Pembrolizumab (Keytruda®)	Place of Service Office Administration Outpatient Facility Infusion Administration Infusion Center Administration HCPCS: J9271 per 1 mg

Condition(s) listed in policy (*see criteria for details*)

- Appendiceal carcinoma
- Adrenocortical carcinoma
- Anal cancer
- Anaplastic large cell lymphoma (ALCL), cutaneous
- Biliary tract cancers (gallbladder cancer and intrahepatic and extrahepatic cholangiocarcinomas
- Breast cancer (triple negative)
- Cervical cancer
- Colorectal cancer
- Cutaneous squamous cell carcinoma
- Endometrial cancer
- Esophageal cancer
- Esophagogastric junction cancer
- Extranodal NK/T-cell lymphoma, nasal type
- Gastric cancer
- Gestational trophoblastic neoplasia
- Head and neck squamous cell carcinoma
- Hepatocellular carcinoma
- Hodgkin lymphoma, classical
- Kaposi sarcoma
- Melanoma: cutaneous
- Melanoma: uveal
- Merkel cell carcinoma
- Mycosis fungoides or Sezary syndrome
- Non-muscle invasive bladder cancer (NMIBC)
- Non-small cell lung cancer
- Primary mediastinal large B-cell lymphoma
- Renal cell carcinoma
- Small cell lung cancer
- Soft tissue sarcoma
- Solid tumor, dMMR/ MSI-H or TMB-H
- Thymic carcinoma
- Urothelial carcinoma
- Vulvar cancer

AHFS therapeutic class: Antineoplastic Agents
Mechanism of action: Human programmed death receptor-1 (PD-1) blocking antibody

(1) Special Instructions and pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Keytruda ® (pembrolizumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Appendiceal carcinoma or Colorectal cancer

1. Patient has defective mismatch repair/high microsatellite instability (dMMR/ MSI-H), **AND**
2. Being used as a single agent, **AND**
3. Meets one of the following:
    a. Being used as neoadjuvant treatment of clinical T4b disease, or
    b. Disease is locally unresectable or medically inoperable, or
    c. Unresectable advanced, metastatic, or metachronous metastatic disease, and patient has not received prior treatment with PD-1/ PD-L1 immune checkpoint inhibitor therapy

Covered Doses
Up to 200 mg IV every 3 weeks, OR up to 400 mg IV every 6 weeks

Coverage Period
Indefinite

ICD-10:
C17.0-C17.2, C17.8, C17.9, C18.0-C18.9, C19, C20, C21.8

Adrenocortical carcinoma

1. Disease is locoregional unresectable or metastatic, **AND**
2. Being used with or without mitotane

Covered Doses
Up to 200 mg IV every 3 weeks, or up to 400 mg IV every 6 weeks

Coverage Period
Indefinite

ICD-10:
C74.00-C74.02, C74.90-C74.92, C7B.00-C7B.04, C7B.8, Z85.858

Anal cancer

1. Metastatic disease, **AND**
2. Used for subsequent treatment of metastatic cancer, **AND**

3. Being used as a single agent

Covered Doses
Up to 200 mg IV every 3 weeks, or up to 400 mg IV every 6 weeks

Coverage Period
Indefinite

ICD-10:
C21.0, C21.1, C21.2, C21.8

Anaplastic large cell lymphoma (ALCL), cutaneous

1. Being used for primary cutaneous ALCL with multifocal lesions, or cutaneous ALCL with regional node (N1), **AND**
2. Disease is relapsed or refractory, **AND**
3. Being used as a single agent

Covered Doses
Up to 200 mg IV every 3 weeks, or up to 400 mg IV every 6 weeks

Coverage Period
Indefinite

ICD-10:
C86.6

Biliary tract cancers (gallbladder cancer and intrahepatic and extrahepatic cholangiocarcinomas)

1. Disease is locally advanced unresectable, resected gross residual (R2), or metastatic, **AND**
2. Being used in combination with gemcitabine and cisplatin

