

Keytruda® (pembrolizumab) (Intravenous)

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I. Length of Authorization ^{1-3,5,15-17}

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

- SCCHN, cHL, NSCLC, SCLC, HCC, Bladder Cancer/Urothelial Carcinoma, MPM, MSI-H/dMMR, PMBCL, Cervical, Anal, Vulvar, MCC, Mycosis Fungoides/Sezary Syndrome, RCC, Thymic, Esophageal & Gastric Cancers, Uveal Melanoma, TMB-H Cancer, cSCC, and Endometrial Carcinoma can be authorized up to a maximum of 24 months of therapy.
- Adjuvant therapy in melanoma can be authorized up to a maximum of 12 months of therapy.

II. Dosing Limits

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

- Keytruda 100 mg/4 mL single use vial: 11 vials per 14 day supply

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

Indication	Billable Units (BU)	Per unit time (days)
SCCHN, cHL, NSCLC, SCLC, Melanoma, Urothelial, Gastric, Esophageal, PMBCL, Anal, Cervical, Vulvar, MSI-H/dMMR, MCC, RCC, Thymic, HCC, Gestational Trophoblastic Tumor, Soft Tissue Sarcoma, TMB-H Cancer, cSCC, Endometrial Carcinoma (that is not MSI-H/dMMR), & Adrenal Gland Tumors (that is not MSI-H/dMMR)	200 BU	21 days
MPM & CNS metastases	1150 BU	14 days
NK/T-Cell Lymphoma, MF/SS, & Uveal Melanoma	250 BU	21 days

III. Initial Approval Criteria ^{1,2}

Coverage is provided in the following conditions:

- Patient must be 18 years of age or older (unless otherwise specified); **AND**

Universal Criteria

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

Cutaneous Melanoma † ⊕ 1,2,22-24

- Used as a single agent; **AND**
 - Used as first-line therapy for unresectable or metastatic disease; **OR**
 - Used as subsequent therapy for unresectable or metastatic* disease; **AND**
 - Used after disease progression or maximum clinical benefit from BRAF targeted therapy; **OR**
 - Used for retreatment of disease as re-induction therapy in patients who experienced disease control (*i.e., complete response, partial response, or stable disease with no residual toxicity*) from prior checkpoint inhibitor therapy, but subsequently have disease progression/relapse > 3 months after treatment discontinuation; **OR**
 - Used as adjuvant treatment; **AND**
 - Patient has lymph node involvement and has undergone complete resection, complete lymph node dissection (CLND), therapeutic lymph node dissection (TLND), or nodal basin ultrasound surveillance; **OR**
 - Patient has satellite/in-transit metastases or recurrence and has no evidence of disease after complete excision; **OR**
 - Patient has undergone TLND and/or complete resection of nodal recurrence; **OR**
 - Patient has undergone complete resection of distant metastatic disease

**Metastatic disease includes stage III clinical satellite/in transit metastases or local satellite/in-transit recurrence in patients with limited resectable and unresectable disease, unresectable nodal recurrence, and disseminated (unresectable) distant metastatic disease*

Uveal Melanoma † 2,53,54

- Used as a single agent; **AND**
- Patient has distant metastatic disease

Gastric or Gastroesophageal Junction Cancer † ⊕ 1,2,39

- Used as a single agent: **AND**
- Patient has adenocarcinoma histology; **AND**
- Patient has recurrent, unresectable (or is not a candidate for surgery) locally advanced, or metastatic disease; **AND**
- Tumor expresses PD-L1 (Combined Positive Score [CPS] ≥1) as determined by an FDA-approved or CLIA compliant test❖; **AND**
- Patient progressed on or after at least two prior systemic treatments; **AND**

- Patients with HER2 positive disease must have previously failed on HER2 directed therapy (e.g., trastuzumab, etc.)

Esophageal Cancer † Φ^{1,2,40,41,44}

- Used as a single agent; **AND**
- Patient has recurrent, unresectable (or is not a candidate for surgery) locally advanced, or metastatic disease; **AND**
 - Patient has squamous cell histology; **AND**
 - Tumor expresses PD-L1 (CPS ≥ 10) as determined by an FDA-approved or CLIA compliant test❖; **AND**
 - Patient progressed on or after at least one prior systemic treatment; **OR**
 - Patient has adenocarcinoma histology; **AND**
 - Tumor expresses PD-L1 (CPS ≥ 1) as determined by an FDA-approved or CLIA compliant test❖; **AND**
 - Used as third-line or subsequent therapy; **AND**
 - Patients with HER2 positive disease must have previously failed on HER2 directed therapy (e.g., trastuzumab, etc.)

