Keytruda® (pembrolizumab)
(Intravenous)

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I. Length of Authorization Δ 1-3,5,15-17,69,85-87

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

- Adrenal Gland Tumors, Anal Carcinoma, Bladder Cancer/Urothelial Carcinoma, Cervical Cancer, cHL, CNS Cancer, Cutaneous Melanoma (in combination with ipilimumab, lenvatinib, OR trametinib and dabrafenib), cSCC, Endometrial Carcinoma, Esophageal/GEJ Cancer, Gastric Cancer, HCC, MCC, MSI-H/dMMR Cancer, NSCLC (first-line or subsequent therapy), PMBCL, Primary Cutaneous Lymphomas, RCC (first-line or subsequent therapy), SCCHN, SCLC, Thymic Carcinoma, TMB-H Cancer, TNBC (recurrent unresectable or metastatic disease), Uveal Melanoma, and Vulvar Cancer can be authorized up to a maximum of twenty-four (24) months of therapy.
- Kaposi Sarcoma may not be renewed.
- Adjuvant therapy in Cutaneous Melanoma, NSCLC, and RCC 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.

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)
Adrenal Gland Tumors, Bladder/Urothelial, Cervical, cHL, Pediatric CNS Cancers, cSCC, Cutaneous Melanoma, Endometrial Carcinoma, Esophageal, GEJ, Gastric, Gestational Trophoblastic Neoplasia, HCC, Kaposi Sarcoma, MCC, MSI-H/dMMR, NSCLC, PMBCL, RCC, SCCHN, Soft Tissue Sarcoma, Thymic, TMB-H Cancer, TNBC, & Vulvar	200 BU	21 days
Adult CNS Cancer & SCLC	1150 BU	14 days
Anal Carcinoma, Primary Cutaneous Lymphomas, Extranodal NK/T-Cell Lymphomas, & Uveal Melanoma	250 BU	21 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 (e.g., cemiplimab, avelumab, nivolumab, atezolizumab, durvalumab, dostarlimab, nivolumab/relatlimab-rmbw, etc.) unless otherwise specified [Δ]; **AND**

Anal Carcinoma ‡ [2,5,52]

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

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

- Used as 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; **OR**
- Used in combination with brentuximab vedotin; **AND**
  - Patient is at least 6 months to 39 years of age*****; **AND**
  - Used as consolidation/additional therapy in patients who achieve a partial response after therapy for relapsed or refractory disease

****** *Pediatric Primary Mediastinal Large B-Cell Lymphoma may be applicable to adolescent and young adult (AYA) patients up to the age of 39 years.*

Urothelial Carcinoma (Bladder Cancer) † ‡ [1,2,8,10,35-37]

- 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
    - Metastatic or local bladder cancer recurrence post-cystectomy
    - 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; **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: [10,18,71,79] – *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, PS ≥ 2, hearing loss of ≥ 25 decibels (dB) at two contiguous frequencies, grade ≥ 2 peripheral neuropathy, or NYHA class ≥ 3. Carboplatin may be substituted for cisplatin particularly in those patients with a CrCl <60 mL/min or a PS of 2.* ▪ *Platinum-ineligible comorbidities may include the following: CrCl < 30 mL/min, PS ≥ 3, grade ≥ 2 peripheral neuropathy, or NYHA 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]

- Patient has recurrent unresectable or metastatic disease OR inflammatory breast cancer with no response to preoperative systemic therapy; **AND**
  - Used in combination with chemotherapy; **AND**
  - Tumor expresses PD-L1 (combined positive score [CPS] ≥10) as determined by an FDA-approved or CLIA-compliant test❖; **OR**
- Patient has high-risk early-stage disease; **AND**
  - Used as neoadjuvant therapy in combination with chemotherapy; **OR**
  - Used as adjuvant therapy as a single agent following use as neoadjuvant therapy in combination with chemotherapy

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 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 ‡ [2,81]

- Patient is ≤ 18 years of age; **AND**
- Patient has hypermutated 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]

- Tumor expresses PD-L1 (CPS ≥1) as determined by an FDA-approved or CLIA-compliant test❖; **AND**
  - Used as a single agent; **AND**
    - Used as subsequent therapy for recurrent or metastatic disease; **OR**
  - Used in combination with chemotherapy, with or without bevacizumab; **AND**
    - Patient has persistent, recurrent, or metastatic disease

Esophageal or Gastroesophageal Junction Cancer † ‡ Φ [1,2,39-41,66,67]

- Patient is not a surgical candidate or has unresectable locally advanced, recurrent, or metastatic disease; **AND**
  - Used in combination with platinum- and fluoropyrimidine-based chemotherapy †; **AND**
    - Used as first-line therapy; **OR**
  - Used in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy †; **AND**
    - Used as first-line therapy for HER2-positive disease; **AND**
    - Patient has adenocarcinoma; **OR**
  - 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**
      - Patient progressed after one or more prior lines of systemic therapy

Gastric Cancer † ‡ Φ [1,2,39,67]

- Patient is not a surgical candidate or has unresectable locally advanced, recurrent, or metastatic disease; **AND**
- Patient has adenocarcinoma; **AND**
- Used in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy; **AND**
- Used as first-line therapy for HER2-positive disease

Gestational Trophoblastic Neoplasia ‡ [2,12,55]

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

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

- Patient has Cancer of the Nasopharynx; **AND**
  - Used in combination with cisplatin and gemcitabine; **AND**
  - Used for oligometastatic or metastatic disease; **OR**
- Patient has Very Advanced Head and Neck Cancer*; **AND**
  - Patient has nasopharyngeal cancer; **AND**
    - Patient has a performance status 0-1; **AND**
    - Used in combination with cisplatin and gemcitabine; **AND**
    - Used for one of the following:
      - Unresectable locoregional recurrence with prior radiation therapy (RT)
      - Unresectable second primary with prior RT
      - Unresectable persistent disease with prior RT
      - Recurrent/persistent disease with distant metastases; **OR**
  - Patient has NON-nasopharyngeal cancer; **AND**
    - Patient is unfit for surgery or has locally advanced disease; **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❖; **OR**

