Keytruda (pembrolizumab)
PAM – 008

Iowa Medicaid Program	Prior Authorization	**Effective Date**	04/30/2015
Revision Number	8	**Last Reviewed**	04/17/2026
Reviewed By	Medicaid Medical Director	**Next Review**	07/17/2026
Approved By	Medicaid Clinical Advisory Committee	**Approved Date**	04/28/2020

Overview

Medication: [1]	pembrolizumab
Brand Name:	Keytruda®
Pharmacologic Category:	Antineoplastic; Programmed Death Receptor-1 (PD-1)-Blocking Antibody
FDA-Approved Indication(s):	See list of FDA-approved indications on following pages
How Supplied:	• Single-dose vial: 100 mg/4 mL (25 mg/mL) solution • Supplied in a carton containing 1 or 2 vials
Dosage and Administration:	• Intravenous (IV) infusion • Dosage is indication-specific (see Appendix A)
Benefit Category:	Medical

Abbreviations/Acronyms

- ALK: anaplastic lymphoma kinase
- BCG: Bacillus Calmette-Guerin
- cHL: classical Hodgkin lymphoma
- CIS: carcinoma in situ
- CNS: central nervous system
- CPS: combined positive score
- CRC: colorectal cancer
- CRT: chemoradiotherapy
- cSCC: cutaneous squamous cell carcinoma
- dMMR: mismatch repair deficient
- EGFR: epidermal growth factor receptor
- FDA: U.S. Food and Drug Administration
- FIGO: International Federation of Gynecology and Obstetrics
- GEJ: gastroesophageal junction
- HCC: hepatocellular carcinoma
- HER2: human epidermal growth factor receptor 2
- HNSCC: head and neck squamous cell carcinoma
- MCC: Merkel cell carcinoma
- MPM: malignant pleural mesothelioma
- MSI-H: microsatellite instability-high
- mut/Mb: mutations/megabase
- NCCN: National Comprehensive Cancer Network
- NMIBC: non-muscle invasive bladder cancer
- NSCLC: non-small cell lung cancer
- ORR: objective response rate
- OS: overall survival
- PD-1: programmed death protein 1
- PD-L1: programmed death-ligand 1
- PFS: progression-free survival
- PMBCL: primary mediastinal large B-cell lymphoma
- pMMR: mismatch repair proficient
- RCC: renal cell carcinoma
- RFS: recurrence-free survival
- ROS1: ROS proto-oncogene 1
- RT: Radiotherapy
- TMB-H: tumor mutational burden-high
- TNBC: triple-negative breast cancer
- TPS: tumor proportion score
- TTP: time to progression

Patient Selection *

Patient Selection for Single-Agent Treatment

- Select patients for treatment with Keytruda® as a single agent based on the presence of positive PD-L1 expression in:
  - Stage III NSCLC who are not candidates for surgical resection or definitive chemoradiation
  - metastatic NSCLC
  - first-line treatment of metastatic or unresectable, recurrent HNSCC
  - previously treated recurrent locally advanced or metastatic esophageal cancer
  - recurrent or metastatic cervical cancer with disease progression on or after chemotherapy
- For the MSI-H/dMMR indications, select patients for treatment with Keytruda® as a single agent based on MSI-H/dMMR status in tumor specimens.
- For the TMB-H indication, select patients for treatment with Keytruda® as a single agent based on TMB-H status in tumor specimens.
- Because subclonal dMMR mutations and microsatellite instability may arise in high-grade gliomas during temozolomide therapy, it is recommended to test for TMB-H, MSI-H, and dMMR in the primary tumor specimens obtained prior to initiation of temozolomide chemotherapy in patients with high-grade gliomas.

Additional Patient Selection Info for MSI-H or dMMR in Patients with non-CRC Solid Tumors

- Due to discordance between local tests and FDA-authorized tests, confirmation of MSI-H or dMMR status is recommended by an FDA-authorized test in patients with MSI-H or dMMR solid tumors, if feasible. If unable to perform confirmatory MSI-H/dMMR testing, the presence of TMB ≥10 mut/Mb, as determined by an FDA-authorized test, may be used to select patients for treatment.

Patient Selection for Combination Therapy

- For use of Keytruda® as a single agent as neoadjuvant treatment, then in combination with radiotherapy (RT) with or without chemotherapy then continued as a single agent as adjuvant treatment, select patients based on presence of positive PD-L1 expression (CPS ≥ 1) in resectable locally advanced HNSCC.
- For use of Keytruda® in combination with chemotherapy, select patients based on the presence of positive PD-L1 expression (CPS ≥ 1) in locally advanced unresectable or metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma, and esophageal or gastroesophageal junction (GEJ) carcinoma.
  - An FDA-authorized test for the detection of PD-L1 for the selection of patients with PD-L1 (CPS ≥ 1) expression in esophageal carcinoma in combination with platinum- and fluoropyrimidine-based chemotherapy is not available.

- For use of Keytruda® in combination with chemotherapy, with or without bevacizumab, select patients based on the presence of positive PD-L1 expression in persistent, recurrent, or metastatic cervical cancer.
- For the pMMR/not MSI-H advanced endometrial carcinoma indication, select patients for treatment with Keytruda® in combination with lenvatinib based on MMR or MSI status in tumor specimens.
- For use of Keytruda® in combination with chemotherapy, select patients based on the presence of positive PD-L1 expression in locally recurrent unresectable or metastatic TNBC.
- For use of Keytruda® in combination with paclitaxel, with or without bevacizumab, select patients based on the presence of positive PD-L1 expression (CPS ≥ 1) in platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal carcinoma.

* Information on FDA-authorized tests for patient selection is available at: www.fda.gov/CompanionDiagnostics

Pediatric Use

The safety and effectiveness of Keytruda® as a single agent have been established in pediatric patients with melanoma, cHL, PMBCL, MCC, MSI-H or dMMR cancer, and TMB-H cancer. Use of Keytruda® in pediatric patients for these indications is supported by evidence from adequate and well-controlled studies in adults with additional pharmacokinetic and safety data in pediatric patients. In KEYNOTE-051, 173 pediatric patients (65 pediatric patients aged 6 months to younger than 12 years and 108 pediatric patients aged 12 to 17 years) with advanced melanoma, lymphoma, or PD-L1 positive or MSI-H solid tumors received Keytruda® 2 mg/kg every 3 weeks. The median duration of exposure was 2.1 months (range: 1 day to 25 months).

The safety and effectiveness of Keytruda® in pediatric patients have not been established in the other approved indications.

Descriptive Narrative

Binding of the PD-1 ligands, PD-L1 and PD-L2, to the PD-1 receptor found on T cells, inhibits T cell proliferation and cytokine production. Upregulation of PD-1 ligands occurs in some tumors and signaling through this pathway can contribute to inhibition of active T-cell immune surveillance of tumors. Keytruda® (pembrolizumab) is a monoclonal antibody that binds to the PD-1 receptor and blocks its interaction with PD-L1 and PD-L2, releasing PD-1 pathway-mediated inhibition of the immune response, including the anti-tumor immune response. In syngeneic mouse tumor models, blocking PD-1 activity resulted in decreased tumor growth.

In syngeneic mouse tumor models, combination treatment of a PD-1 blocking antibody and kinase inhibitor lenvatinib decreased tumor-associated macrophages, increased activated cytotoxic T cells, and reduced tumor growth compared to either treatment alone.[2]

FDA-Approved Indications

1. Melanoma

1a. Keytruda® is indicated for the treatment of patients with unresectable or metastatic melanoma.

1b. Keytruda® is indicated for the adjuvant treatment of adult and pediatric (12 years and older) patients with Stage IIB, IIC, or III melanoma following complete resection.

2. Non-Small Cell Lung Cancer

2a. Keytruda®, in combination with pemetrexed and platinum chemotherapy, is indicated for the first-line treatment of patients with metastatic nonsquamous non-small cell lung cancer (NSCLC), with no EGFR or ALK genomic tumor aberrations.

2b. Keytruda®, in combination with carboplatin and either paclitaxel or paclitaxel protein-bound, is indicated for the first-line treatment of patients with metastatic squamous NSCLC.

2c. Keytruda®, as a single agent, is indicated for the first-line treatment of patients with NSCLC expressing PD-L1 [Tumor Proportion Score (TPS) ≥ 1%] as determined by an FDA-authorized test, with no EGFR or ALK genomic tumor aberrations, and is:

- i. Stage III where patients are not candidates for surgical resection or definitive chemoradiation, or
- ii. metastatic.