Merkel Cell Carcinoma (MCC) † Φ^{1,2,44}

- Patient is at least 2 years of age; **AND**
- Used as a single agent; **AND**
 - Patient has recurrent regional disease and both curative surgery and curative radiation therapy are not feasible; **OR**
 - Patient has recurrent locally advanced or metastatic disease

Non-Small Cell Lung Cancer (NSCLC) †^{1,2,25-29}

- 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 with tumors that are expressing PD-L1 (TPS $\geq 1\%$) as determined by an FDA-approved or CLIA compliant test❖ and with no EGFR or ALK genomic tumor aberrations †; **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:
 - PD-L1 expression-positive (TPS $\geq 1\%$) tumors, as detected by an FDA or CLIA compliant test❖, that are EGFR, ALK, ROS1, BRAF, MET exon 14 skipping mutation, and RET rearrangement negative*
 - Patients with performance status (PS) 0-1 who have EGFR, ALK, ROS1, BRAF, MET exon 14 skipping mutation, and RET

rearrangement negative* tumors and PD-L1 expression <1% (TPS <1%)

- Patients with PS 0-1 who are positive for one of the following molecular biomarkers: BRAF V600E mutation, NTRK gene fusion, MET exon 14 skipping mutation, or RET rearrangements; **AND**
 - Used in combination with pemetrexed AND either carboplatin or cisplatin for non-squamous cell histology for tumors; **OR**
 - Used in combination with carboplatin AND either paclitaxel or albumin-bound paclitaxel for squamous cell histology; **OR**
 - Used as single agent therapy (*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 †; **AND**
 - Used as single agent therapy †; **OR**
 - Used for one of the following:
 - Patients with PS 0-1 who have EGFR, ALK, or ROS1 positive tumors and prior targeted therapy §
 - Patients with PS 0-1 who are positive for one of the following molecular biomarkers: BRAF V600E mutations, NTRK gene fusions, MET exon 14 skipping mutation, or RET rearrangements; **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 therapy; **AND**
 - Used in combination with pemetrexed following a first-line pembrolizumab/pemetrexed/(carboplatin or cisplatin) regimen for disease of non-squamous cell histology; **OR**
 - Used as a single agent following a first-line pembrolizumab/carboplatin/(paclitaxel or nab-paclitaxel) regimen for disease of squamous cell histology; **OR**
 - Used as a single agent following a first-line pembrolizumab monotherapy regimen

** Note: If there is insufficient issue to allow testing for all of the EGFR, ALK, ROS1, BRAF, MET and RET, repeat biopsy and/or plasma testing should be done. If these are not feasible, treatment is guided by available results and, if unknown, these patients are treated as though they do not have driver oncogenes.*

Squamous Cell Carcinoma of the Head and Neck (SCCHN) † 1,2,31,32

- Patient has unresectable, recurrent, or metastatic disease; **AND**
 - Used as first-line therapy; **AND**
 - Used as a single-agent for tumors expressing PD-L1 (CPS ≥1) as determined by an FDA-approved or CLIA-compliant test †; **OR**
 - Used in combination with fluorouracil and a platinum chemotherapy agent; **OR**

- Used as subsequent therapy; **AND**
 - Used as a single-agent therapy for disease that has progressed on or after platinum-containing chemotherapy; **OR**
 - Used in combination with fluorouracil and a platinum chemotherapy agent in patients with non-nasopharyngeal disease and performance status 0-1

Classical Hodgkin Lymphoma (cHL) † ⊕ 1,2,33,61

- Used as a single agent; **AND**
 - Patient is at least 18 years of age and has relapsed or refractory disease; **OR**
 - Patient is at least 2 years of age and has relapsed or refractory disease; **AND**
 - Used after two or more prior lines of therapy †; **OR**
 - Used in patients heavily pretreated with platinum or anthracycline-based chemotherapy; **OR**
 - Used in patients with a decrease in cardiac function

Primary Mediastinal Large B-Cell Lymphoma (PMBCL) † ⊕ 1,2,34

- Patient must be at least 2 years old; **AND**
- Used as single agent; **AND**
- Patient has relapsed or refractory disease; **AND**
- Patient does not require urgent cytoreductive therapy

Urothelial Carcinoma (Bladder Cancer) † ‡ 1,2,8,35-37

- 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; **OR**
 - Disease recurrence after an initial tumor free state following an adequate BCG course of therapy (i.e., 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); **OR**
 - T1 disease following a single induction course of BCG; **AND**
 - Patient has carcinoma in situ (CIS); **AND**
 - Patient is ineligible for or has elected not to undergo cystectomy; **AND**
 - Used as a single agent
- OR -**
- Used as a single agent; **AND**
 - Patient has one of the following diagnoses:
 - Locally advanced or metastatic urothelial carcinoma; **OR**
 - Local bladder cancer recurrence or persistent disease in a preserved bladder; **OR**
 - Local or metastatic bladder cancer recurrence post-cystectomy; **OR**
 - Primary carcinoma of the urethra; **AND**

- Used for recurrent (excluding recurrence of stage T3-4 disease or palpable inguinal lymph nodes) or metastatic disease; **OR**
- Used for clinical stage T3-4, cN1-2 disease, or cN1-2 palpable inguinal lymph nodes (*first-line therapy only*); **AND**
- Metastatic upper genitourinary (GU) tract tumors; **OR**
- Metastatic urothelial carcinoma of the prostate; **AND**
- Used as subsequent therapy after previous platinum treatment*; **OR**
- Used as first-line therapy in cisplatin-ineligible patients*; **AND**
 - Patient is carboplatin-ineligible*; **OR**
 - Tumors express PD-L1 (CPS ≥ 10) as determined by an FDA-approved or CLIA-compliant test❖

*** Note:**

- If platinum treatment occurred greater than 12 months ago, the patient should be re-treated with platinum-based therapy if the patient is still platinum eligible (see below for cisplatin- or carboplatin-ineligible comorbidities).
 - Cisplatin-ineligible comorbidities may include the following: GFR < 60 mL/min, PS ≥ 2 , hearing loss of ≥ 25 decibels (dB) at two contiguous frequencies, or grades ≥ 2 peripheral neuropathy. Carboplatin may be substituted for cisplatin particularly in those patients with a GFR < 60 mL/min or a PS of 2.
 - Carboplatin-ineligible comorbidities may include the following: GFR < 30 mL/min, PS ≥ 3 , grade ≥ 3 peripheral neuropathy, or NYHA class ≥ 3 , etc.