Covered Doses
Up to 200 mg IV every 3 weeks, or up to 400 mg IV every 6 weeks

Coverage Period
Indefinite

ICD-10:
C22.1, C23, C24, C24.8, C24.9

Breast cancer (triple-negative)

1. HER2-negative, **AND**
2. HR negativity (ER and PR negativity), **AND**
3. Meets either of the following:
    a. Used for neoadjuvant and adjuvant treatment, OR
    b. Recurrent unresectable or metastatic disease and all the following:

i. Used in combination with chemotherapy, AND
ii. Tumor has PD-L1 expression ≥ 10 on the Combined Positive Score (CPS) determined by an FDA approved test

Covered Doses
Up to 200 mg IV every 3 weeks, or up to 400 mg IV every 6 weeks

Coverage Period
Neoadjuvant: 24 weeks (8 doses of 200 mg every 3 weeks or 4 doses of 400 mg every 6 weeks)
Adjuvant: 27 weeks (9 doses of 200 mg every 3 weeks or 5 doses of 400 mg every 6 weeks)
Recurrent unresectable or metastatic: Indefinite

ICD-10:
C50.011, C50.012, C50.019, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.521, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929

Cervical cancer

1. Either of the following:
   a. Disease is PD-L1 positive (combined positive score [CPS] ≥1) and all the following:
      i. Persistent, recurrent, or metastatic disease, **AND**
      ii. One of the following:
         1. Being used as a single agent for second-line or subsequent treatment after chemotherapy for recurrent or metastatic disease, or
         2. Being used in combination with cisplatin or carboplatin, paclitaxel, and with or without bevacizumab

   OR

   b. Disease is Stage III-IV and being used in combination with chemotherapy

Covered Doses
Up to 200 mg IV every 3 weeks, OR up to 400 mg IV every 6 weeks

Coverage Period
Indefinite

ICD-10:
C53.0, C53.1, C53.8, C53.9, C79.89, C79.9, Z80.49

Cutaneous squamous cell carcinoma

1. Recurrent, locally advanced, or metastatic disease, **AND**
2. Being used as a single agent

Covered Doses
Adults:
Up to 200 mg IV every 3 weeks, OR up to 400 mg IV every 6 weeks

Coverage Period
Indefinite

ICD-10:
C44.02, C44.121, C44.1221, C44.1222, C44.1291, C44.1292, C44.221, C44.222, C44.229, C44.320, C44.321, C44.329, C44.42, C44.520, C44.521, C44.529, C44.621, C44.622, C44.629, C44.721, C44.722, C44.729, C44.82, C44.92

Endometrial cancer

1. One of the following:
    a. Being used as a single agent therapy and all of the following:
        i. Disease has progressed on one or more prior lines of systemic therapy, and
        ii. Patient has defective mismatch repair or high microsatellite instability,

    OR

    b. Being used in combination with carboplatin and paclitaxel for stage III or IV (metastatic), or recurrent disease,

    OR

    c. Being used in combination with Lenvima and patient does not have defective mismatch repair or high microsatellite instability

Covered Doses
Up to 200 mg IV every 3 weeks, OR up to 400 mg IV every 6 weeks

Coverage Period
Indefinite

ICD-10:
C54.0-C54.3, C54.8, C54.9, C55

Esophageal cancer, Esophagogastric junction (EGJ) cancer and Gastric cancer

1. One of the following:
    a. Disease is unresectable locally advanced, recurrent, or metastatic, OR
    b. Patient is not a surgical candidate

AND

2. One of the following:
    a. Esophageal or EGJ cancer, and being used in combination with a fluoropyrimidine- (fluorouracil or capecitabine) and a platinum-containing (oxaliplatin or cisplatin) chemotherapy for (regardless of histology), OR
    b. HER 2+ gastric or EGJ adenocarcinoma, and being used in combination with trastuzumab, fluoropyrimidine- (fluorouracil or capecitabine), and a platinum-containing (oxaliplatin or

cisplatin) chemotherapy, OR

c. HER 2-negative gastric or EGJ adenocarcinoma and all the following:
    i. Being used as first-line treatment, and
    ii. Being used in combination with fluoropyrimidine- and platinum-containing chemotherapy,

