

Keytruda Qlex™ (pembrolizumab and berahyaluronidase alfa-pmph) (Subcutaneous)

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I. Length of Authorization ^{Δ1}

- Initial: Prior authorization validity will be provided initially for 6 months (180 days), unless otherwise specified.
 - Substitution/Switch-Therapy for Intravenous Pembrolizumab: Prior authorization validity will follow the same parameters for intravenous pembrolizumab based on the indication requested [see *Keytruda IV policy – Document Number: IC-0209* or *Keytruda IV-E policy Document Number: IC-0523, as applicable*]
 - Neoadjuvant therapy for TNBC: Prior authorization validity may be provided for up to a maximum of 24 weeks of therapy.*
 - Neoadjuvant therapy for Head and Neck Squamous Cell Cancer (HNSCC): Prior authorization validity may be provided for up to a maximum of 6 weeks of therapy.
 - Neoadjuvant therapy for NSCLC: Prior authorization validity may be provided for up to a maximum of 12 weeks of therapy
 - Neoadjuvant therapy for Urothelial Carcinoma: Prior authorization validity may be provided for up to a maximum of 9 weeks of therapy (3 doses).
- Renewal: Prior authorization validity may be renewed every 6 months (180 days) thereafter, unless otherwise specified.
 - Substitution/Switch-Therapy for Intravenous Pembrolizumab: Prior authorization validity will follow the same parameters for intravenous pembrolizumab based on the indication requested [see *Keytruda IV policy – Document Number: IC-0209* or *Keytruda IV-E policy Document Number: IC-0523, as applicable*]
 - Biliary Tract Cancer, Urothelial Carcinoma (excluding neoadjuvant/adjvant therapy), Cervical Cancer, cSCC, Endometrial Carcinoma, Esophageal Cancer, Gastric Cancer, HCC, MCC, MSI-H/dMMR Cancer, NSCLC (excluding neoadjuvant/adjvant therapy), RCC (excluding adjuvant therapy), HNSCC (excluding neoadjuvant/adjvant therapy), TMB-H Cancer, TNBC (excluding neoadjuvant/adjvant therapy), Ovarian Cancer, and Malignant Pleural Mesothelioma: Prior authorization validity may be renewed up to a maximum of 24 months of therapy.*

- Neoadjuvant therapy for all the following: Urothelial Carcinoma, TNBC, NSCLC, Head and Neck Squamous Cell Cancer: Prior authorization validity may NOT be renewed.
- Adjuvant therapy for NSCLC (no prior neoadjuvant therapy), RCC, Head and Neck Squamous Cell Cancer, and Cutaneous Melanoma: Prior authorization validity may be renewed up to a maximum of 12 months of therapy.*
- Adjuvant therapy for NSCLC (following neoadjuvant therapy): Prior authorization validity may be renewed for up to a maximum of 39 weeks of therapy.*
- Adjuvant therapy for TNBC: Prior authorization validity may be renewed up to a maximum of 27 weeks of therapy.*
- Adjuvant therapy in Urothelial Carcinoma: Prior authorization validity may be renewed for up to a maximum of 42 weeks of therapy*

***Note: The maximum number of doses is dependent on the dosing frequency and duration of therapy. Refer to Section V for exact dosage.**

Dosing Frequency	Maximum length of therapy	Maximum number of doses
3 weeks	24 weeks	8 doses
	27 weeks	9 doses
	42 weeks	14 doses
	1 year	18 doses
	2 years	35 doses
6 weeks	24 weeks	4 doses
	27 weeks	5 doses
	42 weeks	7 doses
	1 year	9 doses
	2 years	18 doses

II. Dosing Limits

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

- 790 billable units every 6 weeks

III. Initial Approval Criteria ¹

Prior authorization validity is provided in the following conditions:

- Member is at least 18 years of age, unless otherwise specified; **AND**

Universal Criteria

- Member has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy unless otherwise specified ^Δ (Note: Not applicable when used as switch-therapy from intravenous pembrolizumab); **AND**

- Therapy will not be used concomitantly with intravenous pembrolizumab; **AND**
- Therapy will not be used concurrently with intravenous chemotherapy agents (*not applicable when used for FDA approved combination therapy indicated with †*); **AND**
- Intravenous pembrolizumab must be used for members weighing < 55 kg; **AND**

Substitution/Switch-Therapy for Intravenous Pembrolizumab ^{Δ ‡}

- Used as substitution for OR switch-therapy from intravenous pembrolizumab; **AND**
 - Member has previously met criteria for use of intravenous pembrolizumab [*see Keytruda IV policy – Document Number: IC-0209 or Keytruda IV-E policy Document Number: IC-0523, as applicable*]; **AND**
 - Member has been receiving treatment with intravenous pembrolizumab and has shown a beneficial disease response and absence of unacceptable toxicity while on therapy; **OR**
 - Member currently meets criteria for use of intravenous pembrolizumab [*see Keytruda IV policy – Document Number: IC-0209 or Keytruda IV-E policy Document Number: IC-0523, as applicable*]

Biliary Tract Cancer †¹

- Used in combination with gemcitabine and cisplatin; **AND**
- Member has locally advanced unresectable or metastatic disease

Urothelial Carcinoma †¹

- Used in combination with enfortumab vedotin; **AND**
 - Member has locally advanced or metastatic urothelial carcinoma; **OR**
 - Member has muscle invasive bladder cancer (MIBC); **AND**
 - Member is ineligible for cisplatin-containing chemotherapy*; **AND**
 - Used as neoadjuvant treatment, and then continued after cystectomy as adjuvant treatment***; **OR**
- Used as a single agent; **AND**
 - Member has Bacillus Calmette-Guerin (BCG)-unresponsive**, high-risk, non-muscle invasive bladder cancer (NMIBC); **AND**
 - Member has carcinoma in situ (CIS); **AND**
 - Member is ineligible for or has elected not to undergo cystectomy; **OR**
 - Member has locally advanced or metastatic urothelial carcinoma; **AND**
 - Used for disease that progressed during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum containing chemotherapy; **OR**
 - Used for members who are not eligible for any platinum-containing chemotherapy (i.e., both cisplatin and carboplatin-ineligible*)

* **Note:** 10,71,79

- *Cisplatin-ineligible comorbidities may include the following: CrCl < 60 mL/min, ECOG PS ≥ 2 or KPS ≤ 70%, hearing loss of ≥ 25 decibels (dB) at two contiguous frequencies, grade ≥ 2 peripheral neuropathy, or NYHA Heart Failure class ≥ 3. Carboplatin may be substituted for cisplatin in the metastatic setting for cisplatin-ineligible members such as those with a GFR less than 60 mL/min.*
- *Platinum-ineligible comorbidities may include the following: CrCl < 30 mL/min, ECOG PS ≥ 3, grade ≥ 2 peripheral neuropathy, or NYHA Heart Failure class > 3, etc.*

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

***** When used as adjuvant treatment for MIBC, enfortumab vedotin will be given in combination for six doses, and then the member will continue pembrolizumab for the remainder of the adjuvant treatment course.**

Triple-Negative Breast Cancer (TNBC) † Ψ¹

- Member has locally recurrent unresectable or metastatic disease; **AND**
 - Used in combination with chemotherapy; **AND**
 - Tumor expresses PD-L1 (combined positive score [CPS] ≥10) as determined by an FDA-approved or Clinical Laboratory Improvement Amendments (CLIA)-compliant test❖; **OR**
- Member has high-risk early-stage disease; **AND**
 - Used as neoadjuvant therapy in combination with chemotherapy; **OR**
 - Used as adjuvant therapy as a single agent following use as neoadjuvant therapy in combination with chemotherapy