- Used as subsequent therapy for disease that has progressed on or after platinum-containing chemotherapy; **OR**

➢ Used in combination with fluorouracil and a platinum chemotherapy agent OR in combination with docetaxel and either carboplatin or cisplatin; **AND**

- Patient has a performance status 0-1

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

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

- Used as a single agent; **AND**
- Patient was previously treated with sorafenib; **AND**
- Patient has Child-Pugh Class A liver impairment *(i.e., excluding Child-Pugh Class B and C)*

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

- Patient has relapsed or refractory disease; **AND**
  - Used as a single agent; **OR**
  - Used in combination with GVD (gemcitabine, vinorelbine, liposomal doxorubicin); **OR**
- Used as a palliative therapy in patients > 60 years of age; **AND**
  - Patient has relapsed or progressive disease after high-dose therapy (HDT)/autologous stem cell transplantation (ASCT); **OR**
  - Patient has relapsed or refractory disease and is transplant-ineligible based on comorbidities or failure of second-line chemotherapy; **OR**
  - Patient is post-allogeneic transplant

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]

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

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

- 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 subsequent therapy for relapsed or stage IV disease [Δ]; **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 a metastasectomy within one year of having undergone a nephrectomy for relapsed or stage IV disease; **OR**
- Patient has non-clear cell histology; **AND**
  - Used as a single agent for relapsed or stage IV disease ‡

Cutaneous Melanoma † ‡ Φ [1,2,22-24]

- Used as first-line therapy as a single agent for unresectable or metastatic* disease; **OR**
- Used as initial treatment of limited resectable disease; **AND**
  - Used as a single agent; **AND**
    - Patient has stage III disease with clinical satellite/in-transit metastases; **OR**
    - Patient has local satellite/in-transit recurrence; **OR**
- Used as subsequent therapy; **AND**
  - Used for metastatic or unresectable disease with 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; **OR**
  - Used for metastatic or unresectable disease with disease progression or intolerance if BRAF/MEK and/or PD(L)-1 checkpoint inhibition not previously used; **AND**
    - Used in combination with trametinib and dabrafenib; **OR**

- Used for disease progression or relapse following treatment with BRAF/MEK + PD(L)-1 checkpoint inhibitor therapy; **AND**
  - Used in combination with trametinib and dabrafenib; **AND**
  - Used 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 combination BRAF/MEK + PD(L)-1 checkpoint inhibitor therapy, but subsequently have disease progression/relapse > 3 months after treatment discontinuation; **OR**
- Used for metastatic* or unresectable disease with progression or relapse following treatment with anti-PD-1 therapy; **AND**
  - Used as a single agent; **AND**
  - Used 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 anti-PD-1 therapy, but subsequently have disease progression/relapse > 3 months after treatment discontinuation; **OR**
- Used for metastatic* or unresectable disease with progression, intolerance, and/or projected risk of progression with BRAF targeted therapy (e.g., dabrafenib/trametinib, vemurafenib/cobimetinib, encorafenib/binimetinib, etc.); **AND**
  - Used as a single agent; **AND**
    - Anti-PD-1 therapy was not previously used; **OR**
    - Used 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 anti-PD-1 therapy, but subsequently have disease progression/relapse > 3 months after treatment discontinuation; **OR**
  - Used in combination with ipilimumab; **AND**
    - Used after progression on single-agent anti-PD-1 therapy and combination ipilimumab/anti-PD-1 therapy was not previously used; **OR**
    - Used 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 combination ipilimumab/anti-PD-1 therapy, but subsequently have disease progression/relapse > 3 months after treatment discontinuation; **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 sentinel node positive disease either during observation without additional nodal surgery and with mandatory radiographic nodal 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 following neoadjuvant therapy; **OR**
        - Patient has clinical satellite/in-transit metastases and has no evidence of disease (NED) after complete excision; **OR**
    - Patient has local satellite/in-transit recurrence and has NED after complete excision; **OR**
    - Patient has resectable disease limited to nodal recurrence following excision and complete TLND OR following neoadjuvant therapy; **OR**
    - Patient has oligometastatic disease and NED after receiving metastasis-directed therapy (e.g., 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*

Uveal Melanoma ‡ [2,53,54]

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

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

- Patient is at least 6 months 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 †

Adrenal Gland Tumors ‡ [2]

- Patient has locoregional unresectable or metastatic adrenocortical carcinoma (ACC); **AND**
- Used with or without mitotane

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

- 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 adjuvant therapy as a single agent; **AND**
  - Patient has stage IB (T2a ≥4 cm), II, or IIIA disease †; **AND**
    - Used following resection and platinum-based chemotherapy; **OR**
  - Patient has completely resected stage IIIB (T3, N2) disease; **AND**
    - Disease is negative for EGFR exon 19 deletion or exon 21 L858R mutations, or ALK rearrangements; **AND**
    - Patient previously received adjuvant chemotherapy; **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 ≥1%) tumors, as detected by an FDA-approved or CLIA compliant test❖, that are negative for actionable molecular biomarkers*****
      - Patients with performance status (PS) 0-1 who have tumors that are negative for actionable molecular biomarkers***** and PD-L1 expression <1%
      - Patients with PS 0-1 who are positive for one of the following molecular mutations: EGFR exon 20, KRAS G12C, BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, RET rearrangement, or ERBB2 (HER2); **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 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 are positive for one of the following molecular mutations and have received prior targeted therapy§: EGFR exon 19 deletion or L858R tumors, EGFR S768I, L861Q and/or G719X -positive tumors, ALK rearrangement, or ROS1 rearrangement

