C25.1	Malignant neoplasm of body of the pancreas
C25.2	Malignant neoplasm of tail of pancreas
C25.3	Malignant neoplasm of pancreatic duct
C25.7	Malignant neoplasm of other parts of pancreas
C25.8	Malignant neoplasm of overlapping sites of pancreas
C25.9	Malignant neoplasm of pancreas, unspecified
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

ICD-10	ICD-10 Description
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
C37	Malignant neoplasm of thymus
C40.00	Malignant neoplasm of scapula and long bones of unspecified upper limb
C40.01	Malignant neoplasm of scapula and long bones of right upper limb
C40.02	Malignant neoplasm of scapula and long bones of left upper limb
C40.10	Malignant neoplasm of short bones of unspecified upper limb
C40.11	Malignant neoplasm of short bones of right upper limb
C40.12	Malignant neoplasm of short bones of left upper limb
C40.20	Malignant neoplasm of long bones of unspecified lower limb
C40.21	Malignant neoplasm of long bones of right lower limb
C40.22	Malignant neoplasm of long bones of left lower limb
C40.30	Malignant neoplasm of short bones of unspecified lower limb
C40.31	Malignant neoplasm of short bones of right lower limb
C40.32	Malignant neoplasm of short bones of left lower limb
C40.80	Malignant neoplasm of overlapping sites of bone and articular cartilage of unspecified limb
C40.81	Malignant neoplasm of overlapping sites of bone and articular cartilage of right limb
C40.82	Malignant neoplasm of overlapping sites of bone and articular cartilage of left limb
C40.90	Malignant neoplasm of unspecified bones and articular cartilage of unspecified limb
C40.91	Malignant neoplasm of unspecified bones and articular cartilage of right limb
C40.92	Malignant neoplasm of unspecified bones and articular cartilage of left limb
C41.0	Malignant neoplasm of bones of skull and face
C41.1	Malignant neoplasm of mandible
C41.2	Malignant neoplasm of vertebral column
C41.3	Malignant neoplasm of ribs, sternum and clavicle
C41.4	Malignant neoplasm of pelvic bones, sacrum and coccyx
C41.9	Malignant neoplasm of bone and articular cartilage, unspecified
C43.0	Malignant melanoma of lip

ICD-10	ICD-10 Description
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

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
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
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.021	Malignant neoplasm of nipple and areola, right male breast
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.029	Malignant neoplasm of nipple and areola, unspecified male breast
C50.111	Malignant neoplasm of central portion of right female breast

ICD-10	ICD-10 Description
C50.112	Malignant neoplasm of central portion of left female breast
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.121	Malignant neoplasm of central portion of right male breast
C50.122	Malignant neoplasm of central portion of left male breast
C50.129	Malignant neoplasm of central portion of unspecified male breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.229	Malignant neoplasm of upper-inner quadrant of unspecified male breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.329	Malignant neoplasm of lower-inner quadrant of unspecified male breast
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.529	Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.629	Malignant neoplasm of axillary tail of unspecified male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast

ICD-10	ICD-10 Description
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast
C50.829	Malignant neoplasm of overlapping sites of unspecified male breast
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C50.921	Malignant neoplasm of unspecified site of right male breast
C50.922	Malignant neoplasm of unspecified site of left male breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast
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
C56.1	Malignant neoplasm of right ovary
C56.2	Malignant neoplasm of left ovary
C56.3	Malignant neoplasm of bilateral ovaries
C56.9	Malignant neoplasm of unspecified ovary
C57.00	Malignant neoplasm of unspecified fallopian tube
C57.01	Malignant neoplasm of right fallopian tube
C57.02	Malignant neoplasm of left fallopian tube
C57.10	Malignant neoplasm of unspecified broad ligament
C57.11	Malignant neoplasm of right broad ligament
C57.12	Malignant neoplasm of left broad ligament

