PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable – Programmed Death Receptor-1) – Keytruda Prior Authorization Policy
- Keytruda® (pembrolizumab intravenous infusion – Merck)

REVIEW DATE: 05/01/2024

OVERVIEW

Keytruda, a human programmed death receptor-1 (PD-1) blocking antibody, is indicated for the treatment of the following indications:[1]

- **Biliary tract cancer**, in combination with gemcitabine and cisplatin for the treatment of locally advanced unresectable or metastatic disease.
- **Breast cancer, triple-negative**, in the following situations:
  - In combination with chemotherapy for the treatment of locally recurrent unresectable or metastatic disease in patients whose tumors express programmed death-ligand 1 (PD-L1) [combined positive score {CPS} ≥ 10] as determined by an FDA-approved test.
  - For the treatment of high-risk, early-stage disease in combination with chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery.
- **Cervical cancer**, in the following situations:
  - In combination with chemotherapy, with or without bevacizumab, for persistent, recurrent, or metastatic disease in patients whose tumor expresses PD-L1 (CPS ≥ 1) as determined by an FDA-approved test.
  - As a single agent, for treatment of recurrent or metastatic disease with disease progression on or after chemotherapy in patients whose tumors express PD-L1 (CPS ≥ 1) as determined by an FDA-approved test.
  - In combination with chemoradiotherapy for FIGO 2014 Stage III-IVA disease.
- **Classical Hodgkin lymphoma**, in the following situations:
  - For treatment of relapsed or refractory disease in adults.
  - For the treatment of refractory disease, or disease that has relapsed after two or more prior lines of therapy in pediatric patients.
- **Cutaneous squamous cell carcinoma,** for treatment of patients with recurrent, metastatic disease or locally advanced disease that is not curable by surgery or radiation.
- **Endometrial cancer**, in the following situations:
  - In combination with Lenvima® (lenvatinib capsules), for the treatment of advanced disease that is mismatch repair proficient (pMMR) as determined by an FDA-approved test or not microsatellite instability high (MSI-H), in patients, who have disease progression following prior systemic therapy and are not candidates for curative surgery or radiation.
  - As a single agent, for the treatment of advanced disease that is MSI-H or mismatch repair deficient (dMMR) as determined by an FDA-approved test, in patients who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation.
- **Esophageal cancer**, treatment of locally advanced or metastatic esophageal or gastroesophageal junction (GEJ) carcinoma (tumors with epicenter 1 to 5 centimeters above the GEJ) that is not amenable to surgical resection or definitive chemoradiation in the following situations:
  - In combination with platinum- and fluoropyrimidine-based chemotherapy.
  - As a single agent after one or more prior lines of systemic therapy for tumors of squamous cell histology that express PD-L1 (CPS ≥ 10) as determined by an FDA-approved test.

- **Gastric cancer**, in the following situations:
  - For the first-line treatment of locally advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive gastric or GEJ adenocarcinoma, in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy.*
  - 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 GEJ adenocarcinoma.
- **Head and neck squamous cell carcinoma**, in the following situations:
  - As a single agent for the treatment of recurrent or metastatic disease with disease progression on or after platinum-containing chemotherapy.
  - In combination with platinum and fluorouracil for the first-line treatment of metastatic or with unresectable, recurrent disease.
  - As a single agent, for the first line treatment of metastatic or unresectable, recurrent disease in patients whose tumors express PD-L1 (CPS ≥ 1) as determined by an FDA-approved test.
- **Hepatocellular carcinoma**, for treatment of hepatocellular carcinoma secondary to hepatitis B who have received prior systemic therapy other than a PD-1/PD-L1 containing regimen.
- **Melanoma**, in the following situations:
  - For the treatment of unresectable or metastatic disease.
  - As adjuvant treatment of Stage IIB, IIC, or III melanoma following complete resection in patients ≥ 12 years of age.
- **Merkel cell carcinoma**, for treatment of recurrent, locally advanced, or metastatic disease in adults and pediatric patients.
- **Microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) cancer**, for treatment of unresectable or metastatic MSI-H or dMMR solid tumors, as determined by an FDA-approved test, in adult and pediatric patients that have progressed following prior treatment and who have no satisfactory alternative treatment options.
- **Microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer,** for the treatment of unresectable or metastatic disease, as determined by an FDA-approved test.
- **Non-small cell lung cancer** (**NSCLC**), in the following situations:
  - As a single agent for the first-line treatment of tumors that express PD-L1 (tumor proportion score [TPS] ≥ 1%) as determined by an FDA-approved test, with no epidermal growth factor receptor (*EGFR*) or anaplastic lymphoma kinase (*ALK*) genomic tumor aberrations, and is stage III where patients are not candidates for surgical resection or definitive chemoradiation or for metastatic disease.
  - As a single agent for the treatment of metastatic disease in patients whose tumors express PD-L1 (TPS ≥ 1%) as determined by an FDA-approved test and with disease progression on or after platinum-containing chemotherapy. Patients with *EGFR* or *ALK* genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving Keytruda.
  - In combination with pemetrexed and platinum-based chemotherapy, for the first-line treatment of metastatic nonsquamous NSCLC in patients with no *EGFR* or *ALK* genomic tumor aberrations.
  - In combination with carboplatin and either