Cervical Cancer †¹

- Member has FIGO 2014 Stage III-IVA disease*; **AND**
 - Used in combination with chemoradiotherapy (CRT); **OR**
- Tumor expresses PD-L1 (CPS ≥1) as determined by an FDA-approved or CLIA-compliant test❖; **AND**
 - Used as a single agent; **AND**
 - Member has recurrent or metastatic disease with disease progression on or after chemotherapy; **OR**
 - Used in combination with chemotherapy, with or without bevacizumab; **AND**
 - Member has persistent, recurrent, or metastatic disease

**FIGO 2014 Stage III-IVA disease is locally advanced cervical cancer involving the lower third of the vagina, with or without extension to pelvic sidewall, or hydronephrosis/non-functioning kidney, or spread to adjacent pelvic organs*

Esophageal Cancer †¹

- Member has locally advanced or metastatic esophageal or gastroesophageal junction (GEJ) (tumors with epicenter 1 to 5 cm above the GEJ) carcinoma; **AND**
 - Tumor expresses PD-L1 (CPS \geq 1) as determined by an FDA-approved or CLIA compliant test❖; **AND**
 - Disease is not amenable to surgical resection or definitive chemoradiation; **AND**
 - Used in combination with platinum- and fluoropyrimidine-based chemotherapy; **OR**
 - Tumor expresses PD-L1 (CPS \geq 10) as determined by an FDA-approved or CLIA compliant test❖; **AND**
 - Used as a single agent after one or more prior lines of systemic therapy; **AND**
 - Used for tumors of squamous cell histology

Gastric Cancer †¹

- Member has locally advanced unresectable or metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma; **AND**
- Tumor expresses PD-L1 (CPS \geq 1) as determined by an FDA-approved or CLIA compliant test❖; **AND**
- Used as first-line therapy; **AND**
 - Member has HER2-positive disease; **AND**
 - Used in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy; **OR**
 - Member has HER2-negative disease; **AND**
 - Used in combination with fluoropyrimidine- and platinum-containing chemotherapy

Head and Neck Squamous Cell Cancer (HNSCC) †¹

- Used as neoadjuvant therapy, followed by adjuvant therapy for resectable locally advanced disease; **AND**
 - Tumor expresses PD-L1 (CPS \geq 1) as determined by an FDA-approved or CLIA-compliant test❖; **AND**
 - Used as a single agent for neoadjuvant treatment; **OR**
 - Used as adjuvant treatment in combination with radiotherapy (with or without cisplatin) following neoadjuvant treatment, and then continued as a single agent; **OR**
- Used as first line therapy for metastatic or unresectable, recurrent disease; **AND**
 - Used in combination with platinum and fluorouracil-containing chemotherapy; **OR**
 - 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 recurrent or metastatic disease; **AND**

- Used as a single agent; **AND**
- Member had disease progression on or after platinum-containing therapy

Hepatocellular Carcinoma (HCC) †¹

- Used as a single agent; **AND**
- Disease is secondary to hepatitis B; **AND**
- Member has received prior systemic therapy other than a PD-1/PD-L1- containing regimen

Renal Cell Carcinoma (RCC) †¹

- Used as first line therapy for advanced disease; **AND**
 - Used in combination with axitinib; **OR**
 - Used in combination with lenvatinib; **OR**
- Used as adjuvant therapy; **AND**
 - Used as a single agent; **AND**
 - Member has intermediate-high or high risk of recurrence following nephrectomy; **OR**
 - Member has undergone nephrectomy and resection of metastatic lesions

Malignant Pleural Mesothelioma (MPM) †¹

- Used in combination with pemetrexed and platinum chemotherapy; **AND**
- Used as first line therapy for unresectable advanced or metastatic disease

Cutaneous Melanoma †¹

- Used as a single agent for unresectable or metastatic disease; **OR**
- Used as a single agent for adjuvant treatment; **AND**
 - Member has stage IIB, IIC, or III melanoma following complete resection; **AND**
 - Member is at least 12 years of age

Merkel Cell Carcinoma (MCC) †¹

- Member is at least 12 years of age; **AND**
- Used as a single agent; **AND**
- Member has recurrent locally advanced or metastatic disease

Non-Small Cell Lung Cancer (NSCLC) †¹

- Used for stage III disease; **AND**
 - Used as first-line therapy as a single agent in members who are not candidates for surgical resection or definitive chemoradiation; **AND**
 - Used in members with tumors expressing PD-L1 (TPS ≥1%) as determined by an FDA-approved or CLIA compliant test❖ and with no EGFR or ALK genomic tumor aberrations; **OR**

- Used as neoadjuvant therapy, followed by adjuvant therapy; **AND**
 - Member has resectable disease (tumors ≥ 4 cm or node positive); **AND**
 - Used in combination with platinum-containing chemotherapy and then continued as a single agent after surgery; **OR**
- Used as adjuvant therapy; **AND**
 - Used as a single agent; **AND**
 - Used following resection and platinum-based chemotherapy; **AND**
 - Member has stage IB (T2a ≥ 4 cm), II, or IIIA disease; **OR**
- Used for metastatic disease; **AND**
 - Used as first-line therapy; **AND**
 - Used in combination with pemetrexed AND either carboplatin or cisplatin for non-squamous cell histology with no EGFR or ALK genomic tumor aberrations; **OR**
 - Used in combination with carboplatin AND either paclitaxel or albumin-bound paclitaxel for squamous cell histology; **OR**
 - Used as a single agent; **AND**
 - Used in members with tumors expressing PD-L1 (TPS $\geq 1\%$) as determined by an FDA-approved or CLIA compliant test❖; **AND**
 - Member has no EGFR or ALK genomic tumor aberrations; **OR**
 - Used as subsequent therapy as a single agent; **AND**
 - Used in members with tumors expressing PD-L1 (TPS $\geq 1\%$) as determined by an FDA-approved or CLIA compliant test❖; **AND**
 - Member has disease progression on or after platinum-containing chemotherapy (*Note: Members with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations*)

Cutaneous Squamous Cell Carcinoma (cSCC) †¹

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

Endometrial Carcinoma †¹

- Used in combination with lenvatinib; **AND**
 - Disease is mismatch repair proficient (pMMR) or NOT microsatellite instability-high (MSI-H) as determined by an FDA-approved or CLIA-compliant test❖; **AND**
 - Used as subsequent therapy for advanced disease; **AND**
 - Member has disease progression following prior systemic therapy in any setting and is not a candidate for curative surgery or radiation; **OR**
- Used in combination with carboplatin and paclitaxel, followed by single agent therapy; **AND**

- Used for primary advanced or recurrent disease (excluding use in members with carcinosarcoma)

Ovarian Cancer †¹

- Member has epithelial ovarian, fallopian tube, or primary peritoneal carcinoma; **AND**
- Tumor expresses PD-L1 (CPS \geq 1) as determined by an FDA-approved or CLIA compliant test❖; **AND**
- Member has platinum-resistant disease; **AND**
- Member has received one or two prior lines of systemic therapy; **AND**
- Used in combination with paclitaxel with or without bevacizumab

Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Cancer †¹

- Used as a single agent; **AND**
- Member has microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), as determined by an FDA-approved or CLIA compliant test❖; **AND**
 - Member has unresectable or metastatic solid tumors; **AND**
 - Used for disease progression following prior treatment and member has no satisfactory alternative treatment options; **AND**
 - Member is at least 12 years of age; **OR**
 - Used as initial therapy for unresectable or metastatic colorectal cancer; **OR**
 - Used as subsequent therapy for advanced endometrial carcinoma; **AND**
 - Member has disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation

Tumor Mutational Burden-High (TMB-H) Cancer †¹

- Member is at least 12 years of age; **AND**
- Member has tumor mutational burden-high (TMB-H) [\geq 10 mutations/megabase (mut/Mb)] disease, as determined by an FDA-approved or CLIA-compliant test❖; **AND**
- Used as a single agent; **AND**
- Pediatric members must not have a diagnosis of TMB-H central nervous system cancer; **AND**
- Member has unresectable or metastatic solid tumors; **AND**
- Used for disease progression following prior treatment and member has no satisfactory alternative treatment options

Ψ ER Scoring Interpretation (following ER testing by validated IHC assay) ¹¹⁶	
Results	Interpretation
– 0% – <1% of nuclei stain	– ER-negative
– 1%–10% of nuclei stain	– ER-low–positive*

– >10% of nuclei stain	– ER-positive
<p><i>*Note: Invasive cancers with between 1%–10% ER positivity are considered ER-low–positive. However, this group is noted to be heterogeneous and the biologic behavior of ER-low–positive cancers may be more similar to ER-negative cancers. This should be considered in decision making for other adjuvant therapy and overall treatment pathway.</i></p>	

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

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

IV. Renewal Criteria ^{Δ 1}

Prior authorization validity can be renewed based upon the following criteria:

- Member continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Duration of authorization has not been exceeded (*refer to Section I*); **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis/renal dysfunction, rash/dermatitis [including Stevens-Johnson syndrome (SJS), drug rash with eosinophilia and systemic symptoms (DRESS), and toxic epidermal necrolysis (TEN)], myocarditis, pericarditis, vasculitis, solid organ transplant rejection, etc.), severe administration-related reactions, complications of allogeneic hematopoietic stem cell transplantation (HSCT), etc.

^Δ Notes:

- Members responding to therapy who relapse ≥ 6 months after discontinuation due to duration (i.e., receipt of 24 months of therapy) are eligible to re-initiate PD-directed therapy.
- Members 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.
- Members who complete adjuvant therapy and progress ≥ 6 months after discontinuation are eligible to re-initiate PD-directed therapy for metastatic disease.
- Members whose tumors, upon re-biopsy, demonstrate a change in actionable mutation (e.g., MSS initial biopsy; MSI-H subsequent biopsy) may be eligible to re-initiate PD-directed therapy and will be evaluated on a case-by-case basis.

V. Dosage/Administration ^{Δ 1}

Indication	Dose
Substitution/Switch-Therapy for Intravenous	<ul style="list-style-type: none"> • Dose will be provided as one of the following:

Pembrolizumab ‡	<ul style="list-style-type: none"> ○ Every 3-week dosing: 395 mg/4,800 units ○ Every 6-week dosing: 790 mg/9,600 units; AND ● Dosing duration will follow the same indication-specific parameters for intravenous pembrolizumab [see Keytruda IV policy – Document Number: IC-0209 or Keytruda IV-E policy Document Number: IC-0523, as applicable]
Urothelial Carcinoma †	<p><u>Neoadjuvant therapy:</u> 395 mg/4,800 units every 3 weeks for 3 doses or until disease progression that precludes curative-intent cystectomy or unacceptable toxicity</p> <p><u>Adjuvant therapy:</u> 395 mg/4,800 units every 3 weeks for 14 doses or 790 mg/9,600 units every 6 weeks for 7 doses or until disease recurrence or unacceptable toxicity</p> <p><u>All other settings:</u> 395 mg/4,800 units every 3 weeks or 790 mg/9,600 units every 6 weeks until disease progression or unacceptable toxicity for up to 24 months</p>
Head and Neck Squamous Cell Cancer †	<p><u>Neoadjuvant therapy:</u> 395 mg/4,800 units every 3 weeks or 790 mg/9,600 units every 6 weeks for 6 weeks or until disease progression that precludes definitive surgery or unacceptable toxicity</p> <p><u>Adjuvant therapy:</u> 395 mg/4,800 units every 3 weeks or 790 mg/9,600 units every 6 weeks up to a maximum of 12 months in members without disease recurrence or unacceptable toxicity</p> <p><u>All other settings:</u> 395 mg/4,800 units every 3 weeks or 790 mg/9,600 units every 6 weeks until disease progression or unacceptable toxicity for up to 24 months</p>
NSCLC †	<p><u>Neoadjuvant followed by adjuvant treatment:</u></p> <ul style="list-style-type: none"> ● <u>Neoadjuvant therapy:</u> 395 mg/4,800 units every 3 weeks or 790 mg/9,600 units every 6 weeks for 12 weeks or until disease progression that precludes definitive surgery or unacceptable toxicity ● <u>Adjuvant therapy:</u> 395 mg/4,800 units every 3 weeks or 790 mg/9,600 units every 6 weeks for 39 weeks or until disease recurrence or unacceptable toxicity <p><u>Adjuvant treatment (no prior neoadjuvant therapy):</u> 395 mg/4,800 units every 3 weeks or 790 mg/9,600 units every 6 weeks up to a maximum of 12 months in members without disease recurrence or unacceptable toxicity</p> <p><u>All other settings:</u> 395 mg/4,800 units every 3 weeks or 790 mg/9,600 units every 6 weeks until disease progression or unacceptable toxicity for up to 24 months</p>
TNBC †	<p><u>Neoadjuvant therapy:</u> 395 mg/4,800 units every 3 weeks or 790 mg/9,600 units every 6 weeks up to a</p>

	<p>maximum of 24 weeks in members without disease progression or unacceptable toxicity (up to 8 doses of 395 mg/4,800 units every 3 weeks or 4 doses of 790 mg/9,600 units every 6 weeks)</p> <p><u>Adjuvant therapy*:</u></p> <p>395 mg/4,800 units every 3 weeks or 790 mg/9,600 units every 6 weeks up to a maximum of 27 weeks in members without disease recurrence or unacceptable toxicity (up to 9 doses of 395 mg/4,800 units every 3 weeks or 5 doses of 790 mg/9,600 units every 6 weeks)</p> <p><i>* Members who experience disease progression or unacceptable toxicity related to pembrolizumab with neoadjuvant treatment in combination with chemotherapy should not receive adjuvant single agent pembrolizumab.</i></p> <p><u>Locally recurrent unresectable or metastatic disease:</u></p> <p>395 mg/4,800 units every 3 weeks or 790 mg/9,600 units every 6 weeks until disease progression or unacceptable toxicity for up to 24 months</p>
Cutaneous Melanoma †	<p><u>Adjuvant therapy:</u></p> <p>395 mg/4,800 units every 3 weeks or 790 mg/9,600 units every 6 weeks up to a maximum of 12 months in members without disease recurrence or unacceptable toxicity</p> <p><u>Unresectable or metastatic disease:</u></p> <p>395 mg/4,800 units every 3 weeks or 790 mg/9,600 units every 6 weeks until disease progression or unacceptable toxicity</p>
Renal Cell Carcinoma †	<p><u>Adjuvant therapy:</u></p> <p>395 mg/4,800 units every 3 weeks or 790 mg/9,600 units every 6 weeks up to a maximum of 12 months in members without disease recurrence or unacceptable toxicity</p> <p><u>First line therapy:</u></p> <p>395 mg/4,800 units every 3 weeks or 790 mg/9,600 units every 6 weeks until disease progression or unacceptable toxicity for up to 24 months</p>
All other indications †	<p>395 mg/4,800 units every 3 weeks or 790 mg/9,600 units every 6 weeks until disease progression or unacceptable toxicity for up to 24 months</p>

