



## Keytruda® (pembrolizumab) (Intravenous)

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### I. Length of Authorization <sup>Δ</sup> 1-3,5,6,15-17,50,51,53,57,62,65,68,69,72,73,75-77,82,85-87

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 <sup>1,2</sup>

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 <sup>Δ</sup>; **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 older than 18 years of age and less than 39 years of age, who are treated in the pediatric oncology setting.*

## **Urothelial Carcinoma (Bladder Cancer) † ‡ 1,2,8,10,35-37,88**

- Used in combination with enfortumab vedotin †; **AND**
  - Patient has locally advanced or metastatic urothelial carcinoma; **AND**
  - Used for previously untreated disease in patients ineligible for cisplatin-containing chemotherapy\*; **OR**
- Used as a single agent; **AND**
  - Patient has Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) defined as one of the following:
    - Persistent disease despite adequate BCG therapy\*\*
    - Disease recurrence after an initial tumor free state following an adequate BCG course of therapy\*\*
    - T1 disease following a single induction course of BCG therapy; **AND**
  - Patient has carcinoma in situ (CIS); **AND**
  - Patient is ineligible for or has elected not to undergo cystectomy; **OR**
  - Patient has one of the following diagnoses:
    - Locally advanced or metastatic urothelial carcinoma †
    - Muscle invasive bladder cancer with local recurrence or persistent disease in a preserved bladder
    - 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 (i.e., stage II-III) 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 (TPS ≥ 1%) non-small cell lung cancer (NSCLC); **AND**
  - Used as initial treatment in patients with small asymptomatic brain metastases; **OR**
  - Used for relapsed limited brain metastases with either stable systemic disease or reasonable systemic treatment options; **OR**

- Used for recurrent limited brain metastases; **OR**
- Used for recurrent extensive brain metastases with stable systemic disease or reasonable systemic treatment options

### **Pediatric Central Nervous System (CNS) Cancers ‡<sup>2,81</sup>**

- Patient is  $\leq 18$  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  $\geq 3$  years of age and used following standard brain radiation therapy (RT) with or without concurrent temozolomide

### **Cervical Cancer †‡<sup>1,2,42,70</sup>**

- Tumor expresses PD-L1 (CPS  $\geq 1$ ) 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 †‡❖<sup>1,2,39-41,66,67</sup>**

- 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  $\geq 10$ ) as determined by an FDA-approved or CLIA compliant test❖; **AND**
      - Patient progressed after one or more prior lines of systemic therapy

### **Gastric Cancer †‡❖<sup>1,2,39,67</sup>**

#### **KEYTRUDA® (pembrolizumab) Prior Auth Criteria**

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- 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 ‡<sup>2,12,55</sup>**

- 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.,  $\geq 7$  prognostic score or stage IV disease)

#### **Squamous Cell Carcinoma of the Head and Neck (SCCHN) † ‡<sup>1,2,31,32</sup>**

- 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  $\geq 1$ ) 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  $\geq 1$ ) 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 regional nodal disease, metastatic disease at initial presentation (M1), or recurrent or persistent disease.*

### **Hepatocellular Carcinoma (HCC) † Φ<sup>1,43</sup>**

- Used as a single agent; **AND**
- Used as subsequent therapy for progressive disease; **AND**
- Patient has Child-Pugh Class A liver impairment (*i.e., excluding Child-Pugh Class B and C*); **AND**
  - Patient was previously treated with sorafenib; **OR**
  - Patient has unresectable disease and is not a transplant candidate; **OR**
  - Patient has liver-confined disease that is inoperable by performance status, comorbidity, or with minimal or uncertain extrahepatic-disease; **OR**
  - Patient has metastatic disease or extensive liver tumor burden

### **Adult Classical Hodgkin Lymphoma (cHL) † Φ<sup>1,2,33,61</sup>**

- 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 rescue (ASCR); **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<sup>1,2,33,61</sup>**

- 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 ‡<sup>2,85,86</sup>**

- 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) † ‡<sup>1,2,45,74-76</sup>**

- 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 <sup>Δ</sup>; **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<sup>1,2,22-24,65,68,87</sup>**

- 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 † 2,62,63,77**

- 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  $\geq 1\%$ ) 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  $\geq 4$  cm), II, or IIIA disease ‡; **AND**
    - Used following resection and previous adjuvant 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  $\geq 1\%$ ) 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  $\geq 1\%$ ) 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, 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) ‡ † 2,72,73

- 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 ‡ 2,56,88,89,90

- Used in combination with axitinib; **AND**
  - Patient has alveolar soft part sarcoma (ASPS); **OR**
- Used as a single agent\*; **AND**
  - Patient has alveolar soft part sarcoma (ASPS); **OR**
  - Patient has cutaneous angiosarcoma; **OR**
  - Patient has myxofibrosarcoma, undifferentiated pleomorphic sarcoma (UPS), dedifferentiated liposarcoma, cutaneous angiosarcoma, or undifferentiated sarcomas; **AND**
    - Used as subsequent therapy for advanced/metastatic disease with disseminated metastases (*Note: only applies to Extremity/Body Wall, Head/Neck*); **OR**
    - Used as alternative systemic therapy for unresectable or progressive disease after initial therapy for unresectable or stage IV disease (*Note: only applies to Retroperitoneal/Intra-Abdominal*); **OR**
    - Used as subsequent therapy for recurrent unresectable or recurrent stage IV disease (*Note: only applies to Retroperitoneal/Intra-Abdominal*)

*\*For atypical lipomatous tumor/well-differentiated liposarcoma (ALT/WDLS) of the extremity, abdominal wall, trunk that was initially diagnosed as ALT and shows evidence of de-differentiation OR for well-differentiated liposarcoma (WDLS-retroperitoneum, paratesticular) with or without evidence of de-differentiation, treat as other soft tissue sarcomas.*

### 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

### 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 † ‡<sup>2,16,17</sup>**

- 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) † ‡<sup>1,2,46,80</sup>**

- 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 † ‡<sup>2,54</sup>**

- 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  $\geq 1$ ) 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 † ‡<sup>1,2,4,38,51</sup>**

- 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**
- Patient has unresectable or medically inoperable, advanced, recurrent, persistent, or metastatic solid tumors; **AND**
  - Used for disease progression following prior treatment †; **OR**
  - Used as initial therapy; **AND**
    - Patient has one of the following cancers:

- Ampullary Adenocarcinoma ‡
- Biliary Tract Adenocarcinoma (Gallbladder Cancer, Intra-/Extra-hepatic Cholangiocarcinoma) ‡
- Appendiceal Adenocarcinoma – Colon Cancer ‡
- Colorectal Cancer (*Note: neoadjuvant therapy is allowed for resectable liver and/or lung metastases OR for clinical T4b colon cancer only*) † ‡
- Salivary Gland Tumors ‡
- Very Advanced Squamous Cell Carcinoma of the Head and Neck (non-nasopharyngeal type) ‡
- Occult Primary/Cancer of Unknown Primary (CUP) ‡
- Pancreatic Adenocarcinoma ‡
- Small bowel adenocarcinoma ‡
- Endometrial Carcinoma (*excluding patients with isolated metastases*) ‡