- Patients with PS 0-1 who are positive for one of the following molecular mutations: BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, or RET rearrangement; **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 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 exon 14 skipping mutation, RET rearrangement, and ERBB2 (HER2). If there is insufficient issue to allow testing for all of EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, RET, and ERBB2 (HER2), 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.*

Primary Cutaneous Lymphomas ‡ [2,15]

- Used as a single agent; **AND**
  - Patient has Mycosis Fungoides/Sezary Syndrome; **AND**
    - Used as primary therapy OR as subsequent therapy for relapsed or persistent disease; **AND**
      - Patient has stage IIB Mycosis Fungoides with generalized tumor lesions *(for primary therapy ONLY)*; **OR**
      - Patient has stage III Mycosis Fungoides; **OR**
      - Patient has stage IV Sezary Syndrome; **OR**
      - Patient has generalized cutaneous or extracutaneous lesions with large cell transformation (LCT); **OR**
    - Used as subsequent therapy for disease refractory to multiple previous therapies *(excluding use in patients with stage IA Mycosis Fungoides)*; **OR**
  - Patient has primary cutaneous CD30+ T-Cell lymphoproliferative disorders; **AND**
    - Used for relapsed or refractory disease; **AND**
    - Used for primary cutaneous anaplastic large cell lymphoma (ALCL) with multifocal lesions, or cutaneous ALCL with regional node (N1) (excludes systemic ALCL)

Small Cell Lung Cancer (SCLC) ‡ Φ [2]

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

Soft Tissue Sarcoma ‡ [2]

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

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

- Used as a single agent; **AND**
  - Patient has locally advanced, recurrent, or metastatic disease that is not curable by surgery or radiation †; **OR**
  - Patient has unresectable, inoperable, or incompletely resected regional disease OR new regional disease that is not curable by radiation therapy ‡

Extranodal NK/T-Cell Lymphomas ‡ [2,48]

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

Thymic Carcinoma ‡ [2,16,17]

- Used as a single agent; **AND**
  - Used as first-line therapy for unresectable, locally advanced, or metastatic disease in patients who are unable to tolerate first-line combination regimens; **OR**
  - Used as postoperative treatment in patients who are unable to tolerate first-line combination regimens; **OR**
  - Used as second-line therapy for unresectable or metastatic disease

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

- Patient has advanced, recurrent, or metastatic disease that is mismatch repair proficient (pMMR) as determined by an FDA-approved or CLIA-compliant test❖ or NOT microsatellite instability-high (MSI-H); **AND**

- Used as first-line or subsequent therapy *(excluding use as first-line therapy in patients with isolated metastases)*; **AND**
- Used in combination with lenvatinib

Vulvar Cancer ‡ [2]

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

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

- Patient is at least 6 months of age; **AND**
- Used as a single agent; **AND**
- Patient has microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) disease as determined by an FDA-approved or CLIA compliant test❖; **AND**
- Pediatric patients must not have a diagnosis of MSI-H central nervous system cancer; **AND**
- Patient has, but is not limited to*, one of the following cancers:
  - Colorectal Cancer † ‡
    - Used for unresectable or medically inoperable, advanced, or metastatic disease *(Note: neoadjuvant therapy is allowed for resectable liver and/or lung metastases OR for clinical T4b colon cancer only)*
  - Appendiceal Adenocarcinoma – Colon Cancer ‡
    - Used as initial therapy for advanced or metastatic disease; **OR**
    - Used as subsequent therapy for advanced or metastatic disease that progressed following previous oxaliplatin- irinotecan- and/or fluoropyrimidine-based therapy
  - Pancreatic Adenocarcinoma ‡
    - Used as subsequent therapy for locally advanced or metastatic disease after progression; **OR**
    - Used for recurrent or metastatic disease after resection; **OR**
    - Used as first-line therapy for metastatic disease; **OR**
    - Used as continuation (maintenance) therapy for metastatic disease if acceptable tolerance and no disease progression after at least 4-6 months of first-line therapy in patients with good performance status (i.e., ECOG PS 0-1)

- Bone Cancer (Ewing Sarcoma, Chordoma *[chondroid or conventional histology]*, 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 Cancer (Adenocarcinoma) OR Esophageal/Gastroesophageal Junction Adenocarcinoma or Squamous Cell Carcinoma ‡
  - Used as subsequent therapy for patients who are not surgical candidates or have unresectable locally advanced, recurrent, or metastatic disease
- Ovarian, Fallopian Tube, and Primary Peritoneal Cancer ‡
  - Patient has Grade 1 Endometrioid Carcinoma, Carcinosarcoma (Malignant Mixed Müllerian Tumors), Mucinous Carcinoma of the Ovary, Epithelial Ovarian/Fallopian Tube/Primary Peritoneal Cancer, or Clear Cell Carcinoma of the Ovary; **AND**
    - Used for persistent or recurrent disease; **AND**
    - Patient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 with no radiographic evidence of disease); **OR**
  - Patient has Low-Grade Serous Carcinoma; **AND**
    - Patient has recurrent disease
- Uterine Neoplasms (Endometrial Carcinoma) ‡
  - Used as first-line or subsequent therapy *(excluding use as first-line therapy in patients with isolated metastases)*; **AND**
  - Patient has advanced or recurrent disease
- Penile Cancer ‡
  - Used as subsequent therapy for 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 on or after prior systemic treatment
- Vulvar Cancer ‡
  - Patient has adenocarcinoma or squamous cell carcinoma; **AND**
  - Used as subsequent therapy for advanced, recurrent, or metastatic disease

- Cervical Cancer ‡
  - Used as subsequent therapy for recurrent or metastatic disease
- Small Bowel Adenocarcinoma ‡
  - Used for advanced or metastatic disease; **AND**
    - Used as initial therapy; **OR**
    - Used as subsequent therapy for patients with no prior oxaliplatin exposure in the adjuvant treatment setting and no contraindication to oxaliplatin therapy
- Ampullary Adenocarcinoma ‡
  - Used as subsequent therapy for disease progression; **OR**
  - Used as first-line therapy for unresectable localized or metastatic disease
- Breast Cancer ‡
  - Used for recurrent unresectable or metastatic disease OR inflammatory breast cancer with no response to preoperative systemic therapy; **AND**
  - Patient has progressed following prior treatment; **AND**
  - Patient has no satisfactory alternative treatment options; **AND**
    - Used as third-line therapy and beyond; **AND**
      - Patient has triple negative breast cancer (TNBC) Ψ OR hormone receptor positive and HER2-negative disease with visceral crisis or endocrine therapy refractory; **OR**
    - Used as fourth-line therapy and beyond; **AND**
      - Patient has HER2-positive disease
- Occult Primary/Cancer of Unknown Primary (CUP) ‡
  - Used in symptomatic patients with PS 1-2 OR asymptomatic patients with PS 0 and aggressive disease; **AND**
    - Patient has squamous cell carcinoma; **AND**
      - Patient has multiple lung nodules, pleural effusion, or disseminated metastases; **OR**
    - Patient has adenocarcinoma or carcinoma not otherwise specified; **AND**
      - Patient has one of the following:
        - Axillary involvement in those with a prostate or post-prostatectomy 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
- Head and Neck Cancers

- Very Advanced Squamous Cell Carcinoma of the Head and Neck ‡
  - Patient has non-nasopharyngeal cancer; **AND**
  - Patient is unfit for surgery or has locally advanced, unresectable, recurrent/persistent, or metastatic disease
- Salivary Gland Tumors ‡
  - Used for recurrent metastatic disease in patients with a PS 0-3; **OR**
  - Used for unresectable locoregional recurrence or second primary with prior radiation therapy

- Prostate Cancer ‡
  - Patient has castration-resistant metastatic disease; **AND**
  - Patient will continue androgen deprivation therapy (ADT); **AND**
  - Patient received prior docetaxel and prior novel hormone therapy *(excluding patients with visceral metastases)*
- Well-Differentiated Grade 3 Neuroendocrine Tumors ‡
  - Patient has progressed following prior treatment and has no satisfactory alternative treatment options; **AND**
    - Patient has locally advanced/metastatic disease with unfavorable biology (e.g., relative high Ki-67 [≥55%], rapid growth rate, negative SSTR-based PET imaging); **OR**
    - Patient has unresectable locally advanced/metastatic disease with favorable biology (e.g., relatively low Ki-67 [<55%], positive SSTR-based PET imaging); **AND**
      - Patient has clinically significant tumor burden or evidence of disease progression
- Neuroendocrine Tumors (Extrapulmonary Poorly Differentiated Neuroendocrine Carcinoma/Large or Small Cell Carcinoma/Mixed Neuroendocrine-Non-Neuroendocrine Neoplasm) ‡
  - Patient has locoregional unresectable or metastatic disease; **AND**
  - Patient progressed following prior treatment and has no satisfactory alternative treatment options

**Note: Solid tumors not listed, that are MSI-H or TMB-H, will be reviewed on a case-by-case basis and considered medically necessary when all other relevant medication and indication specific criteria are met.*

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

- Patient is at least 6 months of age; **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, but is not limited to*, one of the following cancers:
  - Bone Cancer (Ewing Sarcoma, Chordoma *[chondroid or conventional histology]*, Chondrosarcoma *[excluding dedifferentiated or mesenchymal subtypes]*, or Osteosarcoma *[excluding high-grade undifferentiated pleomorphic sarcoma]*) ‡
    - Patient has unresectable or metastatic disease that progressed following prior treatment; **AND**
    - Patient has no satisfactory alternative treatment options
  - Breast Cancer ‡
    - Patient has recurrent unresectable or metastatic disease OR inflammatory breast cancer with no response to preoperative systemic therapy; **AND**
    - Patient has progressed following prior treatment; **AND**
    - Patient has no satisfactory alternative treatment options; **AND**
      - Used as third-line therapy and beyond; **AND**
        - Patient has triple negative breast cancer (TNBC) Ψ OR hormone receptor positive and HER2-negative disease with visceral crisis or endocrine therapy refractory; **OR**
      - Used as fourth-line therapy and beyond; **AND**
        - Patient has HER2-positive disease
  - Cervical Cancer ‡
    - Used as subsequent therapy for unresectable or metastatic disease; **AND**
    - Patient has progressed following prior treatment; **AND**
    - Patient has no satisfactory alternative treatment options
  - Gastric Cancer (Adenocarcinoma) OR Esophageal/Gastroesophageal Junction Adenocarcinoma or Squamous Cell Carcinoma ‡
    - Used as subsequent therapy for patients who are not surgical candidates or have unresectable locally advanced, recurrent, or metastatic disease
  - Hepatobiliary Adenocarcinoma (Gallbladder Cancer, Intra-/Extra-hepatic Cholangiocarcinoma) ‡
    - Used for unresectable or metastatic disease that has progressed on or after prior systemic treatment
  - Head and Neck Cancers
    - Very Advanced Squamous Cell Carcinoma of the Head and Neck ‡
      - Patient has non-nasopharyngeal cancer; **AND**
      - Patient is unfit for surgery or has locally advanced, unresectable, recurrent/persistent, or metastatic disease
    - Salivary Gland Tumors ‡

- Used for recurrent metastatic disease in patients with a PS 0-3; **OR**
- Used for unresectable locoregional recurrence or second primary with prior radiation therapy

- Cancer of the Nasopharynx ‡
  - Used as subsequent therapy for oligometastatic or metastatic disease

- Thyroid Carcinoma ‡
  - Anaplastic Carcinoma
    - Used as first- or second-line therapy for metastatic disease
  - Follicular Carcinoma, Papillary Carcinoma, Hürthle Cell Carcinoma
    - Patient has progressive and/or symptomatic unresectable locoregional recurrent/persistent or metastatic disease not amenable to radioactive iodine (RAI) therapy
  - Medullary Carcinoma
    - Patient has unresectable locoregional or recurrent/persistent metastatic disease that is either symptomatic or progressing
- Uterine Neoplasms ‡
  - Uterine Sarcoma *(excluding perivascular epithelioid cell tumor [PEComa])*
    - Used as second-line therapy for unresectable or metastatic disease that progressed following prior treatment; **AND**
    - Patient has no satisfactory alternative treatment options
  - Endometrial Carcinoma
    - Used as first-line or subsequent therapy for unresectable or metastatic disease *(excluding use as first-line therapy in patients with isolated metastases)*; **AND**
    - Patient has no satisfactory alternative treatment options
- Vulvar Cancer ‡
  - Patient has adenocarcinoma or squamous cell carcinoma; **AND**
  - Used as subsequent therapy for advanced, recurrent, or metastatic disease that progressed following prior treatment; **AND**
  - Patient has no satisfactory alternative treatment options
- Testicular Cancer ‡
  - Used as third-line therapy
- Occult Primary/Cancer of Unknown Primary (CUP) ‡
  - Used in symptomatic patients with PS 1-2 OR asymptomatic patients with PS 0 and aggressive disease; **AND**
    - Patient has squamous cell carcinoma; **AND**
      - Patient has multiple lung nodules, pleural effusion, or disseminated metastases; **OR**

- Patient has adenocarcinoma or carcinoma not otherwise specified; **AND**
  - Patient has one of the following:
    - Axillary involvement in those with a prostate or post-prostatectomy 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

- Ovarian, Fallopian Tube, and Primary Peritoneal Cancers ‡
  - Patient has Grade 1 Endometrioid Carcinoma, Carcinosarcoma (Malignant Mixed Müllerian Tumors), Mucinous Carcinoma of the Ovary, Epithelial Ovarian/Fallopian Tube/Primary Peritoneal cancer, or Clear Cell Carcinoma of the Ovary; **AND**
    - Used for persistent or recurrent disease; **AND**
    - Patient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 with no radiographic evidence of disease); **OR**
  - Patient has Low-Grade Serous Carcinoma; **AND**
    - Patient has recurrent disease
- Penile Cancer ‡
  - Used as subsequent therapy for unresectable or metastatic disease that has progressed on previously approved lines of therapy
- Prostate Cancer ‡
  - Patient has castration-resistant metastatic disease; **AND**
  - Patient will continue androgen deprivation therapy (ADT); **AND**
  - Patient received prior docetaxel and prior novel hormone therapy *(excluding patients with visceral metastases)*
- Well-Differentiated Grade 3 Neuroendocrine Tumors ‡
  - Patient has progressed following prior treatment and has no satisfactory alternative treatment options; **AND**
    - Patient has locally advanced/metastatic disease with unfavorable biology (e.g., relative high Ki-67 [≥55%], rapid growth rate, negative SSTR-based PET imaging); **OR**
    - Patient has unresectable locally advanced/metastatic disease with favorable biology (e.g., relatively low Ki-67 [<55%], positive SSTR-based PET imaging); **AND**
      - Patient clinically significant tumor burden or evidence of disease progression

- Neuroendocrine Tumors (Extrapulmonary Poorly Differentiated Neuroendocrine Carcinoma/Large or Small Cell Carcinoma/Mixed Neuroendocrine-Non-Neuroendocrine Neoplasm) ‡
  - Patient has locoregional unresectable or metastatic disease; **AND**
  - Patient progressed following prior treatment and has no satisfactory alternative treatment options
- Ampullary Adenocarcinoma ‡
  - Used as subsequent therapy for disease progression; **OR**
  - Used as first-line therapy for unresectable localized or metastatic disease
- Pancreatic Adenocarcinoma ‡
  - Used as subsequent therapy for locally advanced or metastatic disease after progression; **OR**
  - Used for recurrent or metastatic disease after resection; **OR**
  - Used as first-line therapy for metastatic disease; **OR**
  - Used as continuation (maintenance) therapy for metastatic disease if acceptable tolerance and disease no progression after at least 4-6 months of first-line therapy in patients with good performance status (i.e., ECOG PS 0-1)
- Soft Tissue Sarcoma ‡
  - Patient has myxofibrosarcoma, undifferentiated pleomorphic sarcoma (UPS), cutaneous angiosarcoma, or undifferentiated sarcoma; **AND**
  - Patient progressed following prior treatment and has no satisfactory alternative treatment options; **AND**
    - Used as subsequent therapy for advanced or metastatic Extremity/Body Wall, Head/Neck disease; **OR**
    - Used as subsequent therapy for recurrent unresectable or recurrent stage IV Retroperitoneal/Intra-Abdominal disease

**Note: Solid tumors not listed, that are MSI-H or TMB-H, will be reviewed on a case-by-case basis and considered medically necessary when all other relevant medication and indication specific criteria are met.*

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

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

Ψ ER Scoring Interpretation *(following ER testing by validated IHC assay)*	
Results	**Interpretation**
– 0% – <1% of nuclei stain	– ER-negative
– 1%–10% of nuclei stain	– ER-low–positive*
– >10% of nuclei stain	– ER-positive
**Note: Patients with cancers with ER-low–positive (1%–10%) results are a heterogeneous group with reported biologic behavior often similar to ER-negative cancers; thus, as such these cancers inherently*	

behave aggressively and may be treated similar to triple-negative disease. Individualized consideration of risks versus benefits should be incorporated into decision-making.

Genomic Aberration/Mutational Driver Targeted Therapies (Note: *not all inclusive, refer to guidelines for appropriate use*) §				
Sensitizing *EGFR* mutation-positive tumors	*ALK* rearrangement-positive tumors	*ROS1* rearrangement-positive tumors	*BRAF* V600E-mutation positive tumors	*NTRK1/2/3* gene fusion positive tumors
– Afatinib – Erlotinib – Dacomitinib – Gefitinib – Osimertinib – Amivantamab *(exon-20 insertion)* – Mobocertinib *(exon-20 insertion)*	– Alectinib – Brigatinib – Ceritinib – Crizotinib – Lorlatinib	– Ceritinib – Crizotinib – Entrectinib – Lorlatinib	– Dabrafenib ± trametinib – Vemurafenib	– Larotrectinib – Entrectinib
PD-L1 tumor expression ≥ 1%	*MET* exon-14 skipping mutations	*RET* rearrangement-positive tumors	*KRAS G12C* mutation positive tumors	*ERBB2 (HER2)* mutation positive tumors
– Pembrolizumab – Atezolizumab – Nivolumab + ipilimumab – Cemiplimab – Tremelimumab + durvalumab	– Capmatinib – Crizotinib – Tepotinib	– Selpercatinib – Cabozantinib – Pralsetinib	– Sotorasib – Adagrasib	– Fam-trastuzumab deruxtecan-nxki – Ado-trastuzumab emtansine

IV. Renewal Criteria Δ [1-3,5,15-17,69,85,86]

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**
- 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.; **AND**
- For the following indications, patient has not exceeded a maximum of twenty-four (24) months of therapy:
  - Adrenal Gland Tumors
  - Anal Carcinoma
  - Bladder Cancer/Urothelial Carcinoma
  - Cervical Cancer
  - Classical Hodgkin Lymphoma (cHL)

- CNS Cancer
- Cutaneous Melanoma (in combination with ipilimumab, lenvatinib, OR trametinib and dabrafenib only)
- Cutaneous Squamous Cell Carcinoma (cSCC)
- Endometrial Carcinoma
- Esophageal/Gastroesophageal Junction Cancer
- Gastric Cancer
- Hepatocellular Carcinoma (HCC)
- Merkel Cell Carcinoma (MCC)
- MSI-H/dMMR Cancer
- Non-Small Cell Lung Cancer (NSCLC) (first-line or subsequent therapy)
- Primary Cutaneous Lymphomas
- Primary Mediastinal Large B-Cell Lymphoma (PMBCL)
- Renal Cell Carcinoma (RCC) (first-line or subsequent therapy)
- Small Cell Lung Cancer (SCLC)
- Squamous Cell Carcinoma of the Head and Neck (SCCHN)
- Thymic Carcinoma
- Tumor Mutational Burden-High (TMB-H) Cancer
- Triple Negative Breast Cancer (recurrent unresectable or metastatic disease)
- Uveal Melanoma
- Vulvar Cancer

Kaposi Sarcoma

- Coverage may not be renewed

Cutaneous Melanoma (adjuvant treatment)

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

NSCLC (adjuvant treatment)

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

Renal Cell Carcinoma (adjuvant treatment)

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

Triple Negative Breast Cancer (neoadjuvant treatment)

- Patient has not exceeded a maximum of twenty-four (24) weeks of therapy

Triple Negative Breast Cancer (adjuvant treatment)

- Patient has not exceeded a maximum of twenty-seven (27) weeks of therapy

Cutaneous Melanoma (subsequent treatment after prior anti-PD-1 immunotherapy or BRAF/MEK + anti-PD-1 immunotherapy) ‡

- *Refer to Section III for criteria*

NSCLC (continuous maintenance treatment)

- *Refer to Section III for criteria*

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. *(Note: 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 [1-6,8,12,13,15-17,22-48,50-56,62,65,72,73,75-77,83,85-87]

Indication	Dose
Bladder Cancer/Urothelial Carcinoma, Cervical, cSCC, Endometrial Carcinoma *(excluding MSI-H/dMMR)*, Esophageal, GEJ, Gastric, HCC, & SCCHN	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 disease, disease progression, or unacceptable toxicity.*
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 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
RCC	First-line 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 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.*
Adrenal Gland Tumors, Thymic Carcinoma, & Vulvar Cancer	200 mg intravenously every 3 weeks up to a maximum of 24 months in patients without disease progression or unacceptable toxicity
Cutaneous Melanoma	Single agent therapy *(excluding adjuvant treatment):* 200 mg intravenously every 3 weeks or 400 mg every 6 weeks until disease progression or unacceptable toxicity In combination with ipilimumab, lenvatinib, OR trametinib and dabrafenib: 200 mg intravenously every 3 weeks up to a maximum of 24 months in patients without disease progression or unacceptable toxicity Adjuvant treatment: Adults: 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 Pediatrics: 2 mg/kg (up to 200 mg) intravenously every 21 days up to a maximum of 12 months in patients without disease recurrence or unacceptable toxicity
Uveal Melanoma	2 mg/kg intravenously every 3 weeks up to a maximum of 24 months in patients without disease progression or unacceptable toxicity
cHL, MCC, MSI-H/dMMR Cancer, PMBCL, & TMB-H Cancer	Adults*****: 200 mg intravenously every 3 weeks or 400 mg every 6 weeks Pediatrics*****: 2 mg/kg (up to 200 mg) intravenously every 21 days

	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 21 days for up to 24 months in patients without disease progression or unacceptable toxicity
Extranodal NK/T-Cell Lymphomas	2 mg/kg intravenously every 3 weeks
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
Gestational Trophoblastic Neoplasia	200 mg intravenously every 3 weeks or 400 mg intravenously every 6 weeks
Soft Tissue Sarcoma	200 mg intravenously every 3 weeks
Anal Carcinoma	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:

- Standard dose 200 mg IV every 3 weeks for patients > 50 kg
- Use 100 mg IV every 3 weeks for patients ≤ 50 kg

-OR-

- 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

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

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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C00.0	Malignant neoplasm of external upper lip
C00.1	Malignant neoplasm of external lower lip
C00.2	Malignant neoplasm of external lip, unspecified
C00.3	Malignant neoplasm of upper lip, inner aspect
C00.4	Malignant neoplasm of lower lip, inner aspect
C00.5	Malignant neoplasm of lip, unspecified, inner aspect
C00.6	Malignant neoplasm of commissure of lip, unspecified
C00.8	Malignant neoplasm of overlapping sites of lip
C00.9	Malignant neoplasm of lip, unspecified
C01	Malignant neoplasm of base of tongue
C02.0	Malignant neoplasm of dorsal surface of tongue
C02.1	Malignant neoplasm of border of tongue
C02.2	Malignant neoplasm of ventral surface of tongue
C02.3	Malignant neoplasm of anterior two-thirds of tongue, part unspecified
C02.4	Malignant neoplasm of lingual tonsil
C02.8	Malignant neoplasm of overlapping sites of tongue
C02.9	Malignant neoplasm of tongue, unspecified
C03.0	Malignant neoplasm of upper gum
C03.1	Malignant neoplasm of lower gum
C03.9	Malignant neoplasm of gum, unspecified
C04.0	Malignant neoplasm of anterior floor of mouth
C04.1	Malignant neoplasm of lateral floor of mouth
C04.8	Malignant neoplasm of overlapping sites of floor of mouth
C04.9	Malignant neoplasm of floor of mouth, unspecified
C05.0	Malignant neoplasm of hard palate

ICD-10	ICD-10 Description
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
C11.0	Malignant neoplasm of superior wall of nasopharynx
C11.1	Malignant neoplasm of posterior wall of nasopharynx
C11.2	Malignant neoplasm of lateral wall of nasopharynx
C11.3	Malignant neoplasm of anterior wall of nasopharynx
C11.8	Malignant neoplasm of overlapping sites of nasopharynx
C11.9	Malignant neoplasm of nasopharynx, unspecified
C12	Malignant neoplasm of pyriform sinus
C13.0	Malignant neoplasm of postcricoid region
C13.1	Malignant neoplasm of aryepiglottic fold, hypopharyngeal aspect
C13.2	Malignant neoplasm of posterior wall of hypopharynx
C13.8	Malignant neoplasm of overlapping sites of hypopharynx
C13.9	Malignant neoplasm of hypopharynx, unspecified
C14.0	Malignant neoplasm of pharynx, unspecified
C14.2	Malignant neoplasm of Waldeyer's ring
C14.8	Malignant neoplasm of overlapping sites of lip, oral cavity and pharynx

ICD-10	ICD-10 Description
C15.3	Malignant neoplasm of upper third of esophagus
C15.4	Malignant neoplasm of middle third of esophagus
C15.5	Malignant neoplasm of lower third of esophagus
C15.8	Malignant neoplasm of overlapping sites of esophagus
C15.9	Malignant neoplasm of esophagus, unspecified
C16.0	Malignant neoplasm of cardia
C16.1	Malignant neoplasm of fundus of stomach
C16.2	Malignant neoplasm of body of stomach
C16.3	Malignant neoplasm of pyloric antrum
C16.4	Malignant neoplasm of pylorus
C16.5	Malignant neoplasm of lesser curvature of stomach, unspecified
C16.6	Malignant neoplasm of greater curvature of stomach, unspecified
C16.8	Malignant neoplasm of overlapping sites of stomach
C16.9	Malignant neoplasm of stomach, unspecified
C17.0	Malignant neoplasm of duodenum
C17.1	Malignant neoplasm of jejunum
C17.2	Malignant neoplasm of ileum
C17.3	Meckel's diverticulum, malignant
C17.8	Malignant neoplasm of overlapping sites of small intestine
C17.9	Malignant neoplasm of small intestine, unspecified
C18.0	Malignant neoplasm of cecum
C18.1	Malignant neoplasm of appendix
C18.2	Malignant neoplasm of ascending colon
C18.3	Malignant neoplasm of hepatic flexure
C18.4	Malignant neoplasm of transverse colon
C18.5	Malignant neoplasm of splenic flexure
C18.6	Malignant neoplasm of descending colon
C18.7	Malignant neoplasm of sigmoid colon
C18.8	Malignant neoplasm of overlapping sites of colon
C18.9	Malignant neoplasm of colon, unspecified
C19	Malignant neoplasm of rectosigmoid junction
C20	Malignant neoplasm of rectum
C21.0	Malignant neoplasm of anus, unspecified
C21.1	Malignant neoplasm of anal canal
C21.2	Malignant neoplasm of cloacogenic zone
C21.8	Malignant neoplasm of overlapping sites of rectum, anus and anal canal
C22.0	Liver cell carcinoma
C22.1	Intrahepatic bile duct carcinoma

ICD-10	ICD-10 Description
C22.3	Angiosarcoma of liver
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
C30.0	Malignant neoplasm of nasal cavity
C31.0	Malignant neoplasm of maxillary sinus
C31.1	Malignant neoplasm of ethmoidal sinus
C32.0	Malignant neoplasm of glottis
C32.1	Malignant neoplasm of supraglottis
C32.2	Malignant neoplasm of subglottis
C32.3	Malignant neoplasm of laryngeal cartilage
C32.8	Malignant neoplasm of overlapping sites of larynx
C32.9	Malignant neoplasm of larynx, unspecified
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
C43.39	Malignant melanoma of other parts of face
C43.4	Malignant melanoma of scalp and neck
C43.51	Malignant melanoma of anal skin
C43.52	Malignant melanoma of skin of breast
C43.59	Malignant melanoma of other part of trunk
C43.60	Malignant melanoma of unspecified upper limb, including shoulder
C43.61	Malignant melanoma of right upper limb, including shoulder
C43.62	Malignant melanoma of left upper limb, including shoulder
C43.70	Malignant melanoma of unspecified lower limb, including hip
C43.71	Malignant melanoma of right lower limb, including hip
C43.72	Malignant melanoma of left lower limb, including hip
C43.8	Malignant melanoma of overlapping sites of skin
C43.9	Malignant melanoma of skin, unspecified
C44.00	Unspecified malignant neoplasm of skin of lip
C44.02	Squamous cell carcinoma of skin of lip
C44.09	Other specified malignant neoplasm of skin of lip
C44.121	Squamous cell carcinoma of skin of unspecified eyelid, including canthus
C44.1221	Squamous cell carcinoma of skin of right upper eyelid, including canthus
C44.1222	Squamous cell carcinoma of skin of right lower eyelid, including canthus
C44.1291	Squamous cell carcinoma of skin of left upper eyelid, including canthus
C44.1292	Squamous cell carcinoma of skin of left lower eyelid, including canthus
C44.221	Squamous cell carcinoma of skin of unspecified ear and external auricular canal
C44.222	Squamous cell carcinoma of skin of right ear and external auricular canal
C44.229	Squamous cell carcinoma of skin of left ear and external auricular canal
C44.320	Squamous cell carcinoma of skin of unspecified parts of face
C44.321	Squamous cell carcinoma of skin of nose
C44.329	Squamous cell carcinoma of skin of other parts of face
C44.42	Squamous cell carcinoma of skin of scalp and neck
C44.520	Squamous cell carcinoma of anal skin
C44.521	Squamous cell carcinoma of skin of breast
C44.529	Squamous cell carcinoma of skin of other part of trunk
C44.621	Squamous cell carcinoma of skin of unspecified upper limb, including shoulder
C44.622	Squamous cell carcinoma of skin of right upper limb, including shoulder
C44.629	Squamous cell carcinoma of skin of left upper limb, including shoulder
C44.721	Squamous cell carcinoma of skin of unspecified lower limb, including hip
C44.722	Squamous cell carcinoma of skin of right lower limb, including hip
C44.729	Squamous cell carcinoma of skin of left lower limb, including hip
C44.82	Squamous cell carcinoma of overlapping sites of skin

ICD-10	ICD-10 Description
C44.92	Squamous cell carcinoma of skin, unspecified
C46.0	Kaposi's sarcoma of skin
C46.1	Kaposi's sarcoma of soft tissue
C46.2	Kaposi's sarcoma of palate
C46.3	Kaposi's sarcoma of lymph nodes
C46.4	Kaposi's sarcoma of gastrointestinal sites
C46.50	Kaposi's sarcoma of unspecified lung
C46.51	Kaposi's sarcoma of right lung
C46.52	Kaposi's sarcoma of left lung
C46.7	Kaposi's sarcoma of other sites
C46.9	Kaposi's sarcoma, unspecified
C47.0	Malignant neoplasm of peripheral nerves of head, face and neck
C47.10	Malignant neoplasm of peripheral nerves of unspecified upper limb, including shoulder
C47.11	Malignant neoplasm of peripheral nerves of right upper limb, including shoulder
C47.12	Malignant neoplasm of peripheral nerves of left upper limb, including shoulder
C47.20	Malignant neoplasm of peripheral nerves of unspecified lower limb, including hip
C47.21	Malignant neoplasm of peripheral nerves of right lower limb, including hip
C47.22	Malignant neoplasm of peripheral nerves of left lower limb, including hip
C47.3	Malignant neoplasm of peripheral nerves of thorax
C47.4	Malignant neoplasm of peripheral nerves of abdomen
C47.5	Malignant neoplasm of peripheral nerves of pelvis
C47.6	Malignant neoplasm of peripheral nerves of trunk, unspecified
C47.8	Malignant neoplasm of overlapping sites of peripheral nerves and autonomic nervous system
C47.9	Malignant neoplasm of peripheral nerves and autonomic nervous system, unspecified
C48.0	Malignant neoplasm of retroperitoneum
C48.1	Malignant neoplasm of specified parts of peritoneum
C48.2	Malignant neoplasm of peritoneum, unspecified
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum
C49.0	Malignant neoplasm of connective and soft tissue of head, face and neck
C49.10	Malignant neoplasm of connective and soft tissue of unspecified upper limb, including shoulder
C49.11	Malignant neoplasm of connective and soft tissue of right upper limb, including shoulder
C49.12	Malignant neoplasm of connective and soft tissue of left upper limb, including shoulder
C49.20	Malignant neoplasm of connective and soft tissue of unspecified lower limb, including hip
C49.21	Malignant neoplasm of connective and soft tissue of right lower limb, including hip
C49.22	Malignant neoplasm of connective and soft tissue of left lower limb, including hip
C49.3	Malignant neoplasm of connective and soft tissue of thorax
C49.4	Malignant neoplasm of connective and soft tissue of abdomen
C49.5	Malignant neoplasm of connective and soft tissue of pelvis

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
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
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
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

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
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
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
C73	Malignant neoplasm of thyroid gland
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

ICD-10	ICD-10 Description
C79.51	Secondary malignant neoplasm of bone
C79.52	Secondary malignant neoplasm of bone marrow
C79.70	Secondary malignant neoplasm of unspecified adrenal gland
C79.71	Secondary malignant neoplasm of right adrenal gland
C79.72	Secondary malignant neoplasm of left adrenal gland
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
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

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
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
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
C84.97	Mature T/NK-cell lymphomas, spleen

ICD-10	ICD-10 Description
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
C86.6	Primary cutaneous CD30-positive T-cell proliferations
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
D39.2	Neoplasm of uncertain behavior of placenta

ICD-10	ICD-10 Description
O01.9	Hydatidiform mole, unspecified
Z85.00	Personal history of malignant neoplasm of unspecified digestive organ
Z85.01	Personal history of malignant neoplasm of esophagus
Z85.028	Personal history of other malignant neoplasm of stomach
Z85.038	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
Z85.09	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
Z85.43	Personal history of malignant neoplasm of ovary
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
Z85.821	Personal history of Merkel cell carcinoma
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
Z85.858	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: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered at the discretion of the health plan.

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

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

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