VI. Billing Code/Availability Information

HCPCS Code(s):

- J9277 – Injection, pembrolizumab, 1 mg and berahyaluronidase alfa-pmph; 1 billable unit = 1 mg

NDC(s):

- Keytruda Qlex single-dose vial providing 395 mg pembrolizumab and 4,800 units berahyaluronidase alfa per 2.4 mL (165 mg/2,000 units per mL): 00006-3083-xx
- Keytruda Qlex single-dose vial providing 790 mg pembrolizumab and 9,600 units berahyaluronidase alfa per 4.8 mL (165 mg/2,000 units per mL): 00006-5083-xx

VII. References

1. Keytruda Qlex [package insert]. Rahway, NJ; Merck & Co., Inc.; April 2026. Accessed April 2026.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) pembrolizumab. National Comprehensive Cancer Network, 2026. 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 2026.
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 2.2026. National Comprehensive Cancer Network, 2026. 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 2026.
10. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Bladder Cancer. Version 1.2026. National Comprehensive Cancer Network, 2026. 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 2026.
11. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Non-Small Cell Lung Cancer. Version 5.2026. National Comprehensive Cancer

Network, 2026. 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 2026.

12. Ghorani E, Kaur B, Fisher RA, et al. Pembrolizumab is effective for drug-resistant gestational trophoblastic neoplasia. *Lancet*. 2017 Nov 25;390(10110):2343-2345.7
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 85067
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. Intravenous Cancer Drug Waste Issue Brief. Updated February 2024. Retrieved from https://www.hoparx.org/documents/287/HOPA_Drug_Waste_Issue_Brief_-_Updated_02.22.24.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)3240-7. 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, 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.
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-181 study. DOI:
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 3.2025. National Comprehensive Cancer Network, 2026. 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 2026.
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 2.2026. National Comprehensive Cancer Network, 2026. 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 2026.
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 2.2026. National Comprehensive Cancer Network, 2026. 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 2026.
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. Georger 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)30671-0.0
61. Pembrolizumab Improves Progression-Free Survival in Relapsed/Refractory Hodgkin Lymphoma. *Oncologist.* 2020;25 Suppl 1(Suppl 1):S18-S19. doi:10.1634/theoncologist.2020-0561.0
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., Valderrama BP (2026). Treatment of metastatic urothelial cancer of the bladder and urinary tract. In Lerner SP, Shah SM (Eds.), UptoDate. Last updated: Feb 05, 2026. Accessed Mar 30, 2026. 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 1.2026. National Comprehensive Cancer Network, 2026. 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 2026.

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 2.2026. National Comprehensive Cancer Network, 2026. 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 2026.
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.
91. Eskander R, Sill M, Beffa L, et al. Pembrolizumab plus Chemotherapy in Advanced Endometrial Cancer. *N Engl J Med* 2023; 388:2159-2170 DOI: 10.1056/NEJMoa2302312.
92. Marabelle A, Cassier PA, Fakih M, et al. Pembrolizumab for previously treated advanced anal squamous cell carcinoma: results from the non-randomised, multicohort, multicentre, phase 2 KEYNOTE-158 study. *Lancet Gastroenterol Hepatol.* 2022 May;7(5):446-454. doi: 10.1016/S2468-1253(21)00382-4.
93. Hoimes CJ, Flaig TW, Milowsky MI, et al. Enfortumab Vedotin Plus Pembrolizumab in Previously Untreated Advanced Urothelial Cancer. *J Clin Oncol.* 2023 Jan 1;41(1):22-31. doi: 10.1200/JCO.22.01643.
94. Kelley RK, Ueno M, Yoo C, et al; KEYNOTE-966 Investigators. Pembrolizumab in combination with gemcitabine and cisplatin compared with gemcitabine and cisplatin alone for patients with advanced

biliary tract cancer (KEYNOTE-966): a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet*. 2023 Jun 3;401(10391):1853-1865.

95. Ludford K, Ho WJ, Thomas JV, et al. Neoadjuvant pembrolizumab in localized microsatellite instability high/deficient mismatch repair solid tumors. *J Clin Oncol* 2023;41:2181-2190.
96. Bryan LJ, Casulo C, Allen PB, et al. Pembrolizumab added to ifosfamide, carboplatin, and etoposide chemotherapy for relapsed or refractory classic Hodgkin lymphoma: A multi-institutional phase 2 investigator-initiated nonrandomized clinical trial. *JAMA Oncol* 2023;9:683-691.
97. Moskowitz AJ, Shah G, Schöder H, et al. Phase II trial of pembrolizumab plus gemcitabine, vinorelbine, and liposomal doxorubicin as second-line therapy for relapsed or refractory classical Hodgkin lymphoma. *J Clin Oncol* 2021;39:3109-3117.
98. Rha SY, Oh DY, Yañez P, et al. Pembrolizumab plus chemotherapy versus placebo plus chemotherapy for HER2-negative advanced gastric cancer (KEYNOTE-859): a multicentre, randomised, double-blind, phase 3 trial. *Lancet*. 2023 Oct 21; 24(11):1181-1195.
99. 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* 36, no. 6_suppl. DOI: 10.1200/JCO.2018.36.6_suppl.TPS532.
100. Lorusso D, Colombo N, Coleman RL, et al., ENGOT-cx11/KEYNOTE-A18: A phase III, randomized, double-blind study of pembrolizumab with chemoradiotherapy in patients with high-risk locally advanced cervical cancer. *JCO* 38, TPS6096-TPS6096(2020). DOI:10.1200/JCO.2020.38.15_suppl.TPS6096.
101. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Esophageal and Esophagogastric Junction Cancers. Version 2.2026. National Comprehensive Cancer Network, 2026. 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 2026.
102. Metges JP, Kato K, Sun JM, et al. First-line pembrolizumab plus chemotherapy versus chemotherapy in advanced esophageal cancer: Longer-term efficacy, safety, and quality-of-life results from the phase 3 KEYNOTE-590 study. *JCO* 40, 241-241(2022). DOI:10.1200/JCO.2022.40.4_suppl.241.
103. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Gastric Cancer. Version 2.2026. National Comprehensive Cancer Network, 2026. 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 2026.
104. Zsiros E, Lynam S, Attwood KM, et al. Efficacy and Safety of Pembrolizumab in Combination With Bevacizumab and Oral Metronomic Cyclophosphamide in the Treatment of Recurrent Ovarian