#### **Tumor Mutational Burden-High (TMB-H) Cancer † ‡ <sup>1,2</sup>**

- Patient is at least 6 months of age; **AND**
- Patient has solid tumors that are tumor mutational burden-high (TMB-H) [ $\geq 10$  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 unresectable or medically inoperable, advanced, recurrent, persistent, or metastatic solid tumors; **AND**
  - Used for disease progression following prior treatment †; **OR**
  - Used as initial therapy ‡; **AND**
    - Patient has one of the following cancers:
      - Ampullary adenocarcinoma
      - Salivary Gland Tumors
      - Very Advanced Squamous Cell Carcinoma of the Head and Neck (non-nasopharyngeal type)
      - Occult Primary/Cancer of Unknown Primary (CUP)
      - Pancreatic Adenocarcinoma
      - Anaplastic or Medullary Thyroid Carcinoma
      - Follicular, Oncocytic, or Papillary Thyroid Carcinoma (*only applicable to patients not amenable to radioactive iodine therapy*)
      - Endometrial Carcinoma (*excluding patients with isolated metastases*)



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

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

<b>Ψ ER Scoring Interpretation</b> (following ER testing by validated IHC assay)	
<b>Results</b>	<b>Interpretation</b>
– 0% – <1% of nuclei stain	– ER-negative
– 1%–10% of nuclei stain	– ER-low-positive*
– >10% of nuclei stain	– ER-positive
<p><i>*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.</i></p>	

<b>Genomic Aberration/Mutational Driver Targeted Therapies</b> (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
<ul style="list-style-type: none"> <li>– Afatinib</li> <li>– Erlotinib</li> <li>– Dacomitinib</li> <li>– Gefitinib</li> <li>– Osimertinib</li> <li>– Amivantamab (exon-20 insertion)</li> <li>– Mobocertinib (exon-20 insertion)</li> </ul>	<ul style="list-style-type: none"> <li>– Alectinib</li> <li>– Brigatinib</li> <li>– Ceritinib</li> <li>– Crizotinib</li> <li>– Lorlatinib</li> </ul>	<ul style="list-style-type: none"> <li>– Ceritinib</li> <li>– Crizotinib</li> <li>– Entrectinib</li> <li>– Lorlatinib</li> </ul>	<ul style="list-style-type: none"> <li>– Dabrafenib ± trametinib</li> <li>– Vemurafenib</li> </ul>	<ul style="list-style-type: none"> <li>– Larotrectinib</li> <li>– Entrectinib</li> </ul>
PD-L1 tumor expression ≥ 1%	MET exon-14 skipping mutations	RET rearrangement-positive tumors	KRAS G12C mutation positive tumors	ERBB2 (HER2) mutation positive tumors
<ul style="list-style-type: none"> <li>– Pembrolizumab</li> <li>– Atezolizumab</li> <li>– Nivolumab + ipilimumab</li> <li>– Cemiplimab</li> <li>– Durvalumab</li> <li>– Tremelimumab + durvalumab</li> </ul>	<ul style="list-style-type: none"> <li>– Capmatinib</li> <li>– Crizotinib</li> <li>– Tepotinib</li> </ul>	<ul style="list-style-type: none"> <li>– Selpercatinib</li> <li>– Cabozantinib</li> <li>– Pralsetinib</li> </ul>	<ul style="list-style-type: none"> <li>– Sotorasib</li> <li>– Adagrasib</li> </ul>	<ul style="list-style-type: none"> <li>– Fam-trastuzumab deruxtecan-nxki</li> <li>– Ado-trastuzumab emtansine</li> </ul>

#### IV. Renewal Criteria [Δ 1-3,5,6,15-17,50,51,53,57,62,65,68,69,72,73,75-77,82,85-87](#)

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  $\geq 6$  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  $\geq 6$  months after discontinuation are eligible to re-initiate PD-directed therapy for metastatic disease.
- Patients whose tumors, upon re-biopsy, demonstrate a change in actionable mutation (e.g., MSS initial biopsy; MSI-H subsequent biopsy) may be eligible to re-initiate PD-directed therapy and will be evaluated on a case-by-case basis.
- Patients diagnosed with Renal Cell Carcinoma with clear cell histology who have received previous immuno-oncology therapy may be eligible for treatment with pembrolizumab as subsequent therapy and will be evaluated on a case-by-case basis.

## **V. Dosage/Administration** Δ 1-6,8,12,13,15-17,22-48,50-57,62,65,68,72,73,75-77,82,83,85-87

Indication	Dose
Bladder Cancer/Urothelial Carcinoma, Cervical, cSCC, Endometrial Carcinoma (excluding MSI-H/dMMR),	200 mg intravenously every 3 weeks or 400 mg intravenously every 6 weeks up to a maximum of 24 months in patients without disease progression or unacceptable toxicity

Esophageal, GEJ, Gastric, HCC, & SCCHN	<i>*NMIBC treatment may continue up to a maximum of 24 months in patients without persistent or recurrent disease, disease progression, or unacceptable toxicity.</i>
NSCLC	<p><u>First-line, subsequent, or continuation maintenance therapy:</u> 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</p> <p><u>Adjuvant therapy:</u> 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</p>
RCC	<p><u>First-line or subsequent therapy:</u> 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</p> <p><u>Adjuvant therapy:</u> 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</p>
TNBC	<p><u>Recurrent unresectable or metastatic disease:</u> 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</p> <p><u>Neoadjuvant therapy:</u> 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)</p> <p><u>Adjuvant therapy*:</u> 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)</p> <p><i>* 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.</i></p>
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	<p><u>Single agent therapy (excluding adjuvant treatment):</u> 200 mg intravenously every 3 weeks or 400 mg every 6 weeks until disease progression or unacceptable toxicity</p>

	<p><u>In combination with ipilimumab, lenvatinib, OR trametinib and dabrafenib:</u></p> <p>200 mg intravenously every 3 weeks up to a maximum of 24 months in patients without disease progression or unacceptable toxicity</p> <p><u>Adjuvant treatment:</u></p> <p><u>Adults:</u> 200 mg intravenously every 3 weeks or 400 mg every 6 weeks up to a maximum of 12 months in patients without disease recurrence or unacceptable toxicity</p> <p><u>Pediatrics:</u> 2 mg/kg (up to 200 mg) intravenously every 3 weeks up to a maximum of 12 months in patients without disease recurrence or unacceptable toxicity</p>
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	<p><u>Adults*:</u></p> <p>200 mg intravenously every 3 weeks or 400 mg every 6 weeks</p> <p><u>Pediatrics*:</u></p> <p>2 mg/kg (up to 200 mg) intravenously every 3 weeks</p> <p><i>*Up to a maximum of 24 months in patients without disease progression or unacceptable toxicity</i></p>
CNS Cancer	<p><u>Adults:</u></p> <p>10 mg/kg intravenously every 2 weeks for up to 24 months in patients without disease progression or unacceptable toxicity</p> <p><u>Pediatrics:</u></p> <p>2 mg/kg (up to 200 mg) intravenously every 3 weeks for up to 24 months in patients without disease progression or unacceptable toxicity</p>
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
<p><u>Dosing should be calculated using actual body weight and not flat dosing (as applicable) based on the following:</u></p> <ul style="list-style-type: none"> <li>• Standard dose 200 mg IV every 3 weeks for patients &gt; 50 kg</li> <li>• Use 100 mg IV every 3 weeks for patients ≤ 50 kg</li> <li>-OR-</li> <li>• Standard dose 400 mg IV every 6 weeks for patients weighing &gt; 82.5 kg</li> <li>• Use 300 mg IV every 6 weeks for patients weighing between 56 to 82.5 kg</li> <li>• Use 200 mg IV every 6 weeks for patients weighing ≤ 55 kg</li> </ul> <p><i>Note: This information is not meant to replace clinical decision making when initiating or modifying medication therapy and should only be used as a guide. Patient-specific variables should be taken into account.</i></p>	