    OR

d. Esophageal squamous cell carcinoma and all the following:
    i. Being used as a single agent, and
    ii. Disease progression on 1 or more prior lines of systemic therapy, and
    iii. Tumor has PD-L1 expression ≥ 10 on the Combined Positive Score (CPS) as determined by the PD-L1 IHC 22C3 pharmDx test

Covered Doses
Up to 200 mg IV every 3 weeks, OR up to 400 mg IV every 6 weeks

Coverage Period
Indefinite

ICD-10:
C15.3-C15.5, C15.8, C15.9, C16.0-C16.6, C16.8, C16.9, D37.1, D37.8, D37.9, Z85.00, Z85.01, Z85.028

Extranodal NK/T-cell lymphoma, nasal type

1. Relapsed or refractory disease, **AND**
2. Being used as a single agent

Covered Doses
Up to 200 mg IV every 3 weeks, OR up to 400 mg IV every 6 weeks

Coverage Period
Indefinite

ICD-10:
C15.3-C15.5, C15.8, C15.9, C16.0, D37.8, D37.9, Z85.00, Z85.01

Gestational trophoblastic neoplasia

1. Being used as single-agent therapy, **AND**
2. Disease is multiagent chemotherapy-resistant

Covered Doses
Up to 200 mg IV every 3 weeks, OR up to 400 mg IV every 6 weeks

Coverage Period

Indefinite

ICD-10:
D39.2, C58

Head and neck cancers

1. Disease is unresectable, recurrent, persistent, or metastatic, **AND**
2. One of the following:
    a. Being used as a single agent and one of the following:
        i. For first line treatment or subsequent treatment if not previously used, and tumors express PD-L1 (Combined Positive Score [CPS] ≥1) as determined by the PD-L1 IHC 22C3 pharmDx kit, or
        ii. As subsequent line treatment after disease progression on or after platinum-containing chemotherapy and Patient has not received prior treatment with PD-1/PD-L1 immune checkpoint inhibitor therapy

    OR

    b. Being used in combination with platinum and fluorouracil (FU) or docetaxel, OR
    c. Being used in combination with cisplatin and gemcitabine for nasopharyngeal cancer

Covered Doses
Up to 200 mg IV every 3 weeks, OR up to 400 mg IV every 6 weeks

Coverage Period
Indefinite

ICD-10:
C00.0-C00.6, C00.8, C01, C02.0-C02.4, C02.8, C02.9, C03.0, C03.1, C03.9, C04.0, C04.1, C04.8, C04.9, C05.0, C05.1, C06.0, C06.2, C06.80, C06.89, C06.9, C09.0, C09.1, C09.8, C09.9, C10.3, C11.0-C11.3, C11.8, C11.9, C12, C13.0-C13.2, C13.8, C13.9, C14.0, C14.2, C14.8, C31.0, C31.1, C32.0-C32.3, C32.8, C32.9, C44.00, C44.02, C44.09, C76.0, C77.0, C78.89, D37.01, D37.02, D37.05, D37.09, D38.0, D38.5, D38.6, Z85.21, Z85.22, Z85.810, Z85.818, Z85.819

Hepatocellular carcinoma

1. Disease has progressed on or after prior systemic therapy, **AND**
2. Being used as a single agent

Covered Doses
Up to 200 mg IV every 3 weeks, OR up to 400 mg IV every 6 weeks

Coverage Period
Indefinite

ICD-10:
C22.0, C22.8, C22.9

Hodgkin lymphoma, classical

1. One of the following:
    a. Being used as a single agent, or
    b. Being used in combination with GVD (gemcitabine, vinorelbine, liposomal doxorubicin), or
    c. Being used in combination with ICE (ifosfamide, carboplatin, etoposide)

    AND
2. One of the following:
    a. Disease has relapsed, refractory or progressive, OR
    b. Being used as palliative treatment in adults greater than 60 years of age