2d. Keytruda®, as a single agent, is indicated for the treatment of patients with metastatic NSCLC whose tumors express PD-L1 (TPS ≥ 1%) as determined by an FDA-authorized test, with disease progression on or after platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-authorized therapy for these aberrations prior to receiving Keytruda®.

2e. Keytruda® is indicated for the treatment of patients with resectable (tumors ≥ 4 cm or node positive) NSCLC in combination with platinum-containing chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery.

2f. Keytruda®, as a single agent, is indicated as adjuvant treatment following resection and platinum-based chemotherapy for adult patients with Stage IB (T2a ≥ 4 cm), II, or IIIA NSCLC.

3. Malignant Pleural Mesothelioma

3a. Keytruda®, in combination with pemetrexed and platinum chemotherapy, is indicated for the first-line treatment of adult patients with unresectable advanced or metastatic malignant pleural mesothelioma (MPM).

▶ **NEW** indication (FDA-approved 9/17/2024)

4. Head and Neck Squamous Cell Cancer

4a. Keytruda® is indicated for the treatment of adult patients with resectable locally advanced head and neck squamous cell cancer (HNSCC) whose tumors express PD-L1 [Combined Positive Score (CPS) ≥ 1] as determined by an FDA-authorized test, as a single agent as neoadjuvant treatment, continued as adjuvant treatment in combination with radiotherapy (RT) with or without cisplatin and then as a single agent.

▶ **NEW** indication (FDA-approved 6/12/2025)

4b. Keytruda®, in combination with platinum and fluorouracil (FU), is indicated for the first-line treatment of patients with metastatic or with unresectable, recurrent HNSCC.

4c. Keytruda®, as a single agent, is indicated for the first-line treatment of patients with metastatic or with unresectable, recurrent HNSCC whose tumors express PD-L1 [Combined Positive Score (CPS) ≥ 1] as determined by an FDA-authorized test.

4d. Keytruda®, as a single agent, is indicated for the treatment of patients with recurrent or metastatic HNSCC with disease progression on or after platinum-containing chemotherapy.

5. Classical Hodgkin Lymphoma

5a. Keytruda® is indicated for the treatment of adult patients with relapsed or refractory classical Hodgkin lymphoma (cHL).

5b. Keytruda® is indicated for the treatment of pediatric patients with refractory cHL, or cHL that has relapsed after 2 or more lines of therapy.

6. Primary Mediastinal Large B-Cell Lymphoma

6a. Keytruda® is indicated for the treatment of adult and pediatric patients with refractory primary mediastinal large B-cell lymphoma (PMBCL), or who have relapsed after 2 or more prior lines of therapy.

▶ Limitations of Use: Keytruda® is not recommended for treatment of patients with PMBCL who require urgent cytoreductive therapy.

7. Urothelial Carcinoma

7a. Keytruda®, in combination with enfortumab vedotin, is indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer.

7b. Keytruda®, as a single agent, is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma:

i. who are not eligible for any platinum-containing chemotherapy, or

ii. who have disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

7c. Keytruda®, in combination with enfortumab vedotin, as neoadjuvant treatment and then continued after cystectomy as adjuvant treatment, is indicated for the treatment of adult patients with muscle invasive bladder cancer (MIBC) who are ineligible for cisplatin containing chemotherapy.
▶ **NEW** indication (FDA-approved 11/21/2025)

7d. Keytruda®, as a single agent, is indicated for the treatment of patients with Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy.

8. Microsatellite Instability-High or Mismatch Repair Deficient Cancer

8a. Keytruda® is indicated for the treatment of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by an FDA-authorized test, that have progressed following prior treatment and who have no satisfactory alternative treatment options.

9. Microsatellite Instability-High or Mismatch Repair Deficient Colorectal Cancer

9a. Keytruda® is indicated for the treatment of patients with unresectable or metastatic MSI-H or dMMR colorectal cancer (CRC) as determined by an FDA-authorized test.

10. Gastric Cancer

10a. Keytruda®, in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy, is indicated for the first-line treatment of adults with locally advanced unresectable or metastatic HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma whose tumors express PD-L1 (CPS $\geq$ 1) as determined by an FDA-authorized test.
▶ ****CONVERTED** to traditional approval (FDA-approved 3/19/2025)**

10b. Keytruda®, in combination with fluoropyrimidine- and platinum-containing chemotherapy, is indicated for the first-line treatment of adults with locally advanced unresectable or metastatic HER2-negative gastric or gastroesophageal junction (GEJ) adenocarcinoma whose tumors express PD-L1 (CPS $\geq$ 1) as determined by an FDA-authorized test.
▶ **MODIFIED** indication (FDA-approved 5/22/2025)

11. Esophageal Cancer

11a. Keytruda® is indicated for the treatment of patients with locally advanced or metastatic esophageal or gastro-esophageal junction (GEJ) (tumors with epicenter 1 to 5 centimeters above the GEJ) carcinoma that is not amenable to surgical resection or definitive chemoradiation either:

i. in combination with platinum- and fluoropyrimidine-based chemotherapy for patients with tumors that express PD-L1 (CPS $\geq$ 1), or

▶ **MODIFIED** indication (FDA-approved 5/22/2025)

ii. as a single agent after one or more prior lines of systemic therapy for patients with tumors of squamous cell histology that express PD-L1 (CPS ≥ 10) as determined by an FDA-authorized test.

12. Cervical Cancer

12a. Keytruda®, in combination with chemoradiotherapy [CRT], is indicated for the treatment of patients with 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 (FIGO 2014 Stage III-IVA).

▶ **MODIFIED** indication (FDA-approved 6/3/2025)

12b. Keytruda®, in combination with chemotherapy, with or without bevacizumab, is indicated for the treatment of patients with persistent, recurrent, or metastatic cervical cancer whose tumors express PD-L1 (CPS ≥ 1) as determined by an FDA-authorized test.

12c. Keytruda®, as a single agent, is indicated for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy whose tumors express PD-L1 (CPS ≥ 1) as determined by an FDA-authorized test.

13. Hepatocellular Carcinoma

13a. Keytruda® is indicated for the treatment of patients with hepatocellular carcinoma (HCC) secondary to hepatis B who have received prior systemic therapy other than a PD-1/PD-L1-containing regimen.

14. Biliary Tract Cancer

14a. Keytruda®, in combination with gemcitabine and cisplatin, is indicated for the treatment of patients with locally advanced unresectable or metastatic biliary tract cancer (BTC).

15. Merkel Cell Carcinoma

15a. Keytruda® is indicated for the treatment of adult and pediatric patients with recurrent locally advanced or metastatic Merkel cell carcinoma (MCC).

16. Renal Cell Carcinoma

16a. Keytruda®, in combination with axitinib, is indicated for the first-line treatment of adult patients with advanced renal cell carcinoma (RCC).

16b. Keytruda®, in combination with lenvatinib, is indicated for the first-line treatment of adult patients with advanced RCC.

16c. Keytruda® is indicated for the adjuvant treatment of patients with RCC at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions.

17. Endometrial Carcinoma

17a. Keytruda®, in combination with carboplatin and paclitaxel, followed by Keytruda® as a single agent, is indicated for the treatment of adult patients with primary advanced or recurrent endometrial carcinoma.

- **NEW** indication (FDA-approved 6/17/2024)

17b. Keytruda®, in combination with lenvatinib, is indicated for the treatment of adult patients with advanced endometrial carcinoma that is mismatch repair proficient (pMMR) or not MSI-H as determined by an FDA-authorized test, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation.

17c. Keytruda®, as a single agent, is indicated for the treatment of adult patients with advanced endometrial carcinoma that is MSI-H or dMMR, as determined by an FDA-authorized test, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation.

18. Tumor Mutational Burden-High Cancer

18a. Keytruda® is indicated for the treatment of adult and pediatric patients with unresectable or metastatic tumor mutational burden-high (TMB-H) [≥ 10 mutations/megabase (mut/Mb)] solid tumors, as determined by an FDA-authorized test, that have progressed following prior treatment and who have no satisfactory alternative treatment options.

- Accelerated Approval: This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.
- Limitations of Use: The safety and effectiveness of Keytruda® in pediatric patients with TMB-H central nervous system cancers have not been established.

19. Cutaneous Squamous Cell Carcinoma

19a. Keytruda® is indicated for the treatment of patients with recurrent or metastatic cutaneous squamous cell carcinoma (cSCC) or locally advanced cSCC that is not curable by surgery or radiation.

20. Triple-Negative Breast Cancer

20a. Keytruda® is indicated for the treatment of patients with high-risk early-stage triple-negative breast cancer (TNBC) in combination with chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery.

20b. Keytruda®, in combination with chemotherapy, is indicated for the treatment of patients with locally recurrent unresectable or metastatic TNBC whose tumors express PD-L1 (CPS ≥ 10) as determined by an FDA-authorized test.

21. Ovarian Cancer

21a. Keytruda®, in combination with paclitaxel, with or without bevacizumab, is indicated for the treatment of adult patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal carcinoma whose tumors express PD-L1 (CPS ≥ 1) as determined by an FDA-authorized test, and who have received one or two prior systemic treatment regimens.

▶ **NEW** indication (FDA-approved 2/10/2026)

Guidelines

The National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology document evidence-based, consensus-driven management to ensure that all patients receive preventive, diagnostic, treatment, and supportive services that are most likely to lead to optimal outcomes. The guidelines are developed and updated by 63 individual panels, comprising over 1,900 clinicians and oncology researchers from the 33 NCCN Member Institutions. The categories for recommendations are based on both the level of clinical evidence available and the degree of consensus within the NCCN Guidelines Panel.

The library of NCCN Guidelines® currently apply to more than 97 percent of people living with cancer or anyone at risk for a diagnosis of cancer in the United States. The guidelines incorporate real-time updates in keeping with the rapid advancements in the field of cancer research and management and are intended to assist all individuals who impact decision-making in cancer care, including physicians, nurses, pharmacists, payers, patients and their families, and others.

The NCCN Guidelines provide recommendations based on the best evidence available at the time they are derived. Because new data are published continuously, it is essential that the NCCN Guidelines also be continuously updated and revised* to reflect new data and clinical information that may add to or alter current clinical practice standards.[3,4]

The information referenced at the time of this policy writing/revision is from the NCCN Guidelines® for (note version number and effective date):[5]

- B-Cell Lymphomas (v.1.2026 – December 22, 2025)
- Biliary Tract Cancers (v.2.2025 – July 2, 2025)
- Bladder Cancer (v.3.2025 – December 19, 2025)
- Breast Cancer (v.1.2026 – January 16, 2026)
- Cervical Cancer (v.2.2026 – November 10, 2025)
- Colon Cancer (v.5.2025 – October 30, 2025)
- Esophageal and Esophagogastric Junction Cancers (v.2.2026 – January 21, 2026)
- Gastric Cancer (v.2.2026 – January 21, 2026)
- Head and Neck Cancers (v.1.2026 – December 8, 2025)
- Hepatocellular Carcinoma (v.2.2025 – October 22, 2025)
- Hodgkin Lymphoma (v.1.2026 – October 22, 2025)
- Kidney Cancer (v.1.2026 – July 24, 2025)
- Melanoma: Cutaneous (v.1.2026 – February 17, 2026)
- Merkel Cell Carcinoma (v.2.2026 – October 24, 2025)
- Mesothelioma: Pleural (v.2.2026 – October 23, 2025)
- Non-Small Cell Lung Cancer (v.3.2026 – December 24, 2025)
- Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer (v.3.2025 – July 16, 2025)
- Pediatric Hodgkin Lymphoma (v.2.2025 – June 9, 2025)
- Squamous Cell Skin Cancer (v.1.2026 – September 2, 2025)
- Uterine Neoplasms (v.2.2026 – November 14, 2025)

* To view the most recent and complete version of the guidelines, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

NCCN Categories of Evidence and Consensus (all recommendations are category 2A unless otherwise indicated)	
Category 1	Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2A	Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2B	Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
Category 3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

NCCN Categories of Preference (all recommendations are considered appropriate)	
Preferred intervention	Interventions that are based on superior efficacy, safety, and evidence; and, when appropriate, affordability.
Other recommended intervention	Other interventions that may be somewhat less efficacious, more toxic, or based on less mature data; or significantly less affordable for similar outcomes.
Useful in certain circumstances	Other interventions that may be used for select patient populations (defined with recommendation).

Tools for Assessment of Patient Functional Levels

The Karnofsky Performance Status and the Eastern Cooperative Oncology Group Performance Status are widely used methods to assess the functional status of a patient. The Karnofsky Status describes a patient's functional status as a comprehensive 11-point scale correlating to percentage values ranging from 100 percent (no evidence of disease, no symptoms) to 0 percent (death). The Eastern Cooperative Oncology Group Performance Status describes a patient's functional status using a scale which ranges from 0 (healthy, no pain) to 5 (death).

For years, these two assessment methodologies have been important tools in clinical practice. In clinical trials, they are used as selection criteria (similar to processes for selection using age or gender) and for the stratification of subgroups in test patient cohorts.[6] Both are used by doctors and researchers to assess how a patient's disease is progressing, assess how the disease affects the daily living abilities of the patient, and determine appropriate treatment and prognosis.[7] A third functional assessment tool, the Lansky Play-Performance Scale, may be utilized to assess the functional status of patients younger than 16 years of age[8] (the Karnofsky Performance Status is used in patients 16 years of age and older).

Performance Status Assessments					
Eastern Cooperative Oncology Group Performance Status		Karnofsky Performance Status		Lansky Play-Performance Scale	
Score	Description	Score	Description	Score	Description
0	Fully active, able to carry on all pre-disease performance without restriction.	100	Normal, no complaints, no evidence of disease.	100	Fully active, normal.
		90	Able to carry on normal activity, minor signs or symptoms of disease.	90	Minor restrictions in physically strenuous activity.
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature (light housework, office work).	80	Normal activity with effort, some signs or symptoms of disease.	80	Active, but tires more quickly.
		70	Cares for self, unable to carry on normal activity or do active work.	70	Both greater restriction of, and less time spent in, play activity.
2	Ambulatory and capable of all self-care but unable to carry out any work. Activities; up and about more than 50% of waking hours.	60	Requires occasional assistance but is able to care for most of his/her needs.	60	Up and around, but minimal active play; keeps busy with quieter activities.
		50	Requires considerable assistance and frequent medical care.	50	Gets dressed but lies around much of the day; no active play; able to participate in all quiet play and activities.
3	Capable of only limited self-care; confined to bed or chair more than 50% of waking hours.	40	Disabled, requires special care and assistance.	40	Mostly in bed, participates in quiet activities.
		30	Severely disabled, hospitalization indicated. Death not imminent.	30	In bed, needs assistance even for quiet play.
4	Completely disabled; cannot carry on any self-care; totally confined to bed or chair.	20	Very sick, hospitalization indicated. Death not imminent.	20	Often sleeping, play entirely limited to very passive activities.
		10	Moribund, fatal processes progressing rapidly.	10	No play, does not get out of bed.
5	Dead.	0	Dead.	0	Dead.

Criteria

Prior authorization is required for all indications.

All FDA-Approved Indications

Keytruda® is considered medically necessary when **ALL** of the following are met:

1. Prescribed by, or in consultation with, an oncologist; **AND**
2. Member is not receiving therapy for a chronic condition, such as an autoimmune disease, which requires systemic steroids or immunosuppressive agents; **AND**
3. Member does not have an active infection requiring systemic therapy; **AND**
4. The regimen prescribed is within FDA-approved labeling. If dose or schedule exceeds the FDA-approved labeling, therapy regimen (including dosage) must be supported by clinical practice guidelines (i.e., must be recommended in the NCCN Clinical Practice Guidelines®). Supporting clinical documentation must be provided with any request for which the regimen or dosage prescribed does not align with FDA-approved labeling; **AND**
5. All indication-specific criteria are also met (listed following this section).

1. Melanoma

Keytruda® is considered medically necessary when **ALL** of the following are met:

1. Criteria listed in "All Indications" section is met; **AND**
2. Confirmed diagnosis of melanoma; **AND**
3. Member meets one of the following (a, b, or c):
    a. 6 months through 16 years of age and has a current Lansky Play Status $\geq$ 50; or
    b. 17 years of age and has a current Karnofsky Performance Status $\geq$ 50; or
    c. 18 years of age or older and has a current Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1; **AND**
4. Keytruda® is used as monotherapy, and is either (a or b):
    a. Used in the treatment of unresectable or metastatic melanoma; **OR**
    b. Used as adjuvant therapy in Stage IIB, IIC, or III melanoma following complete resection and member is 12 years of age or older.

2. Non-Small Cell Lung Cancer

Keytruda® is considered medically necessary when **ALL** of the following are met:

1. Criteria listed in "All Indications" section is met; **AND**
2. Confirmed diagnosis of non-small cell lung cancer (NSCLC); **AND**
3. Member is 18 years of age or older; **AND**
4. Member has a current Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1; **AND**
5. Keytruda® is prescribed in **ONE** of the following ways (a, b, c, d, e, or f):
    a. In combination with pemetrexed* and platinum chemotherapy as a first-line treatment for metastatic nonsquamous NSCLC, with no EGFR‡ or ALK‡ genomic tumor aberrations; **OR**
    b. In combination with carboplatin and either paclitaxel or paclitaxel protein-bound as first-line treatment for metastatic squamous NSCLC; **OR**
    c. As monotherapy for first-line treatment of NSCLC expressing PD-L1‡ [tumor proportion score (TPS) ≥1 percent], with no EGFR‡ or ALK‡ genomic tumor aberrations, and is either stage III (and member is not a candidate for surgical resection or definitive chemoradiation) or is metastatic; **OR**
    d. As monotherapy for metastatic NSCLC in a member whose tumors express PD-L1‡ (TPS ≥1 %) and with disease progression on or after platinum-containing therapy§; **OR**
    e. In combination with platinum-containing chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery, for patients with resectable (tumors ≥ 4 cm or node positive) NSCLC; **OR**
    f. As monotherapy for adjuvant treatment following resection and platinum-based chemotherapy for adult patients with Stage IB (T2a ≥ 4 cm), II, or IIIA NSCLC.

* Pemetrexed (Alimta®) may require a separate prior authorization.

‡ Genomic testing for epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) tumor aberrations or for programmed death-ligand 1 (PD-L1) expression may require a separate prior authorization.

§ If member has EGFR‡ or ALK‡ genomic tumor aberrations, should have disease progression on FDA-approved therapy for these aberrations prior to receiving Keytruda®.

3. Malignant Pleural Mesothelioma

Keytruda® is considered medically necessary when **ALL** of the following are met:

1. Criteria listed in "All Indications" section is met; **AND**
2. Confirmed diagnosis of malignant pleural mesothelioma (MPM); **AND**
3. Member is 18 years of age or older; **AND**
4. Member has a current Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1; **AND**
5. Keytruda® is prescribed in combination with pemetrexed and platinum chemotherapy as first-line treatment of unresectable advanced or metastatic MPM.

4. Head and Neck Squamous Cell Cancer

Keytruda® is considered medically necessary when **ALL** of the following are met:

1. Criteria listed in "All Indications" section is met; **AND**
2. Confirmed diagnosis of head and neck squamous cell cancer (HNSCC); **AND**
3. Member is 18 years of age or older; **AND**
4. Member has a current Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1; **AND**
5. Keytruda® is prescribed in **ONE** of the following ways (a, b, c, or d):
    a. As monotherapy as neoadjuvant treatment, continued as adjuvant treatment in combination with radiotherapy (RT) with or without cisplatin and then as a single agent, for the treatment of a member with resectable locally advanced HNSCC whose tumor(s) express PD-L1≠ [Combined Positive Score (CPS) ≥ 1]; **OR**
    b. In combination with platinum and fluorouracil as first-line treatment of metastatic or unresectable, recurrent HNSCC; **OR**
    c. As monotherapy for first-line treatment of metastatic or unresectable, recurrent HNSCC with tumors expressing PD-L1 (CPS ≥ 1); **OR**
    d. As monotherapy for recurrent or metastatic HNSCC in a member with disease progression on or after platinum-containing chemotherapy.

≠ Genomic testing for programmed death-ligand 1 (PD-L1) expression may require a separate prior authorization.

5. Classical Hodgkin Lymphoma

Keytruda® is considered medically necessary when **ALL** of the following are met:

1. Criteria listed in "All Indications" section is met; **AND**
2. Confirmed diagnosis of classical Hodgkin lymphoma (cHL); **AND**
3. Member meets one of the following (a, b, or c):
    a. 6 months through 16 years of age and has a current Lansky Play Status ≥ 50; or
    b. 17 years of age and has a current Karnofsky Performance Status ≥ 50; or
    c. 18 years of age or older and has a current Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1; **AND**
4. Keytruda® is prescribed in **ONE** of the following ways (a or b):
    a. For relapsed or refractory cHL in a member who is 18 years of age or older; **OR**
    b. Refractory cHL, or cHL that has relapsed after two or more lines of therapy, in a member who is 2 years of age or older.

6. Primary Mediastinal Large B-Cell Lymphoma

Keytruda® is considered medically necessary when **ALL** of the following are met:

1. Criteria listed in "All Indications" section is met; **AND**
2. Confirmed diagnosis of primary mediastinal large B-cell lymphoma (PMBCL); **AND**
3. Member is 2 years of age or older; **AND**
4. Member has refractory PMBCL or has relapsed after two or more prior lines of therapy; **AND**
5. Member meets one of the following (a, b, or c):
    a. 2 years through 16 years of age and has a current Lansky Play Status ≥ 50; or
    b. 17 years of age and has a current Karnofsky Performance Status ≥ 50; or
    c. 18 years of age or older and has a current Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1; **AND**
6. Keytruda® is prescribed as monotherapy.

Keytruda® is **NOT** considered medically necessary in members with PMBCL who require urgent cytoreductive therapy.

7. Urothelial Cancer

Keytruda® is considered medically necessary when **ALL** of the following are met:

1. Criteria listed in "All Indications" section is met; **AND**
2. Confirmed diagnosis of urothelial cancer; **AND**
3. Member is 18 years of age or older; **AND**
4. Member has a current Eastern Cooperative Oncology Group (ECOG) Performance Status of 0, 1, or 2; **AND**
5. Prescribed by, or in consultation with, an oncologist or urologist; **AND**
6. Keytruda is prescribed in **ONE** of the following ways (a, b, c, or d):
    a. In combination with enfortumab vedotin (Padcev®) for the treatment of locally advanced or metastatic urothelial cancer; **OR**
    b. As monotherapy for the treatment of locally advanced or metastatic urothelial carcinoma in a member who either is not eligible for any platinum-containing therapy or who has had disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy; **OR**
    c. In combination with enfortumab vedotin as neoadjuvant treatment and then continued after cystectomy as adjuvant treatment, for the treatment of a member with muscle invasive bladder cancer (MIBC) who is ineligible for cisplatin containing chemotherapy; **OR**
    d. As monotherapy for the treatment of a member who has Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors and is either ineligible for, or has elected not to undergo, cystectomy.

8. Microsatellite Instability-High or Mismatch Repair Deficient Cancer

Keytruda® is considered medically necessary when **ALL** of the following are met:

1. Criteria listed in "All Indications" section is met; **AND**
2. Confirmed diagnosis of unresectable or metastatic solid tumors classified as microsatellite instability-high (MSI-H)≠ or mismatch repair deficient (dMMR)≠ (indicative of MMR gene mutation or loss of expression); **AND**
3. Disease has progressed following prior treatment and member has no satisfactory alternative treatment options; **AND**
4. Member meets one of the following (a, b, or c):
    a. 6 months through 16 years of age and has a current Lansky Play Status ≥ 50; or
    b. 17 years of age and has a current Karnofsky Performance Status ≥ 50; or
    c. 18 years of age or older and has a current Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1; **AND**
5. Keytruda® is prescribed as monotherapy.

≠ Genomic testing for microsatellite instability-high (MSI-H) and mismatch repair deficient (dMMR) may require a separate prior authorization.

9. Microsatellite Instability-High or Mismatch Repair Deficient Colorectal Cancer

Keytruda® is considered medically necessary when **ALL** of the following are met:

1. Criteria listed in "All Indications" section is met; **AND**
2. Confirmed diagnosis of unresectable or metastatic colorectal cancer (CRC); **AND**
3. Tumor status is classified as microsatellite instability-high (MSI-H)≠ or mismatch repair deficient (dMMR)≠; **AND**
4. Member has a current Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1; **AND**
5. Keytruda® is prescribed as monotherapy.

≠ Genomic testing for microsatellite instability-high (MSI-H) and mismatch repair deficient (dMMR) may require a separate prior authorization.

10. Gastric Cancer

Keytruda® is considered medically necessary when **ALL** of the following are met:

1. Criteria listed in "All Indications" section is met; **AND**
2. Confirmed diagnosis of gastric or gastroesophageal junction (GEJ) adenocarcinoma; **AND**
3. Member has a current Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1; **AND**
4. Member is 18 years of age or older; **AND**
5. Keytruda® is prescribed in **ONE** of the following ways (a or b):
    a. In combination with trastuzumab*, fluoropyrimidine- and platinum-containing chemotherapy for the first-line treatment of a member with locally advanced unresectable or metastatic HER2-positive≠ gastric or gastroesophageal junction (GEJ) adenocarcinoma whose tumor(s) express PD-L1 [Combined Positive Score (CPS) ≥ 1]; **OR**
    b. In combination with fluoropyrimidine- and platinum-containing chemotherapy for the first-line treatment of a member with locally advanced unresectable or metastatic HER2-negative gastric or gastroesophageal junction (GEJ) adenocarcinoma whose tumor(s) express PD-L1 (CPS ≥ 1).

≠ Genomic testing for human epidermal growth factor receptor 2 (HER2) may require a separate prior authorization.
* Trastuzumab may require separate prior authorization.

11. Esophageal Cancer

Keytruda® is considered medically necessary when **ALL** of the following are met:

1. Criteria listed in "All Indications" section is met; **AND**
2. Confirmed diagnosis of esophageal or gastroesophageal junction (GEJ) carcinoma (tumors with epicenter 1 to 5 centimeters above the GEJ); **AND**
3. Disease is locally advanced or metastatic, and is not amenable to surgical resection or definitive chemoradiation; **AND**
4. Member has a current Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1; **AND**
5. Member is 18 years of age or older; **AND**
6. Keytruda® is prescribed in **ONE** of two ways (a or b):
    a. In combination with platinum- and fluoropyrimidine-based chemotherapy in a member whose tumor(s) express PD-L1 [Combined Positive Score (CPS) ≥ 1]; **OR**
    b. As monotherapy after one or more prior lines of systemic therapy for tumor(s) of squamous cell histology that express PD-L1≠ (CPS ≥ 10).

≠ Genomic testing for programmed death-ligand 1 (PD-L1) expression may require a separate prior authorization.

12. Cervical Cancer

Keytruda® is considered medically necessary when **ALL** of the following are met:

1. Criteria listed in "All Indications" section is met; **AND**
2. Confirmed diagnosis of cervical cancer; **AND**
3. Member is 18 years of age or older; **AND**
4. Member has a current Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1; **AND**
5. Keytruda® is prescribed in **ONE** of the following ways (a, b, or c):
    a. In combination with chemoradiotherapy (CRT) for the treatment of a member with 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 (FIGO 2014 Stage III-IVA cervical cancer); **OR**
    b. In combination with chemotherapy, with or without bevacizumab*, for treatment of a member with persistent, recurrent, or metastatic cervical cancer with tumor(s) which express PD-L1‡ [Combined Positive Score (CPS) ≥ 1]; **OR**
    c. As monotherapy for treatment of a member with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy and with tumor(s) which express PD-L1‡ (CPS ≥ 1).

* Bevacizumab may require separate prior authorization.
‡ Genomic testing for programmed death-ligand 1 (PD-L1) expression may require a separate prior authorization.

13. Hepatocellular Carcinoma

Keytruda® is considered medically necessary when **ALL** of the following are met:

1. Criteria listed in "All Indications" section is met; **AND**
2. Confirmed diagnosis of hepatocellular carcinoma (HCC) secondary to hepatitis B; **AND**
3. Member is 18 years of age or older; **AND**
4. Member has received prior systemic therapy other than a PD-1/PD-L1-containing regimen; **AND**
5. Member has a current Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1; **AND**
6. Keytruda® is prescribed as monotherapy.

14. Biliary Tract Cancer

Keytruda® is considered medically necessary when **ALL** of the following are met:

1. Criteria listed in "All Indications" section is met; **AND**
2. Confirmed diagnosis of biliary tract cancer (BTC); **AND**
3. Disease is locally advanced unresectable or metastatic; **AND**
4. Member is 18 years of age or older; **AND**
5. Member has a current Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1; **AND**
6. Keytruda® is prescribed in combination with gemcitabine and cisplatin.

15. Merkel Cell Carcinoma

Keytruda® is considered medically necessary when **ALL** of the following are met:

1. Criteria listed in "All Indications" section is met; **AND**
2. Confirmed diagnosis of Merkel cell carcinoma (MCC): **AND**
3. Disease is recurrent locally advanced or metastatic; **AND**
4. Member meets one of the following (a, b, or c):
    a. 6 months through 16 years of age and has a current Lansky Play Status $\geq$ 50; or
    b. 17 years of age and has a current Karnofsky Performance Status $\geq$ 50; or
    c. 18 years of age or older and has a current Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1.
5. Keytruda® is prescribed as monotherapy.

16. Renal Cell Carcinoma

Keytruda® is considered medically necessary when **ALL** of the following are met:

1. Criteria listed in "All Indications" section is met; **AND**
2. Confirmed diagnosis of renal cell carcinoma (RCC); **AND**
3. Member is 18 years of age or older; **AND**
4. Member meets **ONE** of the following:
    a. Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1; **OR**
    b. Karnofsky Performance Status ≥ 70; **AND**
5. Keytruda® is prescribed in **ONE** of the following ways (a, b, c, or d):
    a. In combination with axitinib* as first-line treatment for an adult member with advanced RCC; **OR**
    b. In combination with lenvatinib* as a first-line treatment for an adult member with advanced RCC; **OR**
    c. As a single-agent adjuvant treatment for a member with RCC at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions.

* Axitinib and lenvatinib may require a separate pharmacy prior authorization (see Iowa Medicaid PDL for more information).

17. Endometrial Carcinoma

Keytruda® is considered medically necessary when **ALL** of the following are met:

1. Criteria listed in "All Indications" section is met; **AND**
2. Confirmed diagnosis of endometrial carcinoma; **AND**
3. Member is 18 years of age or older; **AND**
4. Member has a current Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1; **AND**
5. Keytruda® is prescribed in **ONE** of three ways (a, b, or c):
    a. In combination with carboplatin and paclitaxel, followed by Keytruda® as a single agent, for the treatment of a member with primary advanced or recurrent endometrial carcinoma; **OR**
    b. In combination with lenvatinib* for the treatment of a member with advanced endometrial carcinoma that is mismatch repair proficient (pMMR)≠ or not microsatellite instability-high (MSI-H)≠ who has had disease progression following prior systemic therapy in any setting and is not a candidate for curative surgery or radiation; **OR**
    c. As monotherapy for the treatment of a member with advanced endometrial carcinoma that is MSI-H≠ or mismatch repair deficient (dMMR)≠ who has had disease progression following prior systemic therapy in any setting and is not a candidate for curative surgery or radiation.

≠ Genomic testing for MSI-H, pMMR, and dMMR)may require a separate prior authorization.
* Lenvatinib may require a separate pharmacy prior authorization (see Iowa Medicaid PDL for more information).

18. Tumor Mutational Burden-High Cancer

Keytruda® is considered medically necessary when **ALL** of the following are met:

1. Criteria listed in "All Indications" section is met; **AND**
2. Confirmed diagnosis of an unresectable or metastatic solid tumor; **AND**
3. Member has high tumor mutational burden (TMB-H)≠ solid tumors [≥ 10 mutations/megabase (mut/Mb)]; **AND**
4. Member has disease progression following prior treatment and has no satisfactory alternative treatment options; **AND**
5. For pediatrics: member does **NOT** have TMB-H central nervous system cancer (safety and effectiveness of Keytruda® have not been established).
6. Member meets one of the following (a, b, or c):
    a. 6 months through 16 years of age and has a current Lansky Play Status ≥ 50; or
    b. 17 years of age and has a Karnofsky Performance Status ≥ 50; or
    c. 18 years of age or older and has a current Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1; **AND**
7. Keytruda® is prescribed as monotherapy.

≠ Genomic testing for tumor mutational burden-high cancer (TMB-H) may require a separate prior authorization.

19. Cutaneous Squamous Cell Carcinoma

Keytruda® is considered medically necessary when **ALL** of the following are met:

1. Criteria listed in "All Indications" section is met; **AND**
2. Confirmed diagnosis of cutaneous squamous cell carcinoma (cSCC); **AND**
3. Member is 18 years of age or older; **AND**
4. Member has a current Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1; **AND**
5. Keytruda® is prescribed as monotherapy for treatment of a member with recurrent or metastatic cSCC or locally advanced cSCC that is not curable by surgery or radiation.

20.Triple-Negative Breast Cancer

Keytruda® is considered medically necessary when **ALL** of the following are met:

1. Criteria listed in "All Indications" section is met; **AND**
2. Confirmed diagnosis of triple-negative breast cancer (TNBC)*; **AND**
3. Member is 18 years of age or older; **AND**
4. Member has a current Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1; **AND**
5. Keytruda® is prescribed in **ONE** of the two following ways (a or b):
    a. In combination with chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant therapy after surgery, for treatment of a member with high-risk early stage TNBC; **OR**
    b. In combination with chemotherapy, for treatment of a member with locally recurrent unresectable or metastatic TNBC whose tumor(s) express PD-L1≠ [Combined Positive Score (CPS) ≥ 10].

* Triple-negative breast cancer (TNBC) is estrogen receptor-negative (ER-negative), progesterone receptor-negative (PR-negative), and human epidermal growth factor receptor 2-negative (HER2-negative).

≠ Genomic testing for programmed death-ligand 1 (PD-L1) expression may require a separate prior authorization.

21. Ovarian Cancer

Keytruda® is considered medically necessary when **ALL** of the following are met:

1. Criteria listed in "All Indications" section is met; **AND**
2. Confirmed diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal carcinoma; **AND**
3. Member is 18 years of age or older; **AND**
4. Keytruda® is prescribed in combination with paclitaxel, with or without bevacizumab, for treatment of a member with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal carcinoma whose tumors express PD-L1‡ [Combined Positive Score (CPS) ≥ 1], and who has received one or two prior systemic treatment regimens.

‡ Genomic testing for programmed death-ligand 1 (PD-L1) expression may require a separate prior authorization.

Criteria for Continuation of Therapy

Keytruda® is considered medically necessary for continuation of therapy (for all indications listed above) when **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit or has previously met initial approval criteria; **AND**
2. Documentation of positive clinical response to therapy, as demonstrated by tumor response or lack of disease progression, and an acceptable toxicity profile; **AND**
3. Prescribed by, or in consultation with, an oncologist (unless otherwise noted in the initial criteria); **AND**
4. The regimen prescribed is within FDA-approved labeling. If dose or schedule exceeds the FDA-approved labeling, therapy regimen (including dosage) must be supported by clinical practice guidelines (i.e., must be recommended in the NCCN Clinical Practice Guidelines®). Supporting clinical documentation must be provided with any request for which the regimen or dosage prescribed does not align with FDA-approved labeling; **AND**
5. Request does not exceed the approval duration or quantity limits outlined for each indication in the "Approval Duration and Quantity Limits" section.

Approval Duration and Quantity Limits

	Initial Authorization	Subsequent Authorization(s)
Approval Duration	6 months	Up to 6 months per authorization (not to exceed duration of therapy as indicated in FDA-approved labeling)
Quantity Limits	Not to exceed FDA-approved dosing (see Appendix A)	

Coding and Product Information

The following list(s) of codes and product information are provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS code is inappropriate.

HCPCS	Description
J9271	Injection, pembrolizumab, 1 mg

ICD-10	Description
C4A.0	Merkel cell carcinoma of lip
C4A.1	Merkel cell carcinoma of eyelid, including canthus
C4A.11	Merkel cell carcinoma of right eyelid, including canthus
C4A.12	Merkel cell carcinoma of left eyelid, including canthus
C4A.2	Merkel cell carcinoma of ear and external auricular canal
C4A.3	Merkel cell carcinoma of other and unspecified parts of face
C4A.4	Merkel cell carcinoma of scalp and neck

ICD-10	Description
C4A.5	Merkel cell carcinoma of trunk
C4A.6	Merkel cell carcinoma of upper limb, including shoulder
C4A.7	Merkel cell carcinoma of lower limb, including hip
C4A.8	Merkel cell carcinoma of overlapping sites
C4A.9	Merkel cell carcinoma, unspecified
C00	Malignant neoplasm of lip
C01	Malignant neoplasm of base of tongue
C02	Malignant neoplasm of other and unspecified parts of tongue
C03	Malignant neoplasm of gum
C04	Malignant neoplasm of floor of mouth
C05	Malignant neoplasm of palate
C06	Malignant neoplasm of other and unspecified parts of mouth
C09	Malignant neoplasm of tonsil
C10	Malignant neoplasm of oropharynx
C12	Malignant neoplasm of pyriform sinus
C13	Malignant neoplasm of hypopharynx
C14	Malignant neoplasm of other and ill-defined sites in the lip, oral cavity, and pharynx
C15	Malignant neoplasm of esophagus
C16	Malignant neoplasm of stomach
C18	Malignant neoplasm of colon
C19	Malignant neoplasm of rectosigmoid junction
C20	Malignant neoplasm of rectum
C21	Malignant neoplasm of anus and anal canal
C22	Malignant neoplasm of liver and intrahepatic bile ducts
C22.1	Intrahepatic bile duct carcinoma
C23	Malignant neoplasm of gall bladder
C24	Malignant neoplasm of other and unspecified parts of biliary tract
C30	Malignant neoplasm of nasal cavity and middle ear
C31	Malignant neoplasm of accessory sinuses
C32	Malignant neoplasm of larynx
C33	Malignant neoplasm of trachea
C34	Malignant neoplasm of bronchus and lung
C43	Malignant melanoma of skin
C44	Other and unspecified malignant neoplasm of skin
C44.12	Squamous cell carcinoma of skin of eyelid, including canthus
C44.22	Squamous cell carcinoma of skin and ear and external auricular canal
C44.32	Squamous cell carcinoma of skin and other unspecified parts of face
C44.4	Other and unspecified malignant neoplasm of skin of scalp and neck
C44.52	Squamous cell carcinoma of skin of trunk
C44.62	Squamous cell carcinoma of skin of upper limb, including shoulder
C44.72	Squamous cell carcinoma of skin of lower limb, including hip
C44.8	Other and unspecified malignant neoplasm of overlapping sites of skin
C44.9	Other and unspecified malignant neoplasm of skin, unspecified
C45.0	Mesothelioma of pleura
C50.01	Malignant neoplasm of nipple and areola, female
C50.02	Malignant neoplasm of nipple and areola, male
C50.11	Malignant neoplasm of central portion of breast, female
C50.12	Malignant neoplasm of central portion of breast, male
C50.21	Malignant neoplasm of upper-inner quadrant of breast, female
C50.22	Malignant neoplasm of upper-inner quadrant of breast, male

ICD-10	Description
C50.31	Malignant neoplasm of lower-inner quadrant of breast, female
C50.32	Malignant neoplasm of lower-inner quadrant of breast, male
C50.41	Malignant neoplasm of upper-outer quadrant of breast, female
C50.42	Malignant neoplasm of upper-outer quadrant of breast, male
C50.51	Malignant neoplasm of lower-outer quadrant of breast, female
C50.52	Malignant neoplasm of lower-outer quadrant of breast, male
C50.61	Malignant neoplasm of axillary tail of breast, female
C50.62	Malignant neoplasm of axillary tail of breast, male
C50.81	Malignant neoplasm of overlapping sites of breast, female
C50.82	Malignant neoplasm of overlapping sites of breast, male
C50.91	Malignant neoplasm of breast of unspecified site, female
C50.92	Malignant neoplasm of breast of unspecified site, male
C51	Malignant neoplasm of vulva
C53	Malignant neoplasm of cervix uteri
C54	Malignant neoplasm of corpus uteri
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	Malignant neoplasm of other and unspecified female genital organs
C60	Malignant neoplasm of penis
C63	Malignant neoplasm of other and unspecified male genital organs
C64	Malignant neoplasm of kidney, except renal pelvis
C65	Malignant neoplasm of renal pelvis
C66	Malignant neoplasm of ureter
C67	Malignant neoplasm of bladder
C68	Malignant neoplasm of other and unspecified urinary organs
C76.0	Malignant neoplasm of head, face, and neck (other and ill-defined sites)
C81	Hodgkin lymphoma
C85	Other specified and unspecified types of non-Hodgkin lymphoma

NDC (Strength)	Labeler	Dosage	Pkg Size	Pkg Qty	Units /Pkg
00006-3026-02 Carton containing one single-dose vial, 100 mg/4 mL (25 mg/mL)	Merck Sharp & Dohme LLC (00006)	1 mg	1	EA	100
00006-3026-04 Carton containing two single-dose vials, 100 mg/4 mL (25 mg/mL) each	Merck Sharp & Dohme LLC (00006)	1 mg	1	EA	200

Appendix A: Dosing (per indication)

Abbreviations/Acronyms

- ALK: anaplastic lymphoma kinase
- BCG: Bacillus Calmette-Guerin
- cHL: classical Hodgkin lymphoma
- CIS: carcinoma in situ
- CNS: central nervous system
- CPS: combined positive score
- CRC: colorectal cancer
- CRT: chemoradiotherapy
- cSCC: cutaneous squamous cell carcinoma
- dMMR: mismatch repair deficient
- EGFR: epidermal growth factor receptor
- FDA: U.S. Food and Drug Administration
- FIGO: International Federation of Gynecology and Obstetrics
- GEJ: gastroesophageal junction
- HCC: hepatocellular carcinoma
- HER2: human epidermal growth factor receptor 2
- HNSCC: head and neck squamous cell carcinoma
- MCC: Merkel cell carcinoma
- MPM: malignant pleural mesothelioma
- MSI-H: microsatellite instability-high
- mut/Mb: mutations/megabase
- NCCN: National Comprehensive Cancer Network
- NMIBC: non-muscle invasive bladder cancer
- NSCLC: non-small cell lung cancer
- ORR: objective response rate
- OS: overall survival
- PD-1: programmed death protein 1
- PD-L1: programmed death-ligand 1
- PFS: progression-free survival
- PMBCL: primary mediastinal large B-cell lymphoma
- pMMR: mismatch repair proficient
- RCC: renal cell carcinoma
- RFS: recurrence-free survival
- ROS1: ROS proto-oncogene 1
- RT: radiotherapy
- TMB-H: tumor mutational burden-high
- TNBC: triple-negative breast cancer
- TPS: tumor proportion score
- TTP: time to progression

MONOTHERAPY		
Indication	Recommended Dosage	Duration of Treatment
Adult patients with unresectable or metastatic melanoma	200 mg every 3 weeks, or 400 mg every 6 weeks	Until disease progression or unacceptable toxicity
Adjuvant treatment of adult patients with melanoma, NSCLC, or RCC	200 mg every 3 weeks, or 400 mg every 6 weeks	Until disease recurrence, unacceptable toxicity, or up to 12 months
Adult patients with NSCLC, HNSCC, cHL, PMBCL, locally advanced or metastatic urothelial carcinoma, MSI-H or dMMR cancer, MSI-H or dMMR CRC, MSI-H or dMMR endometrial carcinoma, esophageal cancer, cervical cancer, HCC, MCC, TMB-H cancer, or cSCC	200 mg every 3 weeks, or 400 mg every 6 weeks	Until disease recurrence, unacceptable toxicity, or up to 24 months
Adult patients with high-risk BCG-unresponsive NMIBC	200 mg every 3 weeks, or 400 mg every 6 weeks	Until persistent or recurrent high-risk NMIBC, disease progression, unacceptable toxicity, or up to 24 months
Pediatric patients with cHL, PMBCL, MSI-H or dMMR cancer, MCC, or TMBH cancer	2 mg/kg every 3 weeks (up to a max of 200 mg)	Until disease recurrence, unacceptable toxicity, or up to 24 months
Pediatric patients (12 years of age and older) for adjuvant treatment of melanoma	2 mg/kg every 3 weeks (up to a max of 200 mg)	Until disease recurrence, unacceptable toxicity, or up to 12 months

COMBINATION THERAPY *		
Indication	Recommended Dosage	Duration of Treatment
Adult patients with resectable NSCLC	200 mg every 3 weeks, or 400 mg every 6 weeks Administer prior to chemotherapy when given on the same day	Neoadjuvant treatment in combination with chemotherapy for 12 weeks or until disease progression that precludes definitive surgery or unacceptable toxicity, followed by adjuvant treatment with Keytruda® as a single agent for 39 weeks or until disease recurrence or unacceptable toxicity.
Adult patients with NSCLC, MPM, HNSCC, HER2-negative gastric cancer, esophageal cancer, or BTC	200 mg every 3 weeks, or 400 mg every 6 weeks Administer prior to chemotherapy when given on the same day	Until disease progression, unacceptable toxicity, or up to 24 months
Adult patients with locally advanced or metastatic urothelial carcinoma	200 mg every 3 weeks, or 400 mg every 6 weeks Administer after enfortumab vedotin when given on the same day	Until disease progression, unacceptable toxicity, or up to 24 months
Adult patients with MIBC	200 mg every 3 weeks (neoadjuvant) 200 mg every 3 weeks, or 400 mg every 6 weeks (adjuvant) Administer after enfortumab vedotin when given on the same day	Neoadjuvant • Administer 200 mg every 3 weeks for 3 doses in combination with enfortumab vedotin or until disease progression that precludes curative-intent cystectomy or unacceptable toxicity Adjuvant • Administer 200 mg every 3 weeks for 14 doses or 400 mg every 6 weeks for 7 doses in combination with enfortumab vedotin or until disease recurrence or unacceptable toxicity
Adult patients with locally advanced HNSCC	200 mg every 3 weeks, or 400 mg every 6 weeks Administer prior to cisplatin when given on the same day	Neoadjuvant • Administer Keytruda® for 6 weeks or until disease progression that precludes definitive surgery or unacceptable toxicity Adjuvant • Administer Keytruda® in combination with RT with or without cisplatin • Continue Keytruda® as a single agent until disease recurrence or unacceptable toxicity or up to one year
Adult patients with HER2-positive gastric cancer	200 mg every 3 weeks, or 400 mg every 6 weeks Administer prior to trastuzumab and chemotherapy when given on the same day	Until disease progression, unacceptable toxicity, or up to 24 months
Adult patients with cervical cancer	200 mg every 3 weeks, or 400 mg every 6 weeks Administer prior to chemoradiotherapy or prior to chemotherapy with or without bevacizumab when given on the same day	Until disease progression, unacceptable toxicity, or for Keytruda®, up to 24 months
Adult Patients with RCC	200 mg every 3 weeks, or 400 mg every 6 weeks Administer in combination with axitinib 5 mg orally twice daily** or administer in combination with lenvatinib 20 mg orally once daily	Until disease progression, unacceptable toxicity, or for Keytruda®, up to 24 months

COMBINATION THERAPY *		
Indication	Recommended Dosage	Duration of Treatment
Adult patients with endometrial carcinoma	200 mg every 3 weeks, or 400 mg every 6 weeks Administer prior to carboplatin and paclitaxel when given on the same day, or Administer in combination with lenvatinib 20 mg orally once daily	Until disease progression, unacceptable toxicity, or for Keytruda®, up to 24 months
Adult patients with high-risk early-stage TNBC	200 mg every 3 weeks, or 400 mg every 6 weeks Administer prior to chemotherapy when given on same day	Neoadjuvant treatment in combination with chemotherapy for 24 weeks (8 doses of 200 mg every 3 weeks or 4 doses of 400 mg every 6 weeks) or until disease progression or unacceptable toxicity, followed by adjuvant treatment with Keytruda® as a single agent for up to 27 weeks (9 doses of 200 mg every 3 weeks or 5 doses of 400 mg every 6 weeks) or until disease recurrence or unacceptable toxicity***
Adult patients with locally recurrent unresectable or metastatic TNBC	200 mg every 3 weeks, or 400 mg every 6 weeks Administer prior to chemotherapy when given on the same day	Until disease progression, unacceptable toxicity, or up to 24 months
Adult patients with ovarian cancer	200 mg every 3 weeks, or 400 mg every 6 weeks Administer prior to paclitaxel with or without bevacizumab when given on the same day	Until disease progression, unacceptable toxicity, or up to 24 months

* Refer to the full prescribing information for the agents administered in combination with Keytruda® for recommended dosing information, as appropriate.
** When axitinib is used in combination with Keytruda®, dose escalation of axitinib above the initial 5 mg dose may be considered at intervals of 6 weeks or longer.
*** Patients who experience disease progression or unacceptable toxicity related to Keytruda® with neoadjuvant treatment in combination with chemotherapy should not receive adjuvant single agent Keytruda®.

Compliance

1. Should conflict exist between the policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual or as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. Medical necessity guidelines are developed for selected physician-administered medications found to be safe and proven to be effective in a limited, defined population or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area

who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

References

[1] Keytruda® prescribing information (02/2026). Merck Sharp & Dohme LLC: Rahway, NJ. Available online: www.keytrudahcp.com. Accessed February 16, 2026.

[2] Keytruda® prescribing information (02/2026). Merck Sharp & Dohme LLC: Rahway, NJ. Available online: www.keytrudahcp.com. Accessed February 16, 2026.

[3] National Comprehensive Cancer Network (NCCN). Guidelines Process: About Clinical Practice Guidelines. Available online at www.nccn.org. Accessed October 20, 2025.

[4] National Comprehensive Cancer Network (NCCN). Guidelines Process: Development and Update of Guidelines. Available online at www.nccn.org. Accessed October 20, 2025.

[5] NCCN Clinical Practice Guidelines in Oncology. The NCCN Guidelines® are continuously updated and revised to reflect new data and clinical information that may add to or alter current clinical practice standards. To view the most recent and complete version, go online to NCCN.org. NCCN Guidelines® referenced at the time of this revision (note version number and effective date):

- B-Cell Lymphomas (v.1.2026 – December 22, 2025)
- Biliary Tract Cancers (v.2.2025 – July 2, 2025)
- Bladder Cancer (v.3.2025 – December 19, 2025)
- Breast Cancer (v.1.2026 – January 16, 2026)
- Cervical Cancer (v.2.2026 – November 10, 2025)
- Colon Cancer (v.5.2025 – October 30, 2025)
- Esophageal and Esophagogastric Junction Cancers (v.2.2026 – January 21, 2026)
- Gastric Cancer (v.2.2026 – January 21, 2026)
- Head and Neck Cancers (v.1.2026 – December 8, 2025)
- Hepatocellular Carcinoma (v.2.2025 – October 22, 2025)
- Hodgkin Lymphoma (v.1.2026 – October 22, 2025)
- Kidney Cancer (v.1.2026 – July 24, 2025)
- Melanoma: Cutaneous (v.1.2026 – February 17, 2026)
- Merkel Cell Carcinoma (v.2.2026 – October 24, 2025)
- Mesothelioma: Pleural (v.2.2026 – October 23, 2025)

- Non-Small Cell Lung Cancer (v.3.2026 – December 24, 2025)
- Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer (v.3.2025 – July 16, 2025)
- Pediatric Hodgkin Lymphoma (v.2.2025 – June 9, 2025)
- Squamous Cell Skin Cancer (v.1.2026 – September 2, 2025)
- Uterine Neoplasms (v.2.2026 – November 14, 2025)

[6] Péus D, Newcomb N, Hofer S. Appraisal of the Karnofsky Performance Status and proposal of a simple algorithmic system for its evaluation. *BMC Med Inform Decis Mak*. 2013;13:72. Published 2013 Jul 19. doi:10.1186/1472-6947-13-72.

[7] Oken M, Creech R, Tormey D, et al. Toxicity and response criteria of the Eastern Cooperative Oncology Group. *Am J Clin Oncol*. 1982;5:649-655.

[8] Lansky SB, List MA, Lansky LL, Ritter-Sterr C, Miller DR. The measurement of performance in childhood cancer patients. Cancer. 1987 Oct 1;60(7):1651-6. PMID: 3621134.

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

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Criteria Change History

Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		

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Change Date	Changed By	Description of Change	Version
04/17/2026	CAC	Annual review. Updated NCCN Guidelines and references. For new FDA-approved indications: updated Appendix A with dosing and Coding & Product Information with ICD-10 codes. Added Patient Selection information to Overview section (e.g., biomarkers used in patient selection process).	8

06/17/2024: FDA approved new indication (17a) - in combination with carboplatin and paclitaxel, followed by Keytruda® as a single agent, for the treatment of adult patients with primary advanced or recurrent endometrial carcinoma. Criteria added.

09/17/2024: FDA approved new indication (3a) – in combination with pemetrexed and platinum chemotherapy, as first-line treatment of adults with unresectable advanced or metastatic malignant pleural mesothelioma. Criteria added.

03/19/2025 (FDA): Conversion of the gastric cancer indication in HER2-positive gastric or GEJ adenocarcinoma in adults (10a) from accelerated approval to traditional approval.

05/22/2025: FDA label change – modification to gastric cancer (10b) and esophageal cancer (11a) indications to include language “whose tumors express PD-L1 (CPS $\geq$ 1).” Updated policy (including criteria) to mirror indication.

06/03/2025: FDA label change – modification to cervical cancer indication (12a) to “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.” Policy updated and criteria added.

06/12/2025: FDA approved new indication (4a) – for the treatment of adult patients with resectable locally HNSCC whose tumors express PD-L1 [Combined Positive Score (CPS) $\geq$ 1] as determined by an FDA-authorized test, as a single agent as neoadjuvant treatment, continued as adjuvant treatment in combination with radiotherapy (RT) with or without cisplatin and then as a single agent. Updated policy (including criteria) to mirror indication.

07/24/2025 (FDA): Conversion of the previous accelerated approval to traditional approval for the 400 mg every 6 week dosing regimen in adult patients with classical Hodgkin lymphoma and primary mediastinal large B-cell lymphoma (removes indication 1.21 from prescribing information). Updated policy to remove from indication list.

11/21/2025: FDA approved new indication (7c) – in combination with enfortumab vedotin, as neoadjuvant treatment and then continued after cystectomy as adjuvant treatment, is indicated for the treatment of adult patients with muscle invasive bladder cancer (MIBC) who are ineligible for cisplatin-containing chemotherapy. Criteria added.

02/10/2026: FDA approved new indication (21) – in combination with paclitaxel, with or without bevacizumab, is indicated for the treatment of adult patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal carcinoma whose tumors express PD-L1 (CPS ≥ 1) as determined by an FDA-authorized test, and who have received one or two prior systemic treatment regimens.” Criteria added.

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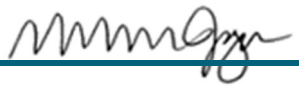
William (Bill) Jagiello, DO 

Criteria Change History *(continued)*

Change Date	Changed By	Description of Change	Version
07/19/2024	CAC	Annual review. Updated NCCN guidelines and references. Updated Appendix A with dosing for new FDA-approved indications and coding section with corresponding ICD-10 codes for new indications.	7

Added Lansky Play Scale and Karnofsky scores to criteria of indications which are approved for use in pediatric patients (melanoma, cHL, PMBCL, MCC, MSI-H or dMMR cancer, and TMB-H cancer).
10/12/2023 (FDA): Conversion of the Merkel cell carcinoma (MCC) indication in both adult and pediatric patients from accelerated approval to regular approval.
10/16/2023: FDA approved new indication – treatment of patients with resectable (tumors ≥4 cm or node positive) NSCLC. Criteria added.
10/31/2023: FDA approved new indication – treatment of patients with locally advanced unresectable or metastatic biliary tract cancer (BTC). Criteria added.
11/07/2023: FDA label change – modification to gastric cancer indication. Added "whose tumors express PD-L1 (CPS ≥ 1)" and *patients* changed to *adults*. Updated policy to mirror indication language.
11/16/2023: FDA approved new indication – treatment of adults with locally advanced unresectable or metastatic HER2-negative gastric or GEJ adenocarcinoma. Criteria added.
12/15/2023: FDA label change – modification to urothelial carcinoma indication. Removed qualifier "who are not eligible for cisplatin-containing chemotherapy." Conversion of this indication from accelerated approval to regular approval. Criteria updated to align with label change.
01/12/2024: FDA approved new indication – treatment of patients with FIGO 2014 Stage III-IVA cervical cancer (in combination with CRT). Criteria added.
01/25/2024: FDA revised indication for HCC to read as follows: "For the treatment of patients with HCC secondary to hepatitis B who have received prior systemic therapy other than a PD-1/PD-L1-containing regimen." Conversion of this indication from accelerated approval to regular approval. Criteria updated.

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Change Date	Changed By	Description of Change	Version
07/21/2023	CAC	Annual review. Moved dosing information to Appendix A. Updated NCCN references ["Guidelines for Hepatobiliary Carcinoma" separated into 2 sections, "Guidelines for Hepatocellular Carcinoma" and NCCN Guidelines for Biliary Tract Cancer). Reference HCC in policy.]	6

12/16/2022 (FDA): Postmarketing requirement fulfilled for alternative dosing regimen for all approved adult solid tumor indications (alternative dosing regimen for adult cHL and adult PMBCL still under accelerated approval).
08/05/2022 (FDA): Labeling updated to reflect the availability of an FDA-approved tes for identifying patients with mismatch repair proficient (pMMR) advanced endometrial carcinoma.
01/26/2023 (FDA): Added criteria for new indication as a single agent, for adjuvant treatment following resection and platinum-based chemotherapy for adult patients with stage IB (T2a ≥ 4 cm), II, or IIIA NSCLC.
04/03/2023 (FDA): Added criteria for new indication, in combination with Padcev®: treatment of adult patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing therapy.

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Change Date	Changed By	Description of Change	Version
04/15/2022	CAC	Annual review. Rewrite.	5

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Criteria Change History *(continued)*

Change Date	Changed By	Description of Change	Version
01/15/2021	CAC	Annual review.	4
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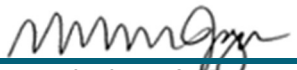
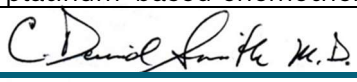
Change Date	**Changed By**	**Description of Change**	**Version**
04/28/2020	CAC	Changed from ETP to PA and added code J9271.	3
Signature William (Bill) Jagiello, DO			
Change Date	**Changed By**	**Description of Change**	**Version**
01/19/2018	CAC	Criterion #3 added “and have progression on or after platinum-based chemotherapy”.	2
Signature C. David Smith, MD			
Change Date	**Changed By**	**Description of Change**	**Version**
01/15/2016	CAC	Removed dosing information. Removed reference to ipilimumab (Yervoy). Added information on non-small cell lung cancer (NSCLC).	1
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CAC = Medicaid Clinical Advisory Committee