## VI. Billing Code/Availability Information

### HCPCS Code:

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

### NDC:

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

## VII. References

1. Keytruda [package insert]. Whitehouse Station, NJ; Merck & Co, Inc; April 2023. Accessed April 2023.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) pembrolizumab. National Comprehensive Cancer Network, 2023. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed April 2023.
3. Alley EW, Lopez J, Santoro A, et al. Clinical safety and activity of pembrolizumab in patients with malignant pleural mesothelioma (KEYNOTE-028): preliminary results from a non-randomised, open-label, phase 1b trial. *Lancet Oncol.* 2017 May;18(5):623-630.
4. Ott PA, Bang YJ, Berton-Rigaud D, et al. Safety and Antitumor Activity of Pembrolizumab in Advanced Programmed Death Ligand 1-Positive Endometrial Cancer: Results From the KEYNOTE-028 Study. *J Clin Oncol.* 2017 Aug 1;35(22):2535-2541.

5. Ott PA, Piha-Paul SA, Munster P, et al. Safety and antitumor activity of the anti-PD-1 antibody pembrolizumab in patients with recurrent carcinoma of the anal canal. *Ann Oncol*. 2017 May 1;28(5):1036-1041. Doi: 10.1093/annonc/mdx029.
6. Zinzani PL, Ribrag V, Moskowitz CH, et al. Safety and tolerability of pembrolizumab in patients with relapsed/refractory primary mediastinal large B-cell lymphoma. *Blood*. 2017 Jul 20;130(3):267-270. Doi: 10.1182/blood-2016-12-758383. Epub 2017 May 10.
7. U.S. Food and Drug Administrations (FDA). Division of Drug Information. Health Alert. <https://www.fda.gov/drugs/drug-safety-and-availability/fda-alerts-health-care-professionals-and-oncology-clinical-investigators-about-efficacy-issue>. Accessed August 2018.
8. Balar AV, Castellano D, O'Donnell PH, et al. First-line pembrolizumab in cisplatin-ineligible patients with locally advanced and unresectable or metastatic urothelial cancer (KEYNOTE-052): a multicenter, single-arm, phase 2 study. *Lancet Oncol* 2017; 18: 1483–92.
9. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Merkel Cell Carcinoma. Version 2.2022. National Comprehensive Cancer Network, 2023. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed April 2023.
10. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Bladder Cancer. Version 1.2023. National Comprehensive Cancer Network, 2023. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed April 2023.
11. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Non-Small Cell Lung Cancer. Version 2.2023. National Comprehensive Cancer Network, 2023. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed April 2023.
12. Ghorani E, Kaur B, Fisher RA, et al. Pembrolizumab is effective for drug-resistant gestational trophoblastic neoplasia. *Lancet*. 2017 Nov 25;390(10110):2343-2345.
13. Chung HC, Lopez-Martin JA, Kao S, et al. Phase 2 study of pembrolizumab in advanced small-cell lung cancer (SCLC): KEYNOTE-158. *J Clin Oncol* 2018;36: Abstract 8506
14. National Institutes of Health. Study of Pembrolizumab (MK-3475) Versus Placebo After Complete Resection of High-Risk Stage III Melanoma (MK-3475-054/KEYNOTE-054). Available at: <http://clinicaltrials.gov/show/NCT02362594>.



15. Khodadoust M, Rook AH, Porcu P, et al. Pembrolizumab in Relapsed and Refractory Mycosis Fungoides and Sézary Syndrome: A Multicenter Phase II Study. *J Clin Oncol*. 2020 Jan 1;38(1):20-28. Doi: 10.1200/JCO.19.01056. Epub 2019 Sep 18.
16. Giaccone, G, Kim C, Thompson J, et al. Pembrolizumab in patients with thymic carcinoma: a single-arm, single-centre, phase 2 study. *Lancet*. Volume 19, ISSUE 3, P347-355, March 01, 2018.
17. Cho J, Kim HS, Ku BM, et al. Pembrolizumab for Patients With Refractory or Relapsed Thymic Epithelial Tumor: An Open-Label Phase II Trial. *J Clin Oncol*. 2018 Jun 15;JCO2017773184. Doi: 10.1200/JCO.2017.77.3184. [Epub ahead of print]
18. Gupta S, Sonpavde G, Grivas P, et al. Defining “platinum-ineligible” patients with metastatic urothelial cancer (mUC). *J Clin Oncol*. 2019 Mar 1;37(7\_suppl):451.
19. Fahrenbruch R, Kintzel P, Bott AM, et al. Dose Rounding of Biologic and Cytotoxic Anticancer Agents: A Position Statement of the Hematology/Oncology Pharmacy Association. *J Oncol Pract*. 2018 Mar;14(3):e130-e136.
20. Hematology/Oncology Pharmacy Association (2019). Intravenous Cancer Drug Waste Issue Brief. Retrieved from [http://www.hoparx.org/images/hopa/advocacy/Issue-Briefs/Drug\\_Waste\\_2019.pdf](http://www.hoparx.org/images/hopa/advocacy/Issue-Briefs/Drug_Waste_2019.pdf)
21. Bach PB, Conti RM, Muller RJ, et al. Overspending driven by oversized single dose vials of cancer drugs. *BMJ*. 2016 Feb 29;352:i788.
22. Schachter J, Ribas A, Long GV, et al. Pembrolizumab versus ipilimumab for advanced melanoma: final overall survival results of a multicentre, randomised, open-label phase 3 study (KEYNOTE-006). *Lancet*. 2017 Oct 21;390(10105):1853-1862. Doi: 10.1016/S0140-6736(17)31601-X. Epub 2017 Aug 16.
23. Ribas A, Puzanov I, Dummer R, et al. Pembrolizumab versus investigator-choice chemotherapy for ipilimumab-refractory melanoma (KEYNOTE-002): a randomised, controlled, phase 2 trial. *Lancet Oncol*. 2015 Aug;16(8):908-18. Doi: 10.1016/S1470-2045(15)00083-2. Epub 2015 Jun 23.
24. Eggermont AMM, Blank CU, Mandala M, et al. Adjuvant Pembrolizumab versus Placebo in Resected Stage III Melanoma. *N Engl J Med*. 2018 May 10;378(19):1789-1801. Doi: 10.1056/NEJMoa1802357. Epub 2018 Apr 15.
25. Gandhi L, Rodríguez-Abreu D, Gadgeel S, et al. Pembrolizumab plus Chemotherapy in Metastatic Non-Small-Cell Lung Cancer. *N Engl J Med*. 2018 May 31;378(22):2078-2092. Doi: 10.1056/NEJMoa1801005. Epub 2018 Apr 16.
26. Paz-Ares L, Luft A, Vicente D, et al. Pembrolizumab plus Chemotherapy for Squamous Non-Small-Cell Lung Cancer. *N Engl J Med*. 2018 Nov 22;379(21):2040-2051. Doi: 10.1056/NEJMoa1810865. Epub 2018 Sep 25.
27. Mok TSK, Wu YL, Kudaba I, et al. Pembrolizumab versus chemotherapy for previously untreated, PD-L1-expressing, locally advanced or metastatic non-small-cell lung cancer (KEYNOTE-042): a randomised, open-label, controlled, phase 3 trial. *Lancet*. 2019 May 4;393(10183):1819-1830. Doi: 10.1016/S0140-6736(18)32409-7. Epub 2019 Apr 4.

28. Reck M, Rodríguez-Abreu D, Robinson AG, et al. Pembrolizumab versus Chemotherapy for PD-L1-Positive Non-Small-Cell Lung Cancer. *N Engl J Med*. 2016 Nov 10;375(19):1823-1833. Epub 2016 Oct 8.
29. Herbst RS, Baas P, Kim DW, et al. Pembrolizumab versus docetaxel for previously treated, PD-L1-positive, advanced non-small-cell lung cancer (KEYNOTE-010): a randomised controlled trial. *Lancet*. 2016 Apr 9;387(10027):1540-1550. Doi: 10.1016/S0140-6736(15)01281-7. Epub 2015 Dec 19.
30. Ott PA, Elez E, Hiet S, et al. Pembrolizumab in Patients With Extensive-Stage Small-Cell Lung Cancer: Results From the Phase Ib KEYNOTE-028 Study. *J Clin Oncol*. 2017 Dec 1;35(34):3823-3829. Doi: 10.1200/JCO.2017.72.5069. Epub 2017 Aug 16.
31. Burtneß B, Harrington KJ, Greil R, et al. Pembrolizumab alone or with chemotherapy versus cetuximab with chemotherapy for recurrent or metastatic squamous cell carcinoma of the head and neck (KEYNOTE-048): a randomised, open-label, phase 3 study. *Lancet*. 2019 Nov 23;394(10212):1915-1928. Doi: 10.1016/S0140-6736(19)32591-7. Epub 2019 Nov 1.
32. Chow LQM, Haddad R, Gupta S, et al. Antitumor Activity of Pembrolizumab in Biomarker-Unselected Patients With Recurrent and/or Metastatic Head and Neck Squamous Cell Carcinoma: Results From the Phase Ib KEYNOTE-012 Expansion Cohort. *Antitumor Activity of Pembrolizumab in Biomarker-Unselected Patients With Recurrent and/or Metastatic Head and Neck Squamous Cell Carcinoma: Results From the Phase Ib KEYNOTE-012 Expansion Cohort*.
33. Chen R, Zinzani PL, Fanale MA, et al. Phase II Study of the Efficacy and Safety of Pembrolizumab for Relapsed/Refractory Classic Hodgkin Lymphoma. *J Clin Oncol*. 2017 Jul 1;35(19):2125-2132. Doi: 10.1200/JCO.2016.72.1316. Epub 2017 Apr 25.
34. Armand P, Rodig S, Melnichenko V, et al. Pembrolizumab in Relapsed or Refractory Primary Mediastinal Large B-Cell Lymphoma. *J Clin Oncol*. 2019 Dec 1;37(34):3291-3299. Doi: 10.1200/JCO.19.01389. Epub 2019 Oct 14.
35. Powles T, Gschwend JE, Loriot Y, et al. Phase 3 KEYNOTE-361 trial: Pembrolizumab (pembro) with or without chemotherapy versus chemotherapy alone in advanced urothelial cancer. DOI: 10.1200/JCO.2017.35.15\_suppl.TPS4590 *Journal of Clinical Oncology* 35, no. 15\_suppl. Published online May 30, 2017.
36. Bellmunt J, de Wit R, Vaughn DJ, et al. Pembrolizumab as Second-Line Therapy for Advanced Urothelial Carcinoma. *N Engl J Med*. 2017 Mar 16;376(11):1015-1026. Doi: 10.1056/NEJMoa1613683. Epub 2017 Feb 17.
37. Balar AV, Kulkarni GS, Uchio, EM, et al. Keynote 057: Phase II trial of Pembrolizumab (pembro) for patients (pts) with high-risk (HR) nonmuscle invasive bladder cancer (NMIBC) unresponsive to bacillus calmette-guérin (BCG). DOI: 10.1200/JCO.2019.37.7\_suppl.350 *Journal of Clinical Oncology* 37, no. 7\_suppl (March 01, 2019) 350-350. Published online February 26, 2019.
38. Le DT, Kim TW, Van Cutsem E, et al. Phase II Open-Label Study of Pembrolizumab in Treatment-Refractory, Microsatellite Instability-High/Mismatch Repair-Deficient

- Metastatic Colorectal Cancer: KEYNOTE-164. *J Clin Oncol*. 2020 Jan 1;38(1):11-19. Doi: 10.1200/JCO.19.02107. Epub 2019 Nov 14.
39. Fuchs CS, Doi T, Jang RW, et al. Safety and Efficacy of Pembrolizumab Monotherapy in Patients With Previously Treated Advanced Gastric and Gastroesophageal Junction Cancer: Phase 2 Clinical KEYNOTE-059 Trial. *JAMA Oncol*. 2018 May 10;4(5):e180013. Doi: 10.1001/jamaoncol.2018.0013. Epub 2018 May 10.
40. Kojima T, Muro K, Francois E, et al. Pembrolizumab versus chemotherapy as second-line therapy for advanced esophageal cancer: Phase III KEYNOTE-181 study. DOI: 10.1200/JCO.2019.37.4\_suppl.2 *Journal of Clinical Oncology* 37, no. 4\_suppl (February 01, 2019) 2-2. Published online January 29, 2019.
41. Shah M, Kojima T, Hochhauser D, et al. Efficacy and Safety of Pembrolizumab for Heavily Pretreated Patients With Advanced, Metastatic Adenocarcinoma or Squamous Cell Carcinoma of the Esophagus: The Phase 2 KEYNOTE-180 Study. *JAMA Oncol*. 2019;4(5):e180013. Doi: 10.1001/jamaoncol.2018.5441.
42. Chung HC, Ros W, Delord JP, et al. Efficacy and Safety of Pembrolizumab in Previously Treated Advanced Cervical Cancer: Results From the Phase II KEYNOTE-158 Study. *J Clin Oncol*. 2019 Jun 10;37(17):1470-1478. Doi: 10.1200/JCO.18.01265. Epub 2019 Apr 3.
43. Zhu AX, Finn RS, Edeline J, et al. Pembrolizumab in patients with advanced hepatocellular carcinoma previously treated with sorafenib (KEYNOTE-224): a non-randomised, open-label phase 2 trial. *Lancet Oncol*. 2018 Jul;19(7):940-952. Doi: 10.1016/S1470-2045(18)30351-6. Epub 2018 Jun 3.
44. Nghiem P, Bhatia S, Lipson EJ, et al. Durable Tumor Regression and Overall Survival in Patients With Advanced Merkel Cell Carcinoma Receiving Pembrolizumab as First-Line Therapy. *J Clin Oncol*. 2019 Mar 20;37(9):693-702. Doi: 10.1200/JCO.18.01896. Epub 2019 Feb 6.
45. Rini BI, Plimack ER, Stus V, et al. Pembrolizumab plus Axitinib versus Sunitinib for Advanced Renal-Cell Carcinoma. *N Engl J Med*. 2019 Mar 21;380(12):1116-1127. Doi: 10.1056/NEJMoa1816714. Epub 2019 Feb 16.
46. Makker V, Taylor MH, Aghajanian C, et al. Lenvatinib (LEN) and pembrolizumab (PEMBRO) in advanced endometrial cancer (EC). *Annals of Oncology*, Volume 30, Issue Supplement\_5, October 2019, MDZ250.002, <https://doi.org/10.1093/annonc/mdz250.002>.
47. Goldberg SB, Gettinger SN, Mahajan A, et al. Pembrolizumab for patients with melanoma or non-small-cell lung cancer and untreated brain metastases: early analysis of a non-randomised, open-label, phase 2 trial. *Lancet Oncol*. 2016 Jul;17(7):976-983. Doi: 10.1016/S1470-2045(16)30053-5. Epub 2016 Jun 3.
48. Kwong YL, Chan TSY, Tan D, et al. PD1 blockade with pembrolizumab is highly effective in relapsed or refractory NK/T-cell lymphoma failing l-asparaginase. *Blood*. 2017 Apr 27;129(17):2437-2442. Doi: 10.1182/blood-2016-12-756841. Epub 2017 Feb 10.
49. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Central Nervous System Cancers. Version 1.2023. National Comprehensive

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50. Kluger HM, Chiang V, Mahajan A, et al. Long-Term Survival of Patients With Melanoma With Active Brain Metastases Treated With Pembrolizumab on a Phase II Trial. *J Clin Oncol*. 2019 Jan 1;37(1):52-60. doi: 10.1200/JCO.18.00204. Epub 2018 Nov 8.
51. Marabelle A, Le DT, Ascierto PA, et al. Efficacy of Pembrolizumab in Patients With Noncolorectal High Microsatellite Instability/Mismatch Repair-Deficient Cancer: Results From the Phase II KEYNOTE-158 Study. *J Clin Oncol*. 2020 Jan 1;38(1):1-10. doi: 10.1200/JCO.19.02105. Epub 2019 Nov 4.
52. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Anal Carcinoma. Version 1.2023. National Comprehensive Cancer Network, 2023. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed April 2023.
53. Kottschade LA, McWilliams RR, Markovic SN, et al. The Use of Pembrolizumab for the Treatment of Metastatic Uveal Melanoma. *Melanoma Res*. 2016 Jun;26(3):300-3. doi: 10.1097/CMR.0000000000000242.
54. Algazi AP, Tsai KK, Shoushtari AN, et al. Clinical Outcomes in Metastatic Uveal Melanoma Treated With PD-1 and PD-L1 Antibodies. *Cancer*. 2016 Nov 15;122(21):3344-3353. doi: 10.1002/cncr.30258.
55. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Gestational Trophoblastic Neoplasia. Version 1.2023. National Comprehensive Cancer Network, 2023. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed April 2023.
56. Burgess MA, Bolejack V, Van Tine BA, et al. Multicenter phase II study of pembrolizumab (P) in advanced soft tissue (STS) and bone sarcomas (BS): Final results of SARC028 and biomarker analyses. *J Clin Oncol* 2017; 35, no. 15\_suppl (May 20, 2017) 11008-11008.
57. Marabelle A, Fakih M, Lopez J, et al. Association of Tumor Mutational Burden with Outcomes in Patients with Select Advanced Solid Tumors Treated with Pembrolizumab in KEYNOTE-158. *Ann Oncol*. 2019;30(suppl\_5):v475-v532. doi: 10.1093/annonc/mdz253.
58. Grob JJ, Gonzalez R, Basset-Seguín N, et al. Pembrolizumab Monotherapy for Recurrent or Metastatic Cutaneous Squamous Cell Carcinoma: A Single-Arm Phase II Trial (KEYNOTE-629). *J Clin Oncol*. 2020 Sep 1;38(25):2916-2925. doi: 10.1200/JCO.19.03054.

59. Andre T, Shiu KK, Kim TW, et al. Pembrolizumab versus chemotherapy for microsatellite instability-high/mismatch repair deficient metastatic colorectal cancer: The phase 3 KEYNOTE-177 Study. *J Clin Oncol.* 2020;38(18\_suppl):LBA4-LBA4.
60. Geoerger B, Kang HJ, Yalon-Oren M, et al. Pembrolizumab in paediatric patients with advanced melanoma or a PD-L1-positive, advanced, relapsed, or refractory solid tumour or lymphoma (KEYNOTE-051): interim analysis of an open-label, single-arm, phase 1-2 trial. *Lancet Oncol.* 2020;21(1):121-133. doi:10.1016/S1470-2045(19)30671-0.
61. Pembrolizumab Improves Progression-Free Survival in Relapsed/Refractory Hodgkin Lymphoma. *Oncologist.* 2020;25 Suppl 1(Suppl 1):S18-S19. doi:10.1634/theoncologist.2020-0561.
62. Raj N, Zheng Y, Kelly V, et al. PD-1 Blockade in Advanced Adrenocortical Carcinoma. *J Clin Oncol.* 2020 Jan 1;38(1):71-80. doi: 10.1200/JCO.19.01586.
63. Naing A, Meric-Bernstam F, Stephen B, et al. Phase 2 study of pembrolizumab in patients with advanced rare cancers [published correction appears in *J Immunother Cancer.* 2020 Apr;8(1):]. *J Immunother Cancer.* 2020;8(1):e000347. doi:10.1136/jitc-2019-000347.
64. Cortes J, Cescon DW, Rugo HS, et al. KEYNOTE-355: Randomized, double-blind, phase III study of pembrolizumab + chemotherapy versus placebo + chemotherapy for previously untreated locally recurrent inoperable or metastatic triple-negative breast cancer. *Journal of Clinical Oncology*38, no. 15\_suppl(May 20, 2020)1000-1000.
65. Olson D, Luke JJ, Poklepovic AS, et al. Significant antitumor activity for low-dose ipilimumab (IPI) with pembrolizumab (PEMBRO) immediately following progression on PD1 Ab in melanoma (MEL) in a phase II trial. *J Clin Oncol* 2020;38(15\_suppl): abstract 10004.
66. Kato K, Shah MA, Enzinger P, et al. KEYNOTE-590: Phase III study of first-line chemotherapy with or without pembrolizumab for advanced esophageal cancer. *Future Oncol.* 2019 Apr;15(10):1057-1066. doi: 10.2217/fon-2018-0609.
67. Chung HC, Bang YJ, S Fuchs C, et al. First-line pembrolizumab/placebo plus trastuzumab and chemotherapy in HER2-positive advanced gastric cancer: KEYNOTE-811. *Future Oncol.* 2021 Feb;17(5):491-501. doi: 10.2217/fon-2020-0737.
68. Carlino MS, Menzies AM, Atkinson V, et al. Long-term Follow-up of Standard-Dose Pembrolizumab Plus Reduced-Dose Ipilimumab in Patients with Advanced Melanoma: KEYNOTE-029 Part 1B. *Clin Cancer Res.* 2020 Oct 1;26(19):5086-5091. doi: 10.1158/1078-0432.CCR-20-0177.
69. Schmid P, Cortes J, Pusztai L, et al. Pembrolizumab for Early Triple-Negative Breast Cancer. *N Engl J Med.* 2020 Feb 27;382(9):810-821. doi: 10.1056/NEJMoa1910549.
70. Colombo N, Dubot C, Lorusso D, et al. Pembrolizumab for Persistent, Recurrent, or Metastatic Cervical Cancer. *N Engl J Med.* 2021 Sep 18. doi: 10.1056/NEJMoa2112435.
71. Bellmunt, J. (2023). Treatment of metastatic urothelial cancer of the bladder and urinary tract. In Lerner SP, Shah S (Eds.), *UptoDate*. Accessed April 12, 2023. Available from <https://www.uptodate.com/contents/treatment-of-metastatic-urothelial-cancer-of-the-bladder-and-urinary-tract>