Covered Doses
Adults:
Up to 200 mg IV every 3 weeks, OR up to 400 mg IV every 6 weeks
Pediatrics:
Up to 2 mg/kg (up to 200 mg) every 3 weeks

Coverage Period
Indefinite

ICD-10:
C81.10-C81.19, C81.20-C81.29, C81.30-C81.39, C81.40-C81.49, C81.70-C81.79, C81.90-C81.99, Z85.71

Kaposi sarcoma

1. Endemic or classic subtype, **AND**
2. Relapsed/refractory advanced cutaneous, oral, visceral, or nodal disease, **AND**
3. Being used as a single agent for subsequent therapy

Covered Doses
Up to 200 mg IV every 3 weeks for 8 cycles (8 doses)

Coverage Period
6 months

ICD-10:
C46.0, C46.1, C46.2, C46.3, C46.4, C46.50, C46.51, C46.52, C46.7, C46.9

Melanoma: cutaneous

1. Meets either of the following:
    a. Adjuvant treatment of disease as a single agent, **OR**
    b. Single agent for treatment of limited resectable disease of one of the following:
        i. stage III disease with clinical satellite/in-transit metastases, or
        ii. local satellite/in-transit recurrence,

        OR
    c. Metastatic or unresectable disease and meets one of the following:

i. Used as a single agent, OR
ii. Used in combination with low-dose ipilimumab (1 mg/kg) or lenvatinib, and has had disease progression on an anti-PD-1/anti-PD-L1 immunotherapy drug, OR
iii. Used in combination with Tafinlar and Mekinist for BRAF V600 activating mutation as subsequent or re-induction therapy

Covered Doses
Up to 200 mg IV every 3 weeks, OR up to 400 mg IV every 6 weeks

Coverage Period
Adjuvant: Up to 1 year
Metastatic or unresectable: Indefinite

ICD-10:
C43.0, C43.10-C43.12, C43.20-C43.22, C43.30, C43.31, C43.39, C43.4, C43.51, C43.52, C43.59-C43.62, C43.70-C43.72, C43.8, C43.9

Melanoma: uveal

1. Disease is unresectable or metastatic, **AND**
2. Being used as single agent therapy

Covered Doses
Up to 200 mg IV every 3 weeks, OR up to 400 mg IV every 6 weeks

Coverage Period
Indefinite

ICD-10:
C69.30-C69.32, C69.40 -C69.42, C69.60-C69.62

Merkel cell carcinoma

1. Disease is recurrent or metastatic (includes disseminated), **AND**
2. Being used as a single agent

Covered Doses
Adults:
Up to 200 mg IV every 3 weeks, OR up to 400 mg IV every 6 weeks
Pediatrics:
Up to 2 mg/kg (up to 200 mg) every 3 weeks

Coverage Period
Indefinite

ICD-10:
C4A.0, C4A.10-C4A.12, C4A.20-C4A.22, C4A.30, C4A.31, C4A.39, C4A.4, C4A.51, C4A.52, C4A.59-C4A.62, C4A.70-C4A.72, C4A.8, C4A.9, C7B.1, Z85.821

Mycosis fungoides or Sezary syndrome

1. Not being used in combination with other systemic therapies

Covered Doses
Up to 200 mg per dose IV every 3 weeks, OR up to 400 mg IV every 6 weeks

Coverage Period
Indefinite

ICD-10:
C84.00-C84.09, C84.10-C84.19

Non-muscle invasive bladder cancer (NMIBC)

1. Diagnosis of high-risk non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS), **AND**
2. Patient did not respond to Bacillus Calmette-Guerin (BCG) therapy

Covered Doses
Monotherapy:
Up to 200 mg IV every 3 weeks, OR up to 400 mg IV every 6 weeks

Coverage Period
Indefinite

ICD-10:
C67.0-C67.9, D09.0, Z85.51

Non-small cell lung cancer

1. Either of the following:
    a. Being used in combination with platinum-containing chemotherapy as neoadjuvant treatment followed by single agent adjuvant treatment after surgery, OR
    b. Being used as a single agent for adjuvant treatment following previous adjuvant chemotherapy, **OR**
    c. Disease is advanced, recurrent, or metastatic and one of the following:
        i. Single agent use, OR
        ii. In combination with either carboplatin or cisplatin, and either paclitaxel or Abraxane for squamous histology, OR
        iii. In combination with either carboplatin or cisplatin, and pemetrexed for nonsquamous histology, OR
        iv. Maintenance treatment and one of the following:
            1. In combination with Alimta after treatment with Keytruda, pemetrexed, and carboplatin/cisplatin for nonsquamous histology, or

2. As a single agent after treatment with Keytruda, Abraxane/paclitaxel and carboplatin/cisplatin for squamous histology

Covered Doses
Up to 200 mg IV every 3 weeks, OR up to 400 mg IV every 6 weeks

Coverage Period
Indefinite

ICD-10:
C33, C34.00-C34.02, C34.10-C34.12, C34.2, C34.30-C34.32, C34.80-C34.82, C34.90-C34.92, Z85.118

Primary mediastinal large B-cell lymphoma

1. Refractory or relapsed disease, **AND**
2. Being used as a single agent

Covered Doses
Adults
Up to 200 mg IV every 3 weeks, OR up to 400 mg IV every 6 weeks
Pediatrics
Up to 2 mg/kg (up to 200 mg) IV every 3 weeks

Coverage Period
Indefinite

ICD-10:
C85.20-C85.29

Renal cell carcinoma

1. Either of the following:
    a. Adjuvant treatment following nephrectomy and one of the following:
        i. Being used as a single agent, or
        ii. ***Through 1/28/2024,*** used in combination with Inlyta (axitinib) or Lenvima (lenvatinib)

    OR

    b. Disease is locally advanced, metastatic, or relapsed/recurrent and one of the following:
        i. Being used as a single agent, and ***effective 1/29/2024 and after,*** patient has non-clear cell histology, or
        ii. Used in combination with Inlyta (axitinib) or Lenvima (lenvatinib)

Covered Doses
Up to 200 mg IV every 3 weeks, OR up to 400 mg IV every 6 weeks

Coverage Period
Indefinite

ICD-10:
C64.1, C64.2, C64.9, C65.1, C65.2, C65.9, Z85.528

Small cell lung cancer

1. Used as single agent, **AND**
2. Either of the following:
    a. Primary progressive disease, or
    b. Relapsed disease and relapse did not occur while receiving maintenance therapy with Imfinzi or Tecentric

Covered Doses
Up to 200 mg IV every 3 weeks, OR up to 400 mg IV every 6 weeks

Coverage Period
Indefinite

ICD-10:
C7A.1, C33, C34.00-C34.02, C34.10-C34.12, C34.2, C34.30-C34.32, C34.80-C34.82, C34.90-C34.92, C78.00-C78.02, C79.31, C79.51, C79.52

Soft tissue sarcoma

1. Meets one of the following:
    a. Alveolar soft part sarcoma, and being used as a single agent or in combination with Inlyta (axitinib), **OR**
    b. Cutaneous angiosarcoma, and being used as a single agent, **OR**
    c. Undifferentiated pleomorphic sarcoma (UPS), myxofibrosarcoma, dedifferentiated liposarcoma, pleomorphic rhabdomyosarcoma, or undifferentiated sarcomas and all of the following:
        i. Being used for unresectable, or metastatic (stage IV) disease, and
        ii. Being used as subsequent therapy

Covered Doses
Up to 200 mg IV every 3 weeks, or up to 400 mg IV every 6 weeks

Coverage Period
Indefinite

ICD-10:
C22.3, C47.0, C47.10-C47.12, C47.20-C47.22, C47.3, C47.4, C47.5, C47.6, C47.8, C47.9, C48.0-C48.2, C48.8, C49.0, C49.10-C49.12, C49.20-C49.22, C49.3, C49.4, C49.5, C49.6, C49.8, C49.9, C49.10-C49.12, C49.20-C49.22, C49.3-C49.6, C49.8, C49.9, Z85.831

Solid tumors, dMMR/ MSI-H or TMB-H

1. Either of the following:
    a. Patient has defective mismatch repair (dMMR)/high microsatellite instability(MSI-H) (laboratory test), OR
    b. Patient has tumor mutational burden-high (TMB-H) [10 mutations/megabase (mut/Mb)] (FDA approved test),

    AND
2. Being used as a single agent, **AND**
3. One of the following:
    a. Initial therapy supported by NCCN, OR
    b. Disease has progressed following prior treatment, OR
    c. There are no alternative treatment options

Covered Doses
Adults:
Up to 200 mg IV every 3 weeks, OR up to 400 mg IV every 6 weeks
Pediatrics:
Up to 2 mg/kg (up to 200 mg) IV every 3 weeks

Coverage Period
Indefinite

ICD-10: Any solid tumor

Thymic carcinoma

1. Postoperative residual tumor (R1/R2 resection), Locally advanced, unresectable, or metastatic disease, **AND**
2. Being used as a single agent

Covered Doses
Up to 200 mg IV every 3 weeks, OR up to 400 mg IV every 6 weeks

Coverage Period
Indefinite

ICD-10:
C37, D15.0

Urothelial carcinoma

1. Locally advanced, recurrent, or metastatic disease, **AND**
2. Either of the following:
    a. Being used as a single agent, and one of the following:
        i. First line treatment in patients who are not eligible for any platinum-containing chemotherapy, or
        ii. Being used as subsequent therapy

OR

b. Being used in combination with Padcev (enfortumab vedotin)

Covered Doses
Up to 200 mg IV every 3 weeks, OR up to 400 mg IV every 6 weeks

Coverage Period
Indefinite

ICD-10:
C61, C65.1, C65.2, C65.9, C66.1, C66.2, C66.9, C67.0-C67.9, C68.0, Z85.59, D09.0, Z85.51

Vulvar cancer

1. Advanced, recurrent, or metastatic disease, **AND**
2. Squamous cell carcinoma or adenocarcinoma histology, **AND**
3. Being used as a single agent, **AND**
4. Disease progression on or after chemotherapy, **AND**
5. Tumor has PD-L1 expression ≥ 1 on the CPS as determined by an FDA approved test

Covered Doses
Up to 200 mg IV every 3 weeks, OR up to 400 mg IV every 6 weeks

Coverage Period
Indefinite

ICD-10:
C51.0-C51.2, C51.8, C51.9

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Keytruda® (pembrolizumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

- 100 mg (single-use vial)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Keytruda® (pembrolizumab) [Prescribing information]. Whitehouse Station, NJ: Merck & CO., inc.; 2023.
- National Comprehensive Cancer Network Drugs and Biologics Compendium. Keytruda (2023). Available at: www.nccn.org.
- National Comprehensive Cancer Network. Anal Carcinoma (Version 3.2023). Available at: www.nccn.org.
- National Comprehensive Cancer Network. B-cell Lymphomas (Version 6.2023). Available at: www.nccn.org.
- National Comprehensive Cancer Network. Bladder Cancer (Version 3.2023). Available at: www.nccn.org.
- National Comprehensive Cancer Network. Breast Cancer (Version 4.2023). Available at: www.nccn.org.
- National Comprehensive Cancer Network. Cervical Cancer (Version 1.2024). Available at: www.nccn.org.
- National Comprehensive Cancer Network. Colon Cancer (Version 3.2023). Available at: www.nccn.org.
- National Comprehensive Cancer Network. Esophageal and Esophagogastric Junction Cancers (Version 3.2023). Available at: www.nccn.org.
- National Comprehensive Cancer Network. Gastric Cancer (Version 2.2023). Available at: www.nccn.org.
- National Comprehensive Cancer Network. Gestational Trophoblastic Neoplasia (Version 1.2023). Available at: www.nccn.org.
- National Comprehensive Cancer Network. Head and Neck Cancers (Version 1.2024). Available at: www.nccn.org.
- National Comprehensive Cancer Network. Hepatobiliary Cancers (Version 2.2023). Available at: www.nccn.org.
- National Comprehensive Cancer Network. Hodgkin Lymphoma (Version 1.2023). Available at: www.nccn.org.
- National Comprehensive Cancer Network. Kidney Cancer (Version 1.2024). Available at: www.nccn.org.
- National Comprehensive Cancer Network. Melanoma: Cutaneous (Version 2.2023). Available at: www.nccn.org.
- National Comprehensive Cancer Network. Merkel Cell Carcinoma (Version 1.2023). Available at: www.nccn.org.
- National Comprehensive Cancer Network. Neuroendocrine and Adrenal Tumors (Version 1.2023). Available at: www.nccn.org.
- National Comprehensive Cancer Network. Non-small Cell Lung Cancer (Version 3.2023). Available at: www.nccn.org.
- National Comprehensive Cancer Network. Primary Cutaneous Lymphomas (Version 1.2023). Available at: www.nccn.org.
- National Comprehensive Cancer Network. Small Cell Lung Cancer (Version 1.2024). Available at: www.nccn.org.
- National Comprehensive Cancer Network. Soft Tissue Sarcoma (Version 2.2023). Available at:

www.nccn.org.
- National Comprehensive Cancer Network. Squamous Cell Skin Cancer (Version 1.2023). Available at: www.nccn.org.
- National Comprehensive Cancer Network. Rectal Cancer (Version 5.2023). Available at: www.nccn.org.
- National Comprehensive Cancer Network. T-cell Lymphomas (Version 1.2023). Available at: www.nccn.org.
- National Comprehensive Cancer Network. Thymomas and Thymic Carcinomas (Version 1.2023). Available at: www.nccn.org.
- National Comprehensive Cancer Network. Uterine Neoplasms Cancer (Version 2.2023). Available at: www.nccn.org.
- National Comprehensive Cancer Network. Vulvar Cancer (Version 1.2024). Available at: www.nccn.org.

(7) Policy Update

Date of last revision: 1Q2024
Date of next review: 4Q2024
Changes from previous policy version:

- New indication in Section (2): Added coverage for biliary tract cancers. *Rationale: In October 2023, FDA approved Keytruda, in combination with gemcitabine and cisplatin, for the treatment of patients with locally advanced unresectable or metastatic biliary tract cancer; NCCN category 1 support*
- Section (2): Cervical cancer – Added coverage in combination with chemoradiotherapy for Stage III-IV cancer. *Rationale: In January 2024, FDA approved Keytruda in combination with chemoradiotherapy, for the treatment of patients with FIGO 2014 Stage III-IVA cervical cancer*
- Section (2): Esophageal cancer, Esophagogastric junction (EGJ) cancer and Gastric cancer – Added coverage for combination first-line treatment of HER2-negative gastric or gastroesophageal junction adenocarcinoma. *Rationale: In November 2023, FDA approved Keytruda in combination with fluoropyrimidine- and platinum-containing chemotherapy, for the first-line treatment of adults with locally advanced unresectable or metastatic HER2-negative gastric or gastroesophageal junction (GEJ) adenocarcinoma*
- Section (2): Non-small cell lung cancer – Expanded coverage to include combination neoadjuvant treatment followed by single agent adjuvant treatment after surgery. *Rationale: In October, 2023 FDA approved Keytruda for treatment of resectable NSCLC in combination with platinum-containing chemotherapy as neoadjuvant treatment, then continued as single agent as adjuvant treatment after surgery; NCCN category 1 support*
- Section (2): Hodgkin lymphoma, classical - Expanded coverage to include combination treatment with ICE. *Rationale: NCCN category 2A support*
- Section (2): Urothelial carcinoma - Removed requirement for cisplatin-ineligibility from coverage of combination treatment with Padcev. *Rationale: In December 2023, FDA expanded the indication of combination Padcev + Keytruda for treatment of adult patients with locally advanced or metastatic urothelial cancer to include cisplatin-eligible patients*