- Cancer: A Phase 2 Nonrandomized Clinical Trial. *JAMA Oncol.* 2021 Jan 1;7(1):78-85. doi: 10.1001/jamaoncol.2020.5945. PMID: 33211063; PMCID: PMC7677872.A
105. Poblete S, Caulkins M, Loecher C, et al. Pembrolizumab in combination with bevacizumab and oral metronomic cyclophosphamide for recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer: Real-life clinical experience [abstract]. *Ann Oncol* 2022;33(Suppl): Abstract 569P. DOI:<https://doi.org/10.1016/j.annonc.2022.07.697.A>
106. Sacco AG, Chen R, Worden FP, et al. Pembrolizumab plus cetuximab in patients with recurrent or metastatic head and neck squamous cell carcinoma: an open-label, multi-arm, non-randomised, multicentre, phase 2 trial. *Lancet Oncol.* 2021 Jun;22(6):883-892. doi: 10.1016/S1470-2045(21)00136-4. Epub 2021 May 11. PMID: 33989559.
107. Qin S, Chen Z, Fang W, et al. Pembrolizumab Versus Placebo as Second-Line Therapy in Patients From Asia With Advanced Hepatocellular Carcinoma: A Randomized, Double-Blind, Phase III Trial. *J Clin Oncol.* 2023 Mar 1;41(7):1434-1443. doi: 10.1200/JCO.22.00620. Epub 2022 Dec 1. PMID: 36455168; PMCID: PMC9995104.
108. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Thyroid Carcinoma. Version 1.2025. National Comprehensive Cancer Network, 2026. 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 2026.
109. Dierks C, et al. Phase II ATLEP trial: final results for lenvatinib/pembrolizumab in metastasized anaplastic and poorly differentiated thyroid carcinoma. *Ann Oncol* 2022;33(Suppl S7):S750-S757. doi:10.1016/annonc/annonc1077
110. Ludford K, Ho WJ, Thomas JV, et al. Neoadjuvant pembrolizumab in localized microsatellite instability high/deficient mismatch repair solid tumors. *J Clin Oncol* 2023;41:2181-2190.
111. Powles T, Valderrama B, Gupta S, et al. Enfortumab Vedotin and Pembrolizumab in Untreated Advanced Urothelial Cancer. *N Engl J Med* 2024;390:875-888
112. Patel SP, Othus M, Chen Y, et al. Neoadjuvant-adjuvant or adjuvant-only pembrolizumab in advanced melanoma. *N Engl J Med* 2023;388:813-823
113. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Small Bowel Adenocarcinoma. Version 2.2026. National Comprehensive Cancer Network, 2026. 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 2026.
114. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Rectal Cancer. Version 2.2026. National Comprehensive Cancer Network, 2026. 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 2026.

115. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Colon Cancer. Version 2.2026. National Comprehensive Cancer Network, 2026. 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 2026.
116. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Breast Cancer. Version 2.2026. National Comprehensive Cancer Network, 2026. 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 2026.
117. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Pembrolizumab: Biliary Tract Cancers, BIL12. National Comprehensive Cancer Network, 2026. 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 Guidelines, go online to NCCN.org. Accessed April 2026.
118. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Pembrolizumab: Biliary Tract Cancers, BIL33. National Comprehensive Cancer Network, 2026. 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 Guidelines, go online to NCCN.org. Accessed April 2026.
119. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Pembrolizumab: Melanoma: Cutaneous MEL39. National Comprehensive Cancer Network, 2026. 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 Guidelines, go online to NCCN.org. Accessed April 2026.
120. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Pembrolizumab: Thymomas and Thymic Carcinomas, THYM19. National Comprehensive Cancer Network, 2026. 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 Guidelines, go online to NCCN.org. Accessed April 2026.
121. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Pembrolizumab: Vulvar Cancer, VUL12. National Comprehensive Cancer Network, 2026. 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 Guidelines, go online to NCCN.org. Accessed April 2026.

122. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Pembrolizumab: Adrenal Gland Tumors, AGT9. National Comprehensive Cancer Network, 2026. 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 Guidelines, go online to NCCN.org. Accessed April 2026.
123. Armand P, Murawski N, Molin D, et al. Pembrolizumab in relapsed or refractory Richter syndrome. *Br J Haematol* 2020;190:e117-e120.
124. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Penile Cancer. Version 1.2026. National Comprehensive Cancer Network, 2026. 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 2026.
125. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Head and Neck Cancers. Version 1.2026. National Comprehensive Cancer Network, 2026. 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 2026.
126. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Pembrolizumab: Penile Cancer, PEN19. National Comprehensive Cancer Network, 2026. 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 Guidelines, go online to NCCN.org. Accessed April 2026.
127. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Pembrolizumab: Penile Cancer, PEN20. National Comprehensive Cancer Network, 2026. 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 Guidelines, go online to NCCN.org. Accessed April 2026.
128. Apolo AB, Ballman KV, Sonpavde G, et al. Adjuvant Pembrolizumab versus Observation in Muscle-Invasive Urothelial Carcinoma. *N Engl J Med*. 2025;392(1):45-55
129. French JD, Haugen BR, Worden FP, et al. Combination targeted therapy with pembrolizumab and lenvatinib in progressive, radioiodine-refractory differentiated thyroid cancers. *Clin Cancer Res* 2024;30:3757-3767.
130. National Institutes of Health. Study of Pembrolizumab Given Prior to Surgery and in Combination With Radiotherapy Given Post-surgery for Advanced Head and Neck Squamous Cell Carcinoma (MK-3475-689). Available at: <https://clinicaltrials.gov/study/NCT03765918>.
131. Blay JY, Chevret S, Le Cesne A, et al. Pembrolizumab in patients with rare and ultra-rare sarcomas (AcSé Pembrolizumab): analysis of a subgroup from a non-randomised, open-label, phase 2, basket trial. *Lancet Oncol*. 2023;24(8):892-902. doi:10.1016/S1470-2045(23)00282-6.

132. Vulsteke C, Kaimakliotis H, Danchaivijitr P, et al. LBA2 Perioperative (perioP) enfortumab vedotin (EV) plus pembrolizumab (pembro) in participants (pts) with muscle-invasive bladder cancer (MIBC) who are cisplatin-ineligible: The phase III KEYNOTE-905 study. *Annals of Oncology*. 2025;36:S1763. Abstract.
133. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Bone Cancer. Version 2.2026. National Comprehensive Cancer Network, 2026. 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 2026.
134. National Institutes of Health. Pembrolizumab/placebo plus paclitaxel with or without bevacizumab for platinum-resistant recurrent ovarian cancer (MK-3475-B96/KEYNOTE-B96/ENGOT-ov65). Available at: <https://clinicaltrials.gov/study/NCT05116189>.
135. Mowery YM, Ballman KV, Hong AM, et al. Safety and efficacy of pembrolizumab, radiation therapy, and surgery versus radiation therapy and surgery for stage III soft tissue sarcoma of the extremity (SU2C-SARC032): an open-label, randomised clinical trial. *Lancet*. 2024;404(10467):2053-2064. doi:10.1016/S0140-6736(24)01812-9
136. Altmann J, Schmitt W, Bashian N, Sehouli J. A dramatic response to checkpoint inhibitor in a woman with small cell carcinoma of the hypercalcemic type of the ovary. *Gyn Oncol*. 2024; 181:99-101.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime’s assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

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

ICD-10	ICD-10 Description
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
C05.2	Malignant neoplasm of uvula
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

ICD-10	ICD-10 Description
C17.0	Malignant neoplasm of duodenum
C17.1	Malignant neoplasm of jejunum
C17.2	Malignant neoplasm of ileum
C17.3	Meckel's diverticulum, malignant
C17.8	Malignant neoplasm of overlapping sites of small intestine
C17.9	Malignant neoplasm of small intestine, unspecified
C18.0	Malignant neoplasm of cecum
C18.1	Malignant neoplasm of appendix
C18.2	Malignant neoplasm of ascending colon
C18.3	Malignant neoplasm of hepatic flexure
C18.4	Malignant neoplasm of transverse colon
C18.5	Malignant neoplasm of splenic flexure
C18.6	Malignant neoplasm of descending colon
C18.7	Malignant neoplasm of sigmoid colon
C18.8	Malignant neoplasm of overlapping sites of colon
C18.9	Malignant neoplasm of colon, unspecified
C19	Malignant neoplasm of rectosigmoid junction
C20	Malignant neoplasm of rectum
C21.0	Malignant neoplasm of anus, unspecified
C21.1	Malignant neoplasm of anal canal
C21.2	Malignant neoplasm of cloacogenic zone
C21.8	Malignant neoplasm of overlapping sites of rectum, anus and anal canal
C22.0	Liver cell carcinoma
C22.1	Intrahepatic bile duct carcinoma
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