72. Chung HC, Piha-Paul SA, Lopez-Martin J, et al. Pembrolizumab After Two or More Lines of Previous Therapy in Patients With Recurrent or Metastatic SCLC: Results From the KEYNOTE-028 and KEYNOTE-158 Studies. *J Thorac Oncol*. 2020 Apr;15(4):618-627. doi: 10.1016/j.jtho.2019.12.109. Epub 2019 Dec 20.
73. Ott PA, Elez E, Hirt S, et al. Pembrolizumab in Patients With Extensive-Stage Small-Cell Lung Cancer: Results From the Phase Ib KEYNOTE-028 Study. *J Clin Oncol*. 2017 Dec 1;35(34):3823-3829. doi: 10.1200/JCO.2017.72.5069. Epub 2017 Aug 16.
74. Motzer R, Alekseev B, Rha SY, et al; CLEAR Trial Investigators. Lenvatinib plus Pembrolizumab or Everolimus for Advanced Renal Cell Carcinoma. *N Engl J Med*. 2021 Apr 8;384(14):1289-1300. doi: 10.1056/NEJMoa2035716.
75. McKay RR, Bossé D, Xie W, et al. The Clinical Activity of PD-1/PD-L1 Inhibitors in Metastatic Non-Clear Cell Renal Cell Carcinoma. *Cancer Immunol Res*. 2018 Jul;6(7):758-765. doi: 10.1158/2326-6066.CIR-17-0475.
76. McDermott DF, Lee JL, Ziobro M, et al. Open-Label, Single-Arm, Phase II Study of Pembrolizumab Monotherapy as First-Line Therapy in Patients With Advanced Non-Clear Cell Renal Cell Carcinoma. *J Clin Oncol*. 2021 Mar 20;39(9):1029-1039. doi: 10.1200/JCO.20.02365.
77. Habra MA, Stephen B, Campbell M, et al. Phase II clinical trial of pembrolizumab efficacy and safety in advanced adrenocortical carcinoma. *J Immunother Cancer*. 2019 Sep 18;7(1):253. doi: 10.1186/s40425-019-0722-x.
78. Choueiri TK, Tomczak P, Park SH, et al; KEYNOTE-564 Investigators. Adjuvant Pembrolizumab after Nephrectomy in Renal-Cell Carcinoma. *N Engl J Med*. 2021 Aug 19;385(8):683-694. doi: 10.1056/NEJMoa2106391.
79. Gupta S, Bellmunt J, Plimack ER, et al. Defining “platinum-ineligible” patients with metastatic urothelial cancer (mUC). *J Clin Oncol*. 2022 June 1;40(16\_suppl):4577.
80. Makker V, Colombo N, Casado Herráez A, et al; Study 309-KEYNOTE-775 Investigators. Lenvatinib plus Pembrolizumab for Advanced Endometrial Cancer. *N Engl J Med*. 2022 Feb 3;386(5):437-448. doi: 10.1056/NEJMoa2108330. Epub 2022 Jan 19.
81. Cacciotti C, Choi J, Alexandrescu S, et al. Immune checkpoint inhibition for pediatric patients with recurrent/refractory CNS tumors: a single institution experience. *J Neurooncol*. 2020 Aug;149(1):113-122. doi: 10.1007/s11060-020-03578-6. Epub 2020 Jul 5. PMID: 32627129.
82. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Pediatric Aggressive Mature B-Cell Lymphomas. Version 1.2023. National Comprehensive Cancer Network, 2023. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer

Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed April 2023.

83. Wilky BA, Trucco MM, Subhawong TK, et al. Axitinib plus pembrolizumab in patients with advanced sarcomas including alveolar soft-part sarcoma: a single-centre, single-arm, phase 2 trial. *Lancet Oncol.* 2019 Jun;20(6):837-848. doi: 10.1016/S1470-2045(19)30153-6.
84. O'Brien M, Paz-Ares L, Marreaud S, et al; EORTC-1416-LCG/ETOP 8-15 – PEARLS/KEYNOTE-091 Investigators. Pembrolizumab versus placebo as adjuvant therapy for completely resected stage IB-IIIA non-small-cell lung cancer (PEARLS/KEYNOTE-091): an interim analysis of a randomised, triple-blind, phase 3 trial. *Lancet Oncol.* 2022 Oct;23(10):1274-1286. doi: 10.1016/S1470-2045(22)00518-6.
85. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Kaposi Sarcoma. Version 1.2023. National Comprehensive Cancer Network, 2023. The NCCN Compendium® is a derivative work of the NCCN Guidelines®, NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed April 2023.
86. Delyon J, Biard L, Renaud M, et al. PD-1 blockade with pembrolizumab in classic or endemic Kaposi's sarcoma: a multicentre, single-arm, phase 2 study. *Lancet Oncol.* 2022 Apr;23(4):491-500. doi: 10.1016/S1470-2045(22)00097-3.
87. Arance AM, de la Cruz-Merino L, Petrella TM, et al. Lenvatinib (len) plus pembrolizumab (pembro) for patients (pts) with advanced melanoma and confirmed progression on a PD-1 or PD-L1 inhibitor: Updated findings of LEAP-004. *Journal of Clinical Oncology* 2021 39:15\_suppl, 9504-9504.
88. Hoimes CJ, Petrylak DP, Flaig TW, et al. EV-103 study: A phase 1b dose-escalation and dose-expansion study of enfortumab vedotin in combination with immune checkpoint inhibitor (CPI) therapy for treatment of patients with locally advanced or metastatic urothelial cancer. *Journal of Clinical Oncology* 2018 36:6\_suppl, TPS532-TPS532.
89. Groisberg R, Hong DS, Behrang A, et al. Characteristics and outcomes of patients with advanced sarcoma enrolled in early phase immunotherapy trials. *J Immunother Cancer.* 2017 Dec 19;5(1):100. doi: 10.1186/s40425-017-0301-y.
90. Florou V, Rosenberg AE, Wieder E, et al. Angiosarcoma patients treated with immune checkpoint inhibitors: a case series of seven patients from a single institution. *J Immunother Cancer.* 2019 Aug 8;7(1):213. doi: 10.1186/s40425-019-0689-7.

## 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



ICD-10	ICD-10 Description
C00.3	Malignant neoplasm of upper lip, inner aspect
C00.4	Malignant neoplasm of lower lip, inner aspect
C00.5	Malignant neoplasm of lip, unspecified, inner aspect
C00.6	Malignant neoplasm of commissure of lip, unspecified
C00.8	Malignant neoplasm of overlapping sites of lip
C00.9	Malignant neoplasm of lip, unspecified
C01	Malignant neoplasm of base of tongue
C02.0	Malignant neoplasm of dorsal surface of tongue
C02.1	Malignant neoplasm of border of tongue
C02.2	Malignant neoplasm of ventral surface of tongue
C02.3	Malignant neoplasm of anterior two-thirds of tongue, part unspecified
C02.4	Malignant neoplasm of lingual tonsil
C02.8	Malignant neoplasm of overlapping sites of tongue
C02.9	Malignant neoplasm of tongue, unspecified
C03.0	Malignant neoplasm of upper gum
C03.1	Malignant neoplasm of lower gum
C03.9	Malignant neoplasm of gum, unspecified
C04.0	Malignant neoplasm of anterior floor of mouth
C04.1	Malignant neoplasm of lateral floor of mouth
C04.8	Malignant neoplasm of overlapping sites of floor of mouth
C04.9	Malignant neoplasm of floor of mouth, unspecified
C05.0	Malignant neoplasm of hard palate
C05.1	Malignant neoplasm of soft palate
C05.8	Malignant neoplasm of overlapping sites of palate
C05.9	Malignant neoplasm of palate, unspecified
C06.0	Malignant neoplasm of cheek mucosa
C06.2	Malignant neoplasm of retromolar area
C06.80	Malignant neoplasm of overlapping sites of unspecified parts of mouth
C06.89	Malignant neoplasm of overlapping sites of other parts of mouth
C06.9	Malignant neoplasm of mouth, unspecified
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