Cervical Cancer †^{1,2,42}

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

Microsatellite Instability-High (MSI-H) Cancer †^{1,2,4,38,51}

- Patient must be at least 2 years of age; **AND**
- Used as a single agent; **AND**
- Patient's disease must be microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); **AND**
- Pediatric patients must not have a diagnosis of MSI-H central nervous system cancer; **AND**
- Patient has one of the following cancers:
 - Colorectal Cancer † ‡
 - Used as first-line therapy in patients with unresectable (or medically inoperable) or metastatic disease; **OR**
 - Used in patients with unresectable or metastatic disease that remain unresectable after primary systemic therapy; **OR**

- Used following local therapy (i.e., resection, diverting ostomy, bypass, or stenting) in patients with abdominal/peritoneal metastases with existing or imminent obstruction; **OR**
- Used in patients with unresectable metastatic disease after previous fluorouracil/leucovorin (5-FU/LV) or capecitabine therapy; **OR**
- Used as primary treatment in patients with unresectable metastatic disease who have received previous adjuvant treatment with FOLFOX (fluorouracil, leucovorin and oxaliplatin) or CapeOX (capecitabine-oxaliplatin) within the past 12 months; **OR**
- Used for unresectable advanced or metastatic disease that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and/or irinotecan
- Pancreatic Adenocarcinoma ‡
 - Used as second-line therapy for locally advanced or metastatic disease after progression; **OR**
 - Used for recurrent disease after resection; **OR**
 - Used as first-line therapy for metastatic disease for patients with poor performance status (i.e., ECOG \geq 2)
- Bone Cancer (Ewing Sarcoma, Chondrosarcoma [excluding dedifferentiated or mesenchymal subtypes], or Osteosarcoma [excluding high-grade undifferentiated pleomorphic sarcoma]) ‡
 - Used for unresectable or metastatic disease that has progressed following prior treatment; **AND**
 - Patient has no satisfactory alternative treatment options
- Gastric Adenocarcinoma OR Esophageal/Gastroesophageal Junction Adenocarcinoma or Squamous Cell Carcinoma ‡
 - Used as subsequent therapy for unresectable (or not a candidate for surgery) locally advanced, recurrent, or metastatic disease
- Ovarian Cancer (epithelial ovarian, fallopian tube, and primary peritoneal cancers) ‡
 - Patient has carcinosarcoma, clear cell, endometrioid, mucinous, or serous histology; **AND**
 - Used for patients with persistent or recurrent disease; **AND**
 - Patient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 with no radiographic evidence of disease)
- Uterine Cancer (endometrial carcinoma) ‡
 - Patient has recurrent, metastatic, or high-risk disease that has progressed following prior treatment
- Penile Cancer ‡
 - Used as subsequent treatment of unresectable or metastatic disease that has progressed following prior treatment; **AND**
 - Patient has no satisfactory alternative treatment options
- Testicular Cancer ‡
 - Used as third-line therapy

- Hepatobiliary Adenocarcinoma (gallbladder cancer, intra-/extra-hepatic cholangiocarcinoma) ‡
 - Used as primary treatment for unresectable or metastatic disease; **OR**
 - Used for unresectable or metastatic disease that has progressed following prior treatment
- Vulvar Squamous Cell Carcinoma
 - Used for advanced, recurrent, or metastatic disease as second-line therapy
- Cervical Cancer
 - Used as second-line therapy for recurrent or metastatic disease
- Small Bowel Adenocarcinoma
 - Used as initial therapy for advanced or metastatic disease in patients with prior oxaliplatin therapy in the adjuvant setting (or contraindication); **OR**
 - Used as subsequent therapy for advanced or metastatic disease
- Breast Cancer
 - Used for recurrent, metastatic, or unresectable disease that has progressed following prior treatment; **AND**
 - Patient has no satisfactory alternative treatment options
- Occult Primary/Cancer of Unknown Primary (CUP)
 - Used for asymptomatic aggressive or symptomatic disease; **AND**
 - Patient has one of the following:
 - Axillary involvement in men if clinically indicated
 - Lung nodules or breast marker-negative pleural effusion
 - Resectable liver disease
 - Peritoneal mass or ascites with non-ovarian histology
 - Retroperitoneal mass of non-germ cell histology in selected patients
 - Unresectable liver disease or disseminated metastases
- Other Solid Tumor (e.g., adrenal gland tumors, poorly differentiated-high grade-neuroendocrine tumors [NET], large or small cell NET, etc.) ‡
 - Used for unresectable or metastatic disease that progressed following prior treatment; **AND**
 - Patient has no satisfactory alternative treatment options

Vulvar Squamous Cell Carcinoma ‡²

- Used as a single agent; **AND**
- Patient has advanced, recurrent, or metastatic disease; **AND**
- Tumor expresses PD-L1 (CPS \geq 1) as determined by an FDA-approved or CLIA-compliant test❖; **AND**
- Used as second-line therapy for disease progression on or after chemotherapy

Thymic Carcinoma ‡^{2,16,17}

- Used as second-line therapy as a single agent; **AND**

- Patient has unresectable disease following first-line chemotherapy for potentially resectable locally advanced disease, solitary metastasis, or ipsilateral pleural metastasis; **OR**
- Patient has extra-thoracic metastatic disease

Malignant Pleural Mesothelioma ‡^{2,3}

- Used as subsequent therapy as a single agent

Central Nervous System (CNS) Cancer ‡^{2,47,50}

- Used as single agent therapy; **AND**
- Primary tumor is due to melanoma or PD-L1 positive non-small cell lung cancer (NSCLC); **AND**
 - Used as initial treatment in patients with small asymptomatic brain metastases; **OR**
 - Used for relapsed disease in patients with limited brain metastases and stable systemic disease or reasonable treatment options; **OR**
 - Patient has recurrent limited brain metastases; **OR**
 - Used for recurrent disease in patients with extensive brain metastases and stable systemic disease or reasonable systemic treatment options

T-Cell Lymphoma/Extranodal NK ‡^{2,48}

- Patient has relapsed or refractory nasal type disease; **AND**
- Disease progressed following additional treatment with an alternative asparaginase-based chemotherapy regimen not previously used; **AND**
- Participation in a clinical trial is unavailable

Anal Carcinoma ‡^{2,5,52}

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

Gestational Trophoblastic Neoplasia ‡^{2,12}

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

Small Cell Lung Cancer (SCLC) †^{1,2,13,30}

- Used as a single agent for subsequent therapy; **AND**
 - Used for metastatic disease with progression on or after platinum-based treatment and at least one other line of therapy †; **OR**
 - Patient relapsed within 6 months following a complete or partial response or after stable disease with initial treatment; **AND**

- Patient did not relapse while on maintenance atezolizumab or durvalumab; **OR**
- Patient has primary progressive disease

Hepatocellular Carcinoma (HCC) † ⊕^{1,2,43}

- Used as a single agent; **AND**
- Patient progressed on or was intolerant to sorafenib; **AND**
- Patient has Child-Pugh Class A (*i.e., excluding Child-Pugh Class B and C*) liver impairment

Mycosis Fungoides/Sezary Syndrome ‡^{2,15}

- Used as primary therapy **OR** for relapsed or persistent disease; **AND**
 - Patient has stage III Mycosis Fungoides; **OR**
 - Patient has stage IV Sezary Syndrome; **OR**
- Used for disease refractory to multiple previous therapies

Renal Cell Carcinoma (RCC) †^{1,2,45}

- Patient has advanced, relapsed, or metastatic disease; **AND**
- Patient has clear cell histology; **AND**
- Used in combination with axitinib

Endometrial Carcinoma (Uterine Cancer) †^{1,2,46}

- Patient has advanced or recurrent disease; **AND**
- Disease has progressed following prior systemic therapy; **AND**
- Patient is not a candidate for curative surgery or radiation; **AND**
- Used in combination with lenvatinib

Soft Tissue Sarcoma ‡²

- Used as a single agent; **AND**
 - Patient has alveolar soft part sarcoma (ASPS); **OR**
 - Patient has metastatic undifferentiated pleomorphic sarcoma (UPS)

Tumor Mutational Burden-High (TMB-H) Cancer †^{1,2}

- Patient must be at least 2 years old; **AND**
- Patient has solid tumors that are tumor mutational burden-high (TMB-H) ≥ 10 mutations/megabase (mut/Mb) 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 one of the following cancers:
 - Cervical Cancer
 - Used as second-line therapy for unresectable or metastatic disease; **AND**
 - Patient has no satisfactory alternative treatment options

- Thyroid Carcinoma
 - Anaplastic Carcinoma
 - Patient has metastatic disease
 - Follicular Carcinoma, Papillary Carcinoma, Hürthle Cell Carcinoma
 - Used for unresectable recurrent, persistent, or metastatic disease not amenable to radioactive iodine (RAI)
 - Medullary Carcinoma
 - Patient has unresectable, recurrent, or persistent metastatic disease
- Uterine Cancer (uterine sarcoma, endometrial carcinoma)
 - Patient has unresectable or metastatic disease that progressed following prior treatment; **AND**
 - Patient has no satisfactory alternative treatment options
- Vulvar Squamous Cell Carcinoma
 - Patient has unresectable or metastatic disease that progressed following prior treatment; **AND**
 - Patient has no satisfactory alternative treatment options
- Other Solid Tumor (e.g., poorly differentiated-high grade-neuroendocrine tumors [NET], large or small cell NET, etc.)
 - Patient has unresectable or metastatic disease that progressed following prior treatment; **AND**
 - Patient has no satisfactory alternative treatment options

Cutaneous Squamous Cell Carcinoma (cSCC) †¹

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

Adrenal Gland Tumors ‡²

- Patient has metastatic adrenocortical carcinoma (ACC)

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

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

Genomic Aberration/Mutational Driver Targeted Therapies (Note: not all inclusive, refer to guidelines for appropriate use) §
Sensitizing <i>EGFR</i> mutation-positive tumors <ul style="list-style-type: none"> – Afatinib – Erlotinib – Dacomitinib – Gefitinib – Osimertinib
<i>ALK</i> rearrangement-positive tumors <ul style="list-style-type: none"> – Alectinib – Brigatinib – Ceritinib – Crizotinib – Lorlatinib
<i>ROS1</i> rearrangement-positive tumors <ul style="list-style-type: none">

<ul style="list-style-type: none"> - Ceritinib - Crizotinib - Entrectinib
<i>BRAF</i> V600E-mutation positive tumors <ul style="list-style-type: none"> - Dabrafenib ± Trametinib - Vemurafenib
<i>NTRK</i> Gene Fusion positive tumors <ul style="list-style-type: none"> - Larotrectinib - Entrectinib
PD-1/PD-L1 expression-positive tumors (≥1%) <ul style="list-style-type: none"> - Pembrolizumab - Atezolizumab - Nivolumab ± ipilimumab
<i>MET</i> Exon-14 skipping mutations <ul style="list-style-type: none"> - Capmatinib - Crizotinib
<i>RET</i> rearrangement-positive tumors <ul style="list-style-type: none"> - Selpercatinib - Cabozantinib - Vandetanib

IV. Renewal Criteria ^{1-3,5,15,16,17}

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion reactions, immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis and renal dysfunction, skin adverse reactions/rashes, etc.), hepatotoxicity when used in combination with axitinib, etc.; **AND**
- For the follow indications, patient has not exceeded a maximum of twenty-four (24) months of therapy:
 - Squamous Cell Carcinoma of the Head and Neck (SCCHN)
 - Non-Small Cell Lung Cancer (NSCLC)
 - Classical Hodgkin Lymphoma (cHL)
 - Primary Mediastinal Large B-Cell Lymphoma (PMBCL)
 - Bladder Cancer/Urothelial Carcinoma
 - MSI-H Cancer (including the following cancers: colorectal, pancreatic, bone, gastric/gastroesophageal, ovarian, uterine, penile, testicular, hepatobiliary, occult primary, and other solid tumors)
 - Anal Cancer
 - Malignant Pleural Mesothelioma (MPM)
 - Gastric/GEJ Adenocarcinoma
 - Esophageal Cancer

- Cervical Cancer
- Vulvar Squamous Cell Carcinoma
- Merkel Cell Carcinoma (MCC)
- Mycosis Fungoides/Sezary Syndrome
- Renal Cell Carcinoma (RCC)
- Small Cell Lung Cancer (SCLC)
- Hepatocellular Carcinoma (HCC)
- Endometrial Carcinoma
- Thymic Carcinoma
- Uveal Melanoma
- Tumor Mutational Burden-High Cancer
- Cutaneous Squamous Cell Carcinoma (cSCC)

Cutaneous Melanoma (adjuvant treatment)

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

Melanoma (metastatic or unresectable disease) ‡

- *Refer to Section III for criteria*

Continuation Maintenance Therapy for NSCLC

- *Refer to Section III for criteria*

V. Dosage/Administration ^{1-6,8,12,13,15-17,22-48,50-55}

Indication	Dose
NSCLC, SCLC, HCC, SCCHN, Gastric/GEJ Carcinoma, Esophageal, Anal, Cervical, Bladder Cancer/Urothelial Carcinoma, RCC, Endometrial Carcinoma (that is NOT MSI-H/dMMR), & cSCC	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
Thymic Carcinoma & Vulvar Carcinoma	200 mg intravenously every 3 weeks up to a maximum of 24 months in patients without disease progression or unacceptable toxicity
Cutaneous Melanoma	<u>Unresectable or metastatic disease:</u> 200 mg intravenously every 3 weeks or 400 mg every 6 weeks until disease progression or unacceptable toxicity <u>Adjuvant treatment:</u> 200 mg intravenously every 3 weeks or 400 mg every 6 weeks up to a maximum of 12 months in patients without disease recurrence or unacceptable toxicity
Uveal Melanoma	2 mg/kg intravenously every 3 weeks until up to a maximum of 24 months in patients without disease progression or unacceptable toxicity

CNS metastases	10 mg/kg intravenously every 2 weeks until progression or unacceptable toxicity
cHL, PMBCL, MCC, MSI-H/dMMR Cancer, & TMB-H Cancer	<u>Adults*</u> : 200 mg intravenously every 3 weeks or 400 mg every 6 weeks <u>Pediatrics*</u> : 2 mg/kg (up to 200 mg) intravenously every 21 days <i>*Up to a maximum of 24 months in patients without disease progression or unacceptable toxicity</i>
MPM	10 mg/kg intravenously every 2 weeks for up to 24 months or until confirmed progression or unacceptable toxicity
NK/T-Cell Lymphoma	2 mg/kg intravenously every 3 weeks
MF/SS	2 mg/kg intravenously every 3 weeks up to a maximum of 24 months
Gestational Trophoblastic Tumor	200 mg intravenously every 3 weeks or 400 mg intravenously every 6 weeks
Soft Tissue Sarcoma & Adrenal Gland Tumors (that is NOT MSI-H/dMMR)	200 mg intravenously every 3 weeks
<p><u>Dosing should be calculated using actual body weight and not flat dosing (as applicable) based on the following:</u></p> <ul style="list-style-type: none"> • Standard dose 200 mg IV every 3 weeks for patients > 50 kg • Use 100 mg IV every 3 weeks for patients ≤ 50 kg <p>-OR-</p> <ul style="list-style-type: none"> • Standard dose 400 mg IV every 6 weeks for patients weighing > 82.5 kg • Use 300 mg IV every 6 weeks for patients weighing between 56 to 82.5 kg • Use 200 mg IV every 6 weeks for patients weighing ≤ 55 kg <p><i>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.</i></p>	

VI. Billing Code/Availability Information

HCPCS Code:

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

NDC:

- Keytruda 100 mg/4 mL single use vial: 00006-3026-XX

VII. References

1. Keytruda [package insert]. Whitehouse Station, NJ; Merck & Co, Inc; October 2020. Accessed October 2020.
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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
C01	Malignant neoplasm of base of tongue
C02.0	Malignant neoplasm of dorsal surface of tongue
C02.1	Malignant neoplasm of border of tongue
C02.2	Malignant neoplasm of ventral surface of tongue
C02.3	Malignant neoplasm of anterior two-thirds of tongue, part unspecified
C02.4	Malignant neoplasm of lingual tonsil
C02.8	Malignant neoplasm of overlapping sites of tongue
C02.9	Malignant neoplasm of tongue, unspecified
C03.0	Malignant neoplasm of upper gum
C03.1	Malignant neoplasm of lower gum
C03.9	Malignant neoplasm of gum, unspecified
C04.0	Malignant neoplasm of anterior floor of mouth
C04.1	Malignant neoplasm of lateral floor of mouth
C04.8	Malignant neoplasm of overlapping sites of floor of mouth
C04.9	Malignant neoplasm of floor of mouth, unspecified
C05.0	Malignant neoplasm of hard palate
C05.1	Malignant neoplasm of soft palate
C06.0	Malignant neoplasm of cheek mucosa
C06.2	Malignant neoplasm of retromolar area
C06.80	Malignant neoplasm of overlapping sites of unspecified parts of mouth
C06.89	Malignant neoplasm of overlapping sites of other parts of mouth
C06.9	Malignant neoplasm of mouth, unspecified
C09.0	Malignant neoplasm of tonsillar fossa
C09.1	Malignant neoplasm of tonsillar pillar (anterior) (posterior)
C09.8	Malignant neoplasm of overlapping sites of tonsil

ICD-10	ICD-10 Description
C09.9	Malignant neoplasm of tonsil, unspecified
C10.3	Malignant neoplasm of posterior wall of oropharynx
C12	Malignant neoplasm of pyriform sinus
C13.0	Malignant neoplasm of postcricoid region
C13.1	Malignant neoplasm of aryepiglottic fold, hypopharyngeal aspect
C13.2	Malignant neoplasm of posterior wall of hypopharynx
C13.8	Malignant neoplasm of overlapping sites of hypopharynx
C13.9	Malignant neoplasm of hypopharynx, unspecified
C14.0	Malignant neoplasm of pharynx, unspecified
C14.2	Malignant neoplasm of Waldeyer's ring
C14.8	Malignant neoplasm of overlapping sites of lip, oral cavity and pharynx
C15.3	Malignant neoplasm of upper third of esophagus
C15.4	Malignant neoplasm of middle third of esophagus
C15.5	Malignant neoplasm of lower third of esophagus
C15.8	Malignant neoplasm of overlapping sites of esophagus
C15.9	Malignant neoplasm of esophagus, unspecified
C16.0	Malignant neoplasm of cardia
C16.1	Malignant neoplasm of fundus of stomach
C16.2	Malignant neoplasm of body of stomach
C16.3	Malignant neoplasm of pyloric antrum
C16.4	Malignant neoplasm of pylorus
C16.5	Malignant neoplasm of lesser curvature of stomach, unspecified
C16.6	Malignant neoplasm of greater curvature of stomach, unspecified
C16.8	Malignant neoplasm of overlapping sites of stomach
C16.9	Malignant neoplasm of stomach, unspecified
C17.0	Malignant neoplasm of duodenum
C17.1	Malignant neoplasm of jejunum
C17.2	Malignant neoplasm of ileum
C17.3	Meckel's diverticulum, malignant
C17.8	Malignant neoplasm of overlapping sites of small intestine
C17.9	Malignant neoplasm of small intestine, unspecified
C18.0	Malignant neoplasm of cecum
C18.1	Malignant neoplasm of appendix
C18.2	Malignant neoplasm of ascending colon
C18.3	Malignant neoplasm of hepatic flexure
C18.4	Malignant neoplasm of transverse colon
C18.5	Malignant neoplasm of splenic flexure
C18.6	Malignant neoplasm of descending colon

ICD-10	ICD-10 Description
C18.7	Malignant neoplasm of sigmoid colon
C18.8	Malignant neoplasm of overlapping sites of colon
C18.9	Malignant neoplasm of colon, unspecified
C19	Malignant neoplasm of rectosigmoid junction
C20	Malignant neoplasm of rectum
C21.0	Malignant neoplasm of anus, unspecified
C21.1	Malignant neoplasm of anal canal
C21.2	Malignant neoplasm of cloacogenic zone
C21.8	Malignant neoplasm of overlapping sites of rectum, anus and anal canal
C22.0	Liver cell carcinoma
C22.1	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

ICD-10	ICD-10 Description
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C37	Malignant neoplasm of thymus
C38.4	Malignant neoplasm of pleura
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

ICD-10	ICD-10 Description
C43.0	Malignant melanoma of lip
C43.10	Malignant melanoma of unspecified eyelid, including canthus
C43.111	Malignant melanoma of right upper eyelid, including canthus
C43.112	Malignant melanoma of right lower eyelid, including canthus
C43.121	Malignant melanoma of left upper eyelid, including canthus
C43.122	Malignant melanoma of left lower eyelid, including canthus
C43.20	Malignant melanoma of unspecified ear and external auricular canal
C43.21	Malignant melanoma of right ear and external auricular canal
C43.22	Malignant melanoma of left ear and external auricular canal
C43.30	Malignant melanoma of unspecified part of face
C43.31	Malignant melanoma of nose
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