ICD-10	ICD-10 Description
C57.20	Malignant neoplasm of unspecified round ligament
C57.21	Malignant neoplasm of right round ligament
C57.22	Malignant neoplasm of left round ligament
C57.3	Malignant neoplasm of parametrium
C57.4	Malignant neoplasm of uterine adnexa, unspecified
C57.7	Malignant neoplasm of other specified female genital organs
C57.8	Malignant neoplasm of overlapping sites of female genital organs
C57.9	Malignant neoplasm of female genital organ, unspecified
C60.0	Malignant neoplasm of prepuce
C60.1	Malignant neoplasm of glans penis
C60.2	Malignant neoplasm of body of penis
C60.8	Malignant neoplasm of overlapping sites of penis
C60.9	Malignant neoplasm of penis, unspecified
C61	Malignant neoplasm of prostate
C62.00	Malignant neoplasm of unspecified undescended testis
C62.01	Malignant neoplasm of undescended right testis
C62.02	Malignant neoplasm of undescended left testis
C62.10	Malignant neoplasm of unspecified descended testis
C62.11	Malignant neoplasm of descended right testis
C62.12	Malignant neoplasm of descended left testis
C62.90	Malignant neoplasm of unspecified testis, unspecified whether descended or undescended
C62.91	Malignant neoplasm of right testis, unspecified whether descended or undescended
C62.92	Malignant neoplasm of left testis, unspecified whether descended or undescended
C63.7	Malignant neoplasm of other specified male genital organs
C63.8	Malignant neoplasm of overlapping sites of male genital organs
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

ICD-10	ICD-10 Description
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
C71.0	Malignant neoplasm of cerebrum, except lobes and ventricles
C71.1	Malignant neoplasm of frontal lobe
C71.2	Malignant neoplasm of temporal lobe
C71.3	Malignant neoplasm of parietal lobe
C71.4	Malignant neoplasm of occipital lobe
C71.5	Malignant neoplasm of cerebral ventricle
C71.6	Malignant neoplasm of cerebellum
C71.7	Malignant neoplasm of brain stem
C71.8	Malignant neoplasm of overlapping sites of brain
C71.9	Malignant neoplasm of brain, unspecified
C72.0	Malignant neoplasm of spinal cord
C72.1	Malignant neoplasm of cauda equina
C72.9	Malignant neoplasm of central nervous system, unspecified
C74.00	Malignant neoplasm of cortex of unspecified adrenal gland
C74.01	Malignant neoplasm of cortex of right adrenal gland
C74.02	Malignant neoplasm of cortex of left adrenal gland
C74.90	Malignant neoplasm of unspecified part of unspecified adrenal gland
C74.91	Malignant neoplasm of unspecified part of right adrenal gland
C74.92	Malignant neoplasm of unspecified part of left adrenal 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

ICD-10	ICD-10 Description
C7A.8	Other malignant neuroendocrine tumors
C7B.00	Secondary carcinoid tumors unspecified site
C7B.01	Secondary carcinoid tumors of distant lymph nodes
C7B.02	Secondary carcinoid tumors of liver
C7B.03	Secondary carcinoid tumors of bone
C7B.04	Secondary carcinoid tumors of peritoneum
C7B.1	Secondary Merkel cell carcinoma
C7B.8	Other secondary neuroendocrine tumors
C80.0	Disseminated malignant neoplasm, unspecified
C80.1	Malignant (primary) neoplasm, unspecified
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
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

ICD-10	ICD-10 Description
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
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, 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
C83.00	Small cell B-cell lymphoma, unspecified site
C83.01	Small cell B-cell lymphoma, lymph nodes of head, face, and neck
C83.02	Small cell B-cell lymphoma, intrathoracic lymph nodes
C83.03	Small cell B-cell lymphoma, intra-abdominal lymph nodes