ICD-10	ICD-10 Description
C10.0	Malignant neoplasm of vallecula
C10.1	Malignant neoplasm of anterior surface of epiglottis
C10.2	Malignant neoplasm of lateral wall of oropharynx
C10.3	Malignant neoplasm of posterior wall of oropharynx
C10.4	Malignant neoplasm of branchial cleft
C10.8	Malignant neoplasm of overlapping sites of oropharynx
C10.9	Malignant neoplasm of oropharynx, unspecified
C11.0	Malignant neoplasm of superior wall of nasopharynx
C11.1	Malignant neoplasm of posterior wall of nasopharynx
C11.2	Malignant neoplasm of lateral wall of nasopharynx
C11.3	Malignant neoplasm of anterior wall of nasopharynx
C11.8	Malignant neoplasm of overlapping sites of nasopharynx
C11.9	Malignant neoplasm of nasopharynx, unspecified
C12	Malignant neoplasm of pyriform sinus
C13.0	Malignant neoplasm of postcricoid region
C13.1	Malignant neoplasm of aryepiglottic fold, hypopharyngeal aspect
C13.2	Malignant neoplasm of posterior wall of hypopharynx
C13.8	Malignant neoplasm of overlapping sites of hypopharynx
C13.9	Malignant neoplasm of hypopharynx, unspecified
C14.0	Malignant neoplasm of pharynx, unspecified
C14.2	Malignant neoplasm of Waldeyer's ring
C14.8	Malignant neoplasm of overlapping sites of lip, oral cavity and pharynx
C15.3	Malignant neoplasm of upper third of esophagus
C15.4	Malignant neoplasm of middle third of esophagus
C15.5	Malignant neoplasm of lower third of esophagus
C15.8	Malignant neoplasm of overlapping sites of esophagus
C15.9	Malignant neoplasm of esophagus, unspecified
C16.0	Malignant neoplasm of cardia
C16.1	Malignant neoplasm of fundus of stomach
C16.2	Malignant neoplasm of body of stomach
C16.3	Malignant neoplasm of pyloric antrum
C16.4	Malignant neoplasm of pylorus
C16.5	Malignant neoplasm of lesser curvature of stomach, unspecified
C16.6	Malignant neoplasm of greater curvature of stomach, unspecified
C16.8	Malignant neoplasm of overlapping sites of stomach
C16.9	Malignant neoplasm of stomach, unspecified
C17.0	Malignant neoplasm of duodenum
C17.1	Malignant neoplasm of jejunum

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
C31.0	Malignant neoplasm of maxillary sinus
C31.1	Malignant neoplasm of ethmoidal sinus
C32.0	Malignant neoplasm of glottis
C32.1	Malignant neoplasm of supraglottis
C32.2	Malignant neoplasm of subglottis
C32.3	Malignant neoplasm of laryngeal cartilage
C32.8	Malignant neoplasm of overlapping sites of larynx
C32.9	Malignant neoplasm of larynx, unspecified
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
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

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
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
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



ICD-10	ICD-10 Description
C4A.51	Merkel cell carcinoma of anal skin
C4A.52	Merkel cell carcinoma of skin of breast
C4A.59	Merkel cell carcinoma of other part of trunk
C4A.60	Merkel cell carcinoma of unspecified upper limb, including shoulder
C4A.61	Merkel cell carcinoma of right upper limb, including shoulder
C4A.62	Merkel cell carcinoma of left upper limb, including shoulder
C4A.70	Merkel cell carcinoma of unspecified lower limb, including hip
C4A.71	Merkel cell carcinoma of right lower limb, including hip
C4A.72	Merkel cell carcinoma of left lower limb, including hip
C4A.8	Merkel cell carcinoma of overlapping sites
C4A.9	Merkel cell carcinoma, unspecified
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.021	Malignant neoplasm of nipple and areola, right male breast
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.029	Malignant neoplasm of nipple and areola, unspecified male breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.121	Malignant neoplasm of central portion of right male breast
C50.122	Malignant neoplasm of central portion of left male breast
C50.129	Malignant neoplasm of central portion of unspecified male breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.229	Malignant neoplasm of upper-inner quadrant of unspecified male breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
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

ICD-10	ICD-10 Description
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.529	Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.629	Malignant neoplasm of axillary tail of unspecified male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast
C50.829	Malignant neoplasm of overlapping sites of unspecified male breast
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C50.921	Malignant neoplasm of unspecified site of right male breast
C50.922	Malignant neoplasm of unspecified site of left male breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast
C51.0	Malignant neoplasm of labium majus
C51.1	Malignant neoplasm of labium minus
C51.2	Malignant neoplasm of clitoris
C51.8	Malignant neoplasm of overlapping sites of vulva
C51.9	Malignant neoplasm of vulva, unspecified
C53.0	Malignant neoplasm of endocervix
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

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
C62.92	Malignant neoplasm of left testis, unspecified whether descended or undescended
C63.7	Malignant neoplasm of other specified male genital organs
C63.8	Malignant neoplasm of overlapping sites of male genital organs
C64.1	Malignant neoplasm of right kidney, except renal pelvis
C64.2	Malignant neoplasm of left kidney, except renal pelvis
C64.9	Malignant neoplasm of unspecified kidney, except renal pelvis
C65.1	Malignant neoplasm of right renal pelvis
C65.2	Malignant neoplasm of left renal pelvis
C65.9	Malignant neoplasm of unspecified renal pelvis
C66.1	Malignant neoplasm of right ureter
C66.2	Malignant neoplasm of left ureter
C66.9	Malignant neoplasm of unspecified ureter
C67.0	Malignant neoplasm of trigone of bladder
C67.1	Malignant neoplasm of dome of bladder
C67.2	Malignant neoplasm of lateral wall of bladder
C67.3	Malignant neoplasm of anterior wall of bladder
C67.4	Malignant neoplasm of posterior wall of bladder
C67.5	Malignant neoplasm of bladder neck
C67.6	Malignant neoplasm of ureteric orifice
C67.7	Malignant neoplasm of urachus
C67.8	Malignant neoplasm of overlapping sites of bladder
C67.9	Malignant neoplasm of bladder, unspecified
C68.0	Malignant neoplasm of urethra
C69.30	Malignant neoplasm of unspecified choroid
C69.31	Malignant neoplasm of right choroid
C69.32	Malignant neoplasm of left choroid
C69.40	Malignant neoplasm of unspecified ciliary body
C69.41	Malignant neoplasm of right ciliary body
C69.42	Malignant neoplasm of left ciliary body
C69.60	Malignant neoplasm of unspecified orbit
C69.61	Malignant neoplasm of right orbit
C69.62	Malignant neoplasm of left orbit
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