ICD-10	ICD-10 Description
C44.42	Squamous cell carcinoma of skin of scalp and neck
C44.520	Squamous cell carcinoma of anal skin
C44.521	Squamous cell carcinoma of skin of breast
C44.529	Squamous cell carcinoma of skin of other part of trunk
C44.621	Squamous cell carcinoma of skin of unspecified upper limb, including shoulder
C44.622	Squamous cell carcinoma of skin of right upper limb, including shoulder
C44.629	Squamous cell carcinoma of skin of left upper limb, including shoulder
C44.721	Squamous cell carcinoma of skin of unspecified lower limb, including hip
C44.722	Squamous cell carcinoma of skin of right lower limb, including hip
C44.729	Squamous cell carcinoma of skin of left lower limb, including hip
C44.82	Squamous cell carcinoma of overlapping sites of skin
C44.92	Squamous cell carcinoma of skin, unspecified
C45.0	Mesothelioma of pleura
C48.0	Malignant neoplasm of retroperitoneum
C48.1	Malignant neoplasm of specified parts of peritoneum
C48.2	Malignant neoplasm of peritoneum, unspecified
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum
C49.0	Malignant neoplasm of connective and soft tissue of head, face and neck
C49.10	Malignant neoplasm of connective and soft tissue of unspecified upper limb, including shoulder
C49.11	Malignant neoplasm of connective and soft tissue of right upper limb, including shoulder
C49.12	Malignant neoplasm of connective and soft tissue of left upper limb, including shoulder
C49.20	Malignant neoplasm of connective and soft tissue of unspecified lower limb, including hip
C49.21	Malignant neoplasm of connective and soft tissue of right lower limb, including hip
C49.22	Malignant neoplasm of connective and soft tissue of left lower limb, including hip
C49.3	Malignant neoplasm of connective and soft tissue of thorax
C49.4	Malignant neoplasm of connective and soft tissue of abdomen
C49.5	Malignant neoplasm of connective and soft tissue of pelvis
C49.6	Malignant neoplasm of connective and soft tissue of trunk, unspecified
C49.8	Malignant neoplasm of overlapping sites of connective and soft tissue
C49.9	Malignant neoplasm of connective and soft tissue, unspecified
C4A.0	Merkel cell carcinoma of lip
C4A.10	Merkel cell carcinoma of eyelid, including canthus
C4A.111	Merkel cell carcinoma of right upper eyelid, including canthus
C4A.112	Merkel cell carcinoma of right lower eyelid, including canthus
C4A.121	Merkel cell carcinoma of left upper eyelid, including canthus
C4A.122	Merkel cell carcinoma of left lower eyelid, including canthus
C4A.20	Merkel cell carcinoma of unspecified ear and external auricular canal
C4A.21	Merkel cell carcinoma of right ear and external auricular canal

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
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
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
C53.0	Malignant neoplasm of endocervix

ICD-10	ICD-10 Description
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
C56.9	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
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
C58	Malignant neoplasm of placenta
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

ICD-10	ICD-10 Description
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
C67.3	Malignant neoplasm of anterior wall of bladder
C67.4	Malignant neoplasm of posterior wall of bladder
C67.5	Malignant neoplasm of bladder neck
C67.6	Malignant neoplasm of ureteric orifice
C67.7	Malignant neoplasm of urachus
C67.8	Malignant neoplasm of overlapping sites of bladder
C67.9	Malignant neoplasm of bladder, unspecified
C68.0	Malignant neoplasm of urethra
C69.30	Malignant neoplasm of unspecified choroid
C69.31	Malignant neoplasm of right choroid
C69.32	Malignant neoplasm of left choroid
C69.40	Malignant neoplasm of unspecified ciliary body
C69.41	Malignant neoplasm of right ciliary body
C69.42	Malignant neoplasm of left ciliary body
C69.60	Malignant neoplasm of unspecified orbit
C69.61	Malignant neoplasm of right orbit
C69.62	Malignant neoplasm of left orbit
C73	Malignant neoplasm of thyroid gland
C74.00	Malignant neoplasm of cortex of unspecified adrenal gland

ICD-10	ICD-10 Description
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
C78.89	Secondary malignant neoplasm of other digestive organs
C79.31	Secondary malignant neoplasm of brain
C79.51	Secondary malignant neoplasm of bone
C79.52	Secondary malignant neoplasm of bone marrow
C7A.1	Malignant poorly differentiated neuroendocrine tumors
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

ICD-10	ICD-10 Description
C81.21	Mixed cellularity Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.22	Mixed cellularity Hodgkin lymphoma, intrathoracic lymph nodes
C81.23	Mixed cellularity Hodgkin lymphoma, intra-abdominal lymph nodes
C81.24	Mixed cellularity Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.25	Mixed cellularity Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.26	Mixed cellularity Hodgkin lymphoma, intrapelvic lymph nodes
C81.27	Mixed cellularity Hodgkin lymphoma, spleen
C81.28	Mixed cellularity Hodgkin lymphoma, lymph nodes of multiple sites
C81.29	Mixed cellularity Hodgkin lymphoma, extranodal and solid organ sites
C81.30	Lymphocyte depleted Hodgkin lymphoma, unspecified site
C81.31	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.32	Lymphocyte depleted Hodgkin lymphoma, intrathoracic lymph nodes
C81.33	Lymphocyte depleted Hodgkin lymphoma, intra-abdominal lymph nodes
C81.34	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.35	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.36	Lymphocyte depleted Hodgkin lymphoma, intrapelvic lymph nodes
C81.37	Lymphocyte depleted Hodgkin lymphoma, spleen
C81.38	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of multiple sites
C81.39	Lymphocyte depleted Hodgkin lymphoma, extranodal and solid organ sites
C81.40	Lymphocyte-rich Hodgkin lymphoma, unspecified site
C81.41	Lymphocyte-rich Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.42	Lymphocyte-rich Hodgkin lymphoma, intrathoracic lymph nodes
C81.43	Lymphocyte-rich Hodgkin lymphoma, intra-abdominal lymph nodes
C81.44	Lymphocyte-rich Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.45	Lymphocyte-rich Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.46	Lymphocyte-rich Hodgkin lymphoma, intrapelvic lymph nodes
C81.47	Lymphocyte-rich Hodgkin lymphoma, spleen
C81.48	Lymphocyte-rich Hodgkin lymphoma, lymph nodes of multiple sites
C81.49	Lymphocyte-rich Hodgkin lymphoma, extranodal and solid organ sites
C81.70	Other Hodgkin lymphoma unspecified site
C81.71	Other Hodgkin lymphoma lymph nodes of head, face, and neck
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

ICD-10	ICD-10 Description
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
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
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
C84.90	Mature T/NK-cell lymphomas, unspecified site
C84.91	Mature T/NK-cell lymphomas, lymph nodes of head, face, and neck
C84.92	Mature T/NK-cell lymphomas, intrathoracic lymph nodes
C84.93	Mature T/NK-cell lymphomas, intra-abdominal lymph nodes
C84.94	Mature T/NK-cell lymphomas, lymph nodes of axilla and upper limb
C84.95	Mature T/NK-cell lymphomas, lymph nodes of inguinal region and lower limb
C84.96	Mature T/NK-cell lymphomas, intrapelvic lymph nodes

ICD-10	ICD-10 Description
C84.97	Mature T/NK-cell lymphomas, spleen
C84.98	Mature T/NK-cell lymphomas, lymph nodes of multiple sites
C84.99	Mature T/NK-cell lymphomas, extranodal and solid organ sites
C84.Z0	Other mature T/NK-cell lymphomas, Unspecified site
C84.Z1	Other mature T/NK-cell lymphomas, lymph nodes of head, face, and neck
C84.Z2	Other mature T/NK-cell lymphomas, intrathoracic lymph nodes
C84.Z3	Other mature T/NK-cell lymphomas, intra-abdominal lymph nodes
C84.Z4	Other mature T/NK-cell lymphomas, lymph nodes of axilla and upper limb
C84.Z5	Other mature T/NK-cell lymphomas, lymph nodes of inguinal region and lower limb
C84.Z6	Other mature T/NK-cell lymphomas, intrapelvic lymph nodes
C84.Z7	Other mature T/NK-cell lymphomas, spleen
C84.Z8	Other mature T/NK-cell lymphomas, lymph nodes of multiple sites
C84.Z9	Other mature T/NK-cell lymphomas, extranodal and solid organ sites
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
C86.0	Other specified types of T/NK-cell lymphoma
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
D38.5	Neoplasm of uncertain behavior of other respiratory organs
D38.6	Neoplasm of uncertain behavior of respiratory organ, unspecified
D39.2	Neoplasm of uncertain behavior of placenta
Z85.00	Personal history of malignant neoplasm of unspecified digestive organ

ICD-10	ICD-10 Description
Z85.01	Personal history of malignant neoplasm of esophagus
Z85.028	Personal history of other malignant neoplasm of stomach
Z85.038	Personal history of other malignant neoplasm of large intestine
Z85.068	Personal history of other malignant neoplasm of small intestine
Z85.07	Personal history of malignant neoplasm of pancreas
Z85.118	Personal history of other malignant neoplasm of bronchus and lung
Z85.21	Personal history of malignant neoplasm of larynx
Z85.22	Personal history of malignant neoplasm of nasal cavities, middle ear, and accessory sinuses
Z85.3	Personal history of malignant neoplasm of breast
Z85.43	Personal history of malignant neoplasm of ovary
Z85.47	Personal history of malignant neoplasm of testis
Z85.49	Personal history of malignant neoplasm of other male genital organs
Z85.51	Personal history of malignant neoplasm of bladder
Z85.59	Personal history of malignant neoplasm of other urinary tract organ
Z85.71	Personal history of Hodgkin Lymphoma
Z85.810	Personal history of malignant neoplasm of tongue
Z85.818	Personal history of malignant neoplasm of other sites of lip, oral cavity and pharynx
Z85.819	Personal history of malignant neoplasm of unspecified site of lip, oral cavity and pharynx
Z85.820	Personal history of malignant melanoma of skin
Z85.821	Personal history of Merkel cell carcinoma
Z85.828	Personal history of other malignant neoplasm of skin
Z85.830	Personal history of malignant neoplasm of bone
Z85.831	Personal history of malignant neoplasm of soft tissue
Z85.858	Personal history of malignant neoplasm of other endocrine glands

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

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

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

Jurisdiction(s): J&M	NCD/LCD/Article Document (s): A56141
https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A56141&bc=gAAAAAAAAAAAA	

Medicare Part B Administrative Contractor (MAC) Jurisdictions

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