ICD-10	ICD-10 Description
C83.04	Small cell B-cell lymphoma, lymph nodes of axilla and upper limb
C83.05	Small cell B-cell lymphoma, lymph nodes of inguinal region and lower limb
C83.06	Small cell B-cell lymphoma, intrapelvic lymph nodes
C83.07	Small cell B-cell lymphoma, spleen
C83.08	Small cell B-cell lymphoma, lymph nodes of multiple sites
C83.09	Small cell B-cell lymphoma, extranodal and solid organ sites
C83.30	Diffuse large B-cell lymphoma, unspecified site
C83.31	Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck
C83.32	Diffuse large B-cell lymphoma, intrathoracic lymph nodes
C83.33	Diffuse large B-cell lymphoma, intra-abdominal lymph nodes
C83.34	Diffuse large B-cell lymphoma, lymph nodes of axilla and upper limb
C83.35	Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C83.36	Diffuse large B-cell lymphoma, intrapelvic lymph nodes
C83.37	Diffuse large B-cell lymphoma, spleen
C83.38	Diffuse large B-cell lymphoma, lymph nodes of multiple sites
C83.39	Diffuse large B-cell lymphoma, extranodal and solid organ sites
C83.90	Non-follicular (diffuse) lymphoma, unspecified, unspecified site
C83.91	Non-follicular (diffuse) lymphoma, unspecified, lymph nodes of head, face, and neck
C83.92	Non-follicular (diffuse) lymphoma, unspecified, intrathoracic lymph nodes
C83.93	Non-follicular (diffuse) lymphoma, unspecified, intra-abdominal lymph nodes
C83.94	Non-follicular (diffuse) lymphoma, unspecified, lymph nodes of axilla and upper limb
C83.95	Non-follicular (diffuse) lymphoma, unspecified, lymph nodes of inguinal region and lower limb
C83.96	Non-follicular (diffuse) lymphoma, unspecified, intrapelvic lymph nodes
C83.97	Non-follicular (diffuse) lymphoma, unspecified, spleen
C83.98	Non-follicular (diffuse) lymphoma, unspecified, lymph nodes of multiple sites
C83.99	Non-follicular (diffuse) lymphoma, unspecified, extranodal and solid organ sites
C84.00	Mycosis fungoides, unspecified site
C84.01	Mycosis fungoides, lymph nodes of head, face, and neck
C84.02	Mycosis fungoides, intrathoracic lymph nodes
C84.03	Mycosis fungoides, intra-abdominal lymph nodes
C84.04	Mycosis fungoides, lymph nodes of axilla and upper limb
C84.05	Mycosis fungoides, lymph nodes of inguinal region and lower limb
C84.06	Mycosis fungoides, intrapelvic lymph nodes
C84.07	Mycosis fungoides, spleen
C84.08	Mycosis fungoides, lymph nodes of multiple sites
C84.09	Mycosis fungoides, extranodal and solid organ sites
C84.10	Sézary disease, unspecified site

ICD-10	ICD-10 Description
C84.11	Sézary disease, lymph nodes of head, face, and neck
C84.12	Sézary disease, intrathoracic lymph nodes
C84.13	Sézary disease, intra-abdominal lymph nodes
C84.14	Sézary disease, lymph nodes of axilla and upper limb
C84.15	Sézary disease, lymph nodes of inguinal region and lower limb
C84.16	Sézary disease, intrapelvic lymph nodes
C84.17	Sézary disease, spleen
C84.18	Sézary disease, lymph nodes of multiple sites
C84.19	Sézary disease, extranodal and solid organ sites
C85.20	Mediastinal (thymic) large B-cell lymphoma, unspecified site
C85.21	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of head, face and neck
C85.22	Mediastinal (thymic) large B-cell lymphoma, intrathoracic lymph nodes
C85.23	Mediastinal (thymic) large B-cell lymphoma, intra-abdominal lymph nodes
C85.24	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of axilla and upper limb
C85.25	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C85.26	Mediastinal (thymic) large B-cell lymphoma, intrapelvic lymph nodes
C85.27	Mediastinal (thymic) large B-cell lymphoma, spleen
C85.28	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of multiple sites
C85.29	Mediastinal (thymic) large B-cell lymphoma, extranodal and solid organ sites
C86.60	Primary cutaneous CD30-positive T-cell proliferations not having achieved remission
C91.10	Chronic lymphocytic leukemia of B-cell type not having achieved remission
C91.12	Chronic lymphocytic leukemia of B-cell type in relapse
D09.0	Carcinoma in situ of bladder
D15.0	Benign neoplasm of other and unspecified intrathoracic organs
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
D38.4	Neoplasm of uncertain behavior of thymus
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

ICD-10	ICD-10 Description
Z85.028	Personal history of other malignant neoplasm of stomach
Z85.068	Personal history of other malignant neoplasm of small intestine
Z85.07	Personal history of malignant neoplasm of pancreas
Z85.09	Personal history of malignant neoplasm of other digestive organs
Z85.118	Personal history of other malignant neoplasm of bronchus and lung
Z85.238	Personal history of other malignant neoplasm of thymus
Z85.3	Personal history of malignant neoplasm of breast
Z85.42	Personal history of malignant neoplasm of other parts of uterus
Z85.46	Personal history of malignant neoplasm of prostate
Z85.47	Personal history of malignant neoplasm of testis
Z85.51	Personal history of malignant neoplasm of bladder
Z85.528	Personal history of other malignant neoplasm of kidney
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
Z85.830	Personal history of malignant neoplasm of bone
Z85.831	Personal history of malignant neoplasm of soft tissue
Z85.841	Personal history of malignant neoplasm of brain
Z85.848	Personal history of malignant neoplasm of other parts of nervous tissue
Z85.850	Personal history of malignant neoplasm of thyroid
Z85.858	Personal history of malignant neoplasm of other endocrine glands

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		
Jurisdictio	**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

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdictio	**Applicable State/US Territory**	**Contractor**
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