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ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
C81.10	Nodular sclerosis Hodgkin lymphoma, unspecified site
C81.11	Nodular sclerosis Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.12	Nodular sclerosis Hodgkin lymphoma, intrathoracic lymph nodes
C81.13	Nodular sclerosis Hodgkin lymphoma, intra-abdominal lymph nodes
C81.14	Nodular sclerosis Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.15	Nodular sclerosis Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.16	Nodular sclerosis Hodgkin lymphoma, intrapelvic lymph nodes
C81.17	Nodular sclerosis Hodgkin lymphoma, spleen
C81.18	Nodular sclerosis Hodgkin lymphoma, lymph nodes of multiple sites
C81.19	Nodular sclerosis Hodgkin lymphoma, extranodal and solid organ sites
C81.20	Mixed cellularity Hodgkin lymphoma, unspecified site
C81.21	Mixed cellularity Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.22	Mixed cellularity Hodgkin lymphoma, intrathoracic lymph nodes
C81.23	Mixed cellularity Hodgkin lymphoma, intra-abdominal lymph nodes
C81.24	Mixed cellularity Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.25	Mixed cellularity Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.26	Mixed cellularity Hodgkin lymphoma, intrapelvic lymph nodes
C81.27	Mixed cellularity Hodgkin lymphoma, spleen
C81.28	Mixed cellularity Hodgkin lymphoma, lymph nodes of multiple sites
C81.29	Mixed cellularity Hodgkin lymphoma, extranodal and solid organ sites
C81.30	Lymphocyte depleted Hodgkin lymphoma, unspecified site
C81.31	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.32	Lymphocyte depleted Hodgkin lymphoma, intrathoracic lymph nodes
C81.33	Lymphocyte depleted Hodgkin lymphoma, intra-abdominal lymph nodes
C81.34	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.35	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.36	Lymphocyte depleted Hodgkin lymphoma, intrapelvic lymph nodes
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



ICD-10	ICD-10 Description
C81.48	Lymphocyte-rich Hodgkin lymphoma, lymph nodes of multiple sites
C81.49	Lymphocyte-rich Hodgkin lymphoma, extranodal and solid organ sites
C81.70	Other Hodgkin lymphoma unspecified site
C81.71	Other Hodgkin lymphoma lymph nodes of head, face, and neck
C81.72	Other Hodgkin lymphoma intrathoracic lymph nodes
C81.73	Other Hodgkin lymphoma intra-abdominal lymph nodes
C81.74	Other Hodgkin lymphoma lymph nodes of axilla and upper limb
C81.75	Other Hodgkin lymphoma lymph nodes of inguinal region and lower limb
C81.76	Other Hodgkin lymphoma intrapelvic lymph nodes
C81.77	Other Hodgkin lymphoma spleen
C81.78	Other Hodgkin lymphoma lymph nodes of multiple sites
C81.79	Other Hodgkin lymphoma extranodal and solid organ sites
C81.90	Hodgkin lymphoma, unspecified, unspecified site
C81.91	Hodgkin lymphoma, unspecified, lymph nodes of head, face, and neck
C81.92	Hodgkin lymphoma, unspecified, intrathoracic lymph nodes
C81.93	Hodgkin lymphoma, unspecified, intra-abdominal lymph nodes
C81.94	Hodgkin lymphoma, unspecified, lymph nodes of axilla and upper limb
C81.95	Hodgkin lymphoma, unspecified, lymph nodes of inguinal region and lower limb
C81.96	Hodgkin lymphoma, unspecified, intrapelvic lymph nodes
C81.97	Hodgkin lymphoma, unspecified, spleen
C81.98	Hodgkin lymphoma, unspecified, lymph nodes of multiple sites
C81.99	Hodgkin lymphoma, unspecified, extranodal and solid organ sites
C83.90	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

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
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
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
Z85.068	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

ICD-10	ICD-10 Description
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)
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

## PreferredOne Community Health Plan Nondiscrimination Notice

PreferredOne Community Health Plan (“PCHP”) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. PCHP does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

PCHP:

Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact a Grievance Specialist.

If you believe that PCHP has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist  
PreferredOne Community Health Plan  
PO Box 59052  
Minneapolis, MN 55459-0052  
Phone: 1.800.940.5049 (TTY: 763.847.4013)  
Fax: 763.847.4010  
[customerservice@preferredone.com](mailto:customerservice@preferredone.com)

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Room 509F, HHH Building  
Washington, D.C. 20201  
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

## Language Assistance Services

ATTENTION: If you do not speak English, language assistance services, free of charge, are available to you. Call 1.800.940.5049 (TTY: 763.847.4013).

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.800.940.5049 (TTY: 763.847.4013).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.800.940.5049 (TTY: 763.847.4013).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, taiaajiila qarqaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 1.800.940.5049 (TTY: 763.847.4013).

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.800.940.5049 (TTY: 763.847.4013).

注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 1.800.940.5049 (TTY: 763.847.4013)。

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.800.940.5049 (телетайп: 763.847.4013).

ໂບດຊາບ: ຖ້າວ່າທ່ານເວົ້າພາສາລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສຍຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທ 1.800.940.5049 (TTY: 763.847.4013).

ማስታወሻ፡ የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፡ በነጻ ሊያግዝዎት ተዘጋጅተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 1.800.940.5049 (መስማት ለተሳናቸው፡ 763.847.4013 ) .

ဟ်သုာ်ဟ်သး- နမာ်ကတိ၊ ကညီ ကိာ်အယံ၊ နမာ် ကိာ်အတၢ်မၤစၢၤလၢ တလၢာ်ဘၣ်လၢာ်စၢၤ နီတမံၤဘၣ်သန့လီၤ. ကိး 1.800.940.5049 (TTY: 763.847.4013).

**ACHTUNG:** Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.800.940.5049 (TTY: 763.847.4013).

ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតល្បួល គឺអាចមានសំរាប់បំរើអ្នក។ ចរ ទូរស័ព្ទ 1.800.940.5049 (TTY: 763.847.4013)។

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 1.800.940.5049 (رقم هاتف الصم والبكم: 763.847.4013).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.800.940.5049 (TTY: 763.847.4013).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.800.940.5049 (TTY: 763.847.4013), 번으로 전화해 주십시오.

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 1.800.940.5049 (TTY: 763.847.4013).

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PIC:

Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

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- Qualified interpreters
- Information written in other languages

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Grievance Specialist  
PreferredOne Insurance Company  
PO Box 59212  
Minneapolis, MN 55459-0212  
Phone: 1.800.940.5049 (TTY: 763.847.4013)  
Fax: 763.847.4010  
[customerservice@preferredone.com](mailto:customerservice@preferredone.com)

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Room 509F, HHH Building  
Washington, D.C. 20201  
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

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បំពេញ: ប្រសិនបើ អ្នកនិយាយភាសាខ្មែរ, សេវាជំនួយភាសា ដោយមិនគិតថ្លៃ គឺអាចមានសំរាប់អ្នក។ ហៅ 1.800.940.5049 (TTY: 763.847.4013)។

ማስታወሻ: የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፡ በነጻ ሊያገኙበት ተዘጋጅተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 1.800.940.5049 (ማስማት ለተሳናቸው: 763.847.4013)፡፡

ဟံသာဝတီ: နမူနာတို့ ကညီ ကျိအသိ, နမူနာ ကျိအတိအကျတို့ တလက်ကွက်လက်စွာ နှိတ်မိသည့်သို့လည်း ကိ: 1.800.940.5049 (TTY: 763.847.4013).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.800.940.5049 (TTY: 763.847.4013).

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