ICD-10	ICD-10 Description
C25.7	Malignant neoplasm of other parts of pancreas
C25.8	Malignant neoplasm of overlapping sites of pancreas
C25.9	Malignant neoplasm of pancreas, unspecified
C30.0	Malignant neoplasm of nasal cavity
C31.0	Malignant neoplasm of maxillary sinus
C31.1	Malignant neoplasm of ethmoidal sinus
C32.0	Malignant neoplasm of glottis
C32.1	Malignant neoplasm of supraglottis
C32.2	Malignant neoplasm of subglottis
C32.3	Malignant neoplasm of laryngeal cartilage
C32.8	Malignant neoplasm of overlapping sites of larynx
C32.9	Malignant neoplasm of larynx, unspecified
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
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

ICD-10	ICD-10 Description
C40.20	Malignant neoplasm of long bones of unspecified lower limb
C40.21	Malignant neoplasm of long bones of right lower limb
C40.22	Malignant neoplasm of long bones of left lower limb
C40.30	Malignant neoplasm of short bones of unspecified lower limb
C40.31	Malignant neoplasm of short bones of right lower limb
C40.32	Malignant neoplasm of short bones of left lower limb
C40.80	Malignant neoplasm of overlapping sites of bone and articular cartilage of unspecified limb
C40.81	Malignant neoplasm of overlapping sites of bone and articular cartilage of right limb
C40.82	Malignant neoplasm of overlapping sites of bone and articular cartilage of left limb
C40.90	Malignant neoplasm of unspecified bones and articular cartilage of unspecified limb
C40.91	Malignant neoplasm of unspecified bones and articular cartilage of right limb
C40.92	Malignant neoplasm of unspecified bones and articular cartilage of left limb
C41.0	Malignant neoplasm of bones of skull and face
C41.1	Malignant neoplasm of mandible
C41.2	Malignant neoplasm of vertebral column
C41.3	Malignant neoplasm of ribs, sternum and clavicle
C41.4	Malignant neoplasm of pelvic bones, sacrum and coccyx
C41.9	Malignant neoplasm of bone and articular cartilage, unspecified
C43.0	Malignant melanoma of lip
C43.10	Malignant melanoma of unspecified eyelid, including canthus
C43.111	Malignant melanoma of right upper eyelid, including canthus
C43.112	Malignant melanoma of right lower eyelid, including canthus
C43.121	Malignant melanoma of left upper eyelid, including canthus
C43.122	Malignant melanoma of left lower eyelid, including canthus
C43.20	Malignant melanoma of unspecified ear and external auricular canal
C43.21	Malignant melanoma of right ear and external auricular canal
C43.22	Malignant melanoma of left ear and external auricular canal
C43.30	Malignant melanoma of unspecified part of face
C43.31	Malignant melanoma of nose
C43.39	Malignant melanoma of other parts of face
C43.4	Malignant melanoma of scalp and neck
C43.51	Malignant melanoma of anal skin
C43.52	Malignant melanoma of skin of breast
C43.59	Malignant melanoma of other part of trunk
C43.60	Malignant melanoma of unspecified upper limb, including shoulder
C43.61	Malignant melanoma of right upper limb, including shoulder

ICD-10	ICD-10 Description
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
C44.02	Squamous cell carcinoma of skin of lip
C44.121	Squamous cell carcinoma of skin of unspecified eyelid, including canthus
C44.1221	Squamous cell carcinoma of skin of right upper eyelid, including canthus
C44.1222	Squamous cell carcinoma of skin of right lower eyelid, including canthus
C44.1291	Squamous cell carcinoma of skin of left upper eyelid, including canthus
C44.1292	Squamous cell carcinoma of skin of left lower eyelid, including canthus
C44.221	Squamous cell carcinoma of skin of unspecified ear and external auricular canal
C44.222	Squamous cell carcinoma of skin of right ear and external auricular canal
C44.229	Squamous cell carcinoma of skin of left ear and external auricular canal
C44.320	Squamous cell carcinoma of skin of unspecified parts of face
C44.321	Squamous cell carcinoma of skin of nose
C44.329	Squamous cell carcinoma of skin of other parts of face
C44.42	Squamous cell carcinoma of skin of scalp and neck
C44.520	Squamous cell carcinoma of anal skin
C44.521	Squamous cell carcinoma of skin of breast
C44.529	Squamous cell carcinoma of skin of other part of trunk
C44.621	Squamous cell carcinoma of skin of unspecified upper limb, including shoulder
C44.622	Squamous cell carcinoma of skin of right upper limb, including shoulder
C44.629	Squamous cell carcinoma of skin of left upper limb, including shoulder
C44.721	Squamous cell carcinoma of skin of unspecified lower limb, including hip
C44.722	Squamous cell carcinoma of skin of right lower limb, including hip
C44.729	Squamous cell carcinoma of skin of left lower limb, including hip
C44.82	Squamous cell carcinoma of overlapping sites of skin
C44.92	Squamous cell carcinoma of skin, unspecified
C45.0	Mesothelioma of pleura
C45.1	Mesothelioma of peritoneum
C45.2	Mesothelioma of pericardium
C45.7	Mesothelioma of other sites
C45.9	Mesothelioma, unspecified
C46.0	Kaposi's sarcoma of skin

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

ICD-10	ICD-10 Description
C49.6	Malignant neoplasm of connective and soft tissue of trunk, unspecified
C49.8	Malignant neoplasm of overlapping sites of connective and soft tissue
C49.9	Malignant neoplasm of connective and soft tissue, unspecified
C4A.0	Merkel cell carcinoma of lip
C4A.10	Merkel cell carcinoma of eyelid, including canthus
C4A.111	Merkel cell carcinoma of right upper eyelid, including canthus
C4A.112	Merkel cell carcinoma of right lower eyelid, including canthus
C4A.121	Merkel cell carcinoma of left upper eyelid, including canthus
C4A.122	Merkel cell carcinoma of left lower eyelid, including canthus
C4A.20	Merkel cell carcinoma of unspecified ear and external auricular canal
C4A.21	Merkel cell carcinoma of right ear and external auricular canal
C4A.22	Merkel cell carcinoma of left ear and external auricular canal
C4A.30	Merkel cell carcinoma of unspecified part of face
C4A.31	Merkel cell carcinoma of nose
C4A.39	Merkel cell carcinoma of other parts of face
C4A.4	Merkel cell carcinoma of scalp and neck
C4A.51	Merkel cell carcinoma of anal skin
C4A.52	Merkel cell carcinoma of skin of breast
C4A.59	Merkel cell carcinoma of other part of trunk
C4A.60	Merkel cell carcinoma of unspecified upper limb, including shoulder
C4A.61	Merkel cell carcinoma of right upper limb, including shoulder
C4A.62	Merkel cell carcinoma of left upper limb, including shoulder
C4A.70	Merkel cell carcinoma of unspecified lower limb, including hip
C4A.71	Merkel cell carcinoma of right lower limb, including hip
C4A.72	Merkel cell carcinoma of left lower limb, including hip
C4A.8	Merkel cell carcinoma of overlapping sites
C4A.9	Merkel cell carcinoma, unspecified
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.021	Malignant neoplasm of nipple and areola, right male breast
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.029	Malignant neoplasm of nipple and areola, unspecified male breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.119	Malignant neoplasm of central portion of unspecified female breast

ICD-10	ICD-10 Description
C50.121	Malignant neoplasm of central portion of right male breast
C50.122	Malignant neoplasm of central portion of left male breast
C50.129	Malignant neoplasm of central portion of unspecified male breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.229	Malignant neoplasm of upper-inner quadrant of unspecified male breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.329	Malignant neoplasm of lower-inner quadrant of unspecified male breast
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.529	Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.629	Malignant neoplasm of axillary tail of unspecified male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast

ICD-10	ICD-10 Description
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
C50.A0	Malignant inflammatory neoplasm of unspecified breast
C50.A1	Malignant inflammatory neoplasm of right breast
C50.A2	Malignant inflammatory neoplasm of left breast
C51.0	Malignant neoplasm of labium majus
C51.1	Malignant neoplasm of labium minus
C51.2	Malignant neoplasm of clitoris
C51.8	Malignant neoplasm of overlapping sites of vulva
C51.9	Malignant neoplasm of vulva, unspecified
C52	Malignant neoplasm of vagina
C53.0	Malignant neoplasm of endocervix
C53.1	Malignant neoplasm of exocervix
C53.8	Malignant neoplasm of overlapping sites of cervix uteri
C53.9	Malignant neoplasm of cervix uteri, unspecified
C54.0	Malignant neoplasm of isthmus uteri
C54.1	Malignant neoplasm of endometrium
C54.2	Malignant neoplasm of myometrium
C54.3	Malignant neoplasm of fundus uteri
C54.8	Malignant neoplasm of overlapping sites of corpus uteri
C54.9	Malignant neoplasm of corpus uteri, unspecified
C55	Malignant neoplasm of uterus, part unspecified
C56.1	Malignant neoplasm of right ovary
C56.2	Malignant neoplasm of left ovary
C56.3	Malignant neoplasm of bilateral ovaries
C56.9	Malignant neoplasm of unspecified ovary
C57.00	Malignant neoplasm of unspecified fallopian tube
C57.01	Malignant neoplasm of right fallopian tube
C57.02	Malignant neoplasm of left fallopian tube

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
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
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
C78.00	Secondary malignant neoplasm of unspecified lung
C78.01	Secondary malignant neoplasm of right lung
C78.02	Secondary malignant neoplasm of left lung

ICD-10	ICD-10 Description
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
C79.70	Secondary malignant neoplasm of unspecified adrenal gland
C79.71	Secondary malignant neoplasm of right adrenal gland
C79.72	Secondary malignant neoplasm of left adrenal gland
C7A.1	Malignant poorly differentiated neuroendocrine tumors
C7A.8	Other malignant neuroendocrine tumors
C7B.00	Secondary carcinoid tumors unspecified site
C7B.01	Secondary carcinoid tumors of distant lymph nodes
C7B.02	Secondary carcinoid tumors of liver
C7B.03	Secondary carcinoid tumors of bone
C7B.04	Secondary carcinoid tumors of peritoneum
C7B.1	Secondary Merkel cell carcinoma
C7B.8	Other secondary neuroendocrine tumors
C80.0	Disseminated malignant neoplasm, unspecified
C80.1	Malignant (primary) neoplasm, unspecified
C81.10	Nodular sclerosis Hodgkin lymphoma, unspecified site
C81.11	Nodular sclerosis Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.12	Nodular sclerosis Hodgkin lymphoma, intrathoracic lymph nodes
C81.13	Nodular sclerosis Hodgkin lymphoma, intra-abdominal lymph nodes
C81.14	Nodular sclerosis Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.15	Nodular sclerosis Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.16	Nodular sclerosis Hodgkin lymphoma, intrapelvic lymph nodes
C81.17	Nodular sclerosis Hodgkin lymphoma, spleen
C81.18	Nodular sclerosis Hodgkin lymphoma, lymph nodes of multiple sites
C81.19	Nodular sclerosis Hodgkin lymphoma, extranodal and solid organ sites
C81.20	Mixed cellularity Hodgkin lymphoma, unspecified site
C81.21	Mixed cellularity Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.22	Mixed cellularity Hodgkin lymphoma, intrathoracic lymph nodes
C81.23	Mixed cellularity Hodgkin lymphoma, intra-abdominal lymph nodes
C81.24	Mixed cellularity Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.25	Mixed cellularity Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.26	Mixed cellularity Hodgkin lymphoma, intrapelvic lymph nodes
C81.27	Mixed cellularity Hodgkin lymphoma, spleen
C81.28	Mixed cellularity Hodgkin lymphoma, lymph nodes of multiple sites

ICD-10	ICD-10 Description
C81.29	Mixed cellularity Hodgkin lymphoma, extranodal and solid organ sites
C81.30	Lymphocyte depleted Hodgkin lymphoma, unspecified site
C81.31	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.32	Lymphocyte depleted Hodgkin lymphoma, intrathoracic lymph nodes
C81.33	Lymphocyte depleted Hodgkin lymphoma, intra-abdominal lymph nodes
C81.34	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.35	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.36	Lymphocyte depleted Hodgkin lymphoma, intrapelvic lymph nodes
C81.37	Lymphocyte depleted Hodgkin lymphoma, spleen
C81.38	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of multiple sites
C81.39	Lymphocyte depleted Hodgkin lymphoma, extranodal and solid organ sites
C81.40	Lymphocyte-rich Hodgkin lymphoma, unspecified site
C81.41	Lymphocyte-rich Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.42	Lymphocyte-rich Hodgkin lymphoma, intrathoracic lymph nodes
C81.43	Lymphocyte-rich Hodgkin lymphoma, intra-abdominal lymph nodes
C81.44	Lymphocyte-rich Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.45	Lymphocyte-rich Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.46	Lymphocyte-rich Hodgkin lymphoma, intrapelvic lymph nodes
C81.47	Lymphocyte-rich Hodgkin lymphoma, spleen
C81.48	Lymphocyte-rich Hodgkin lymphoma, lymph nodes of multiple sites
C81.49	Lymphocyte-rich Hodgkin lymphoma, extranodal and solid organ sites
C81.70	Other Hodgkin lymphoma unspecified site
C81.71	Other Hodgkin lymphoma lymph nodes of head, face, and neck
C81.72	Other Hodgkin lymphoma intrathoracic lymph nodes
C81.73	Other Hodgkin lymphoma intra-abdominal lymph nodes
C81.74	Other Hodgkin lymphoma lymph nodes of axilla and upper limb
C81.75	Other Hodgkin lymphoma lymph nodes of inguinal region and lower limb
C81.76	Other Hodgkin lymphoma intrapelvic lymph nodes
C81.77	Other Hodgkin lymphoma spleen
C81.78	Other Hodgkin lymphoma lymph nodes of multiple sites
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

ICD-10	ICD-10 Description
C81.95	Hodgkin lymphoma, unspecified, lymph nodes of inguinal region and lower limb
C81.96	Hodgkin lymphoma, unspecified, intrapelvic lymph nodes
C81.97	Hodgkin lymphoma, unspecified, spleen
C81.98	Hodgkin lymphoma, unspecified, lymph nodes of multiple sites
C81.99	Hodgkin lymphoma, unspecified, extranodal and solid organ sites
C83.00	Small cell B-cell lymphoma, unspecified site
C83.01	Small cell B-cell lymphoma, lymph nodes of head, face, and neck
C83.02	Small cell B-cell lymphoma, intrathoracic lymph nodes
C83.03	Small cell B-cell lymphoma, intra-abdominal lymph nodes
C83.04	Small cell B-cell lymphoma, lymph nodes of axilla and upper limb
C83.05	Small cell B-cell lymphoma, lymph nodes of inguinal region and lower limb
C83.06	Small cell B-cell lymphoma, intrapelvic lymph nodes
C83.07	Small cell B-cell lymphoma, spleen
C83.08	Small cell B-cell lymphoma, lymph nodes of multiple sites
C83.09	Small cell B-cell lymphoma, extranodal and solid organ sites
C83.30	Diffuse large B-cell lymphoma, unspecified site
C83.31	Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck
C83.32	Diffuse large B-cell lymphoma, intrathoracic lymph nodes
C83.33	Diffuse large B-cell lymphoma, intra-abdominal lymph nodes
C83.34	Diffuse large B-cell lymphoma, lymph nodes of axilla and upper limb
C83.35	Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C83.36	Diffuse large B-cell lymphoma, intrapelvic lymph nodes
C83.37	Diffuse large B-cell lymphoma, spleen
C83.38	Diffuse large B-cell lymphoma, lymph nodes of multiple sites
C83.39	Diffuse large B-cell lymphoma, extranodal and solid organ sites
C83.90	Non-follicular (diffuse) lymphoma, unspecified, unspecified site
C83.91	Non-follicular (diffuse) lymphoma, unspecified, lymph nodes of head, face, and neck
C83.92	Non-follicular (diffuse) lymphoma, unspecified, intrathoracic lymph nodes
C83.93	Non-follicular (diffuse) lymphoma, unspecified, intra-abdominal lymph nodes
C83.94	Non-follicular (diffuse) lymphoma, unspecified, lymph nodes of axilla and upper limb
C83.95	Non-follicular (diffuse) lymphoma, unspecified, lymph nodes of inguinal region and lower limb
C83.96	Non-follicular (diffuse) lymphoma, unspecified, intrapelvic lymph nodes
C83.97	Non-follicular (diffuse) lymphoma, unspecified, spleen
C83.98	Non-follicular (diffuse) lymphoma, unspecified, lymph nodes of multiple sites
C83.99	Non-follicular (diffuse) lymphoma, unspecified, extranodal and solid organ sites
C84.00	Mycosis fungoides, unspecified site

ICD-10	ICD-10 Description
C84.01	Mycosis fungoides, lymph nodes of head, face, and neck
C84.02	Mycosis fungoides, intrathoracic lymph nodes
C84.03	Mycosis fungoides, intra-abdominal lymph nodes
C84.04	Mycosis fungoides, lymph nodes of axilla and upper limb
C84.05	Mycosis fungoides, lymph nodes of inguinal region and lower limb
C84.06	Mycosis fungoides, intrapelvic lymph nodes
C84.07	Mycosis fungoides, spleen
C84.08	Mycosis fungoides, lymph nodes of multiple sites
C84.09	Mycosis fungoides, extranodal and solid organ sites
C84.10	Sézary disease, unspecified site
C84.11	Sézary disease, lymph nodes of head, face, and neck
C84.12	Sézary disease, intrathoracic lymph nodes
C84.13	Sézary disease, intra-abdominal lymph nodes
C84.14	Sézary disease, lymph nodes of axilla and upper limb
C84.15	Sézary disease, lymph nodes of inguinal region and lower limb
C84.16	Sézary disease, intrapelvic lymph nodes
C84.17	Sézary disease, spleen
C84.18	Sézary disease, lymph nodes of multiple sites
C84.19	Sézary disease, extranodal and solid organ sites
C84.90	Mature T/NK-cell lymphomas, unspecified site
C84.91	Mature T/NK-cell lymphomas, lymph nodes of head, face, and neck
C84.92	Mature T/NK-cell lymphomas, intrathoracic lymph nodes
C84.93	Mature T/NK-cell lymphomas, intra-abdominal lymph nodes
C84.94	Mature T/NK-cell lymphomas, lymph nodes of axilla and upper limb
C84.95	Mature T/NK-cell lymphomas, lymph nodes of inguinal region and lower limb
C84.96	Mature T/NK-cell lymphomas, intrapelvic lymph nodes
C84.97	Mature T/NK-cell lymphomas, spleen
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

ICD-10	ICD-10 Description
C84.Z7	Other mature T/NK-cell lymphomas, spleen
C84.Z8	Other mature T/NK-cell lymphomas, lymph nodes of multiple sites
C84.Z9	Other mature T/NK-cell lymphomas, extranodal and solid organ sites
C85.20	Mediastinal (thymic) large B-cell lymphoma, unspecified site
C85.21	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of head, face and neck
C85.22	Mediastinal (thymic) large B-cell lymphoma, intrathoracic lymph nodes
C85.23	Mediastinal (thymic) large B-cell lymphoma, intra-abdominal lymph nodes
C85.24	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of axilla and upper limb
C85.25	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C85.26	Mediastinal (thymic) large B-cell lymphoma, intrapelvic lymph nodes
C85.27	Mediastinal (thymic) large B-cell lymphoma, spleen
C85.28	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of multiple sites
C85.29	Mediastinal (thymic) large B-cell lymphoma, extranodal and solid organ sites
C86.00	Extranodal NK/T-cell lymphoma, nasal type not having achieved remission
C86.60	Primary cutaneous CD30-positive T-cell proliferations not having achieved remission
C91.10	Chronic lymphocytic leukemia of B-cell type not having achieved remission
C91.12	Chronic lymphocytic leukemia of B-cell type in relapse
D09.0	Carcinoma in situ of bladder
D15.0	Benign neoplasm of other and unspecified intrathoracic organs
D37.02	Neoplasm of uncertain behavior of tongue
D37.031	Neoplasm of uncertain behavior of the sublingual salivary glands
D37.032	Neoplasm of uncertain behavior of the submandibular salivary glands
D37.039	Neoplasm of uncertain behavior of the major salivary glands, unspecified
D37.04	Neoplasm of uncertain behavior of the minor salivary glands
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
D37.3	Neoplasm of uncertain behavior of appendix
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
D48.60	Neoplasm of uncertain behavior of unspecified breast

ICD-10	ICD-10 Description
D48.61	Neoplasm of uncertain behavior of right breast
D48.62	Neoplasm of uncertain behavior of left breast
O01.9	Hydatidiform mole, unspecified
Z85.00	Personal history of malignant neoplasm of unspecified digestive organ
Z85.01	Personal history of malignant neoplasm of esophagus
Z85.028	Personal history of other malignant neoplasm of stomach
Z85.038	Personal history of other malignant neoplasm of large intestine
Z85.068	Personal history of other malignant neoplasm of small intestine
Z85.07	Personal history of malignant neoplasm of pancreas
Z85.09	Personal history of malignant neoplasm of other digestive organs
Z85.118	Personal history of other malignant neoplasm of bronchus and lung
Z85.12	Personal history of malignant neoplasm of trachea
Z85.22	Personal history of malignant neoplasm of nasal cavities, middle ear, and accessory sinuses
Z85.238	Personal history of other malignant neoplasm of thymus
Z85.3	Personal history of malignant neoplasm of breast
Z85.42	Personal history of malignant neoplasm of other parts of uterus
Z85.43	Personal history of malignant neoplasm of ovary
Z85.46	Personal history of malignant neoplasm of prostate
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
Z85.810	Personal history of malignant neoplasm of tongue
Z85.818	Personal history of malignant neoplasm of other sites of lip, oral cavity, and pharynx
Z85.820	Personal history of malignant melanoma of skin
Z85.821	Personal history of Merkel cell carcinoma
Z85.830	Personal history of malignant neoplasm of bone
Z85.831	Personal history of malignant neoplasm of soft tissue
Z85.841	Personal history of malignant neoplasm of brain
Z85.848	Personal history of malignant neoplasm of other parts of nervous tissue
Z85.850	Personal history of malignant neoplasm of thyroid
Z85.858	Personal history of malignant neoplasm of other endocrine glands

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

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local

Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents:

<https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

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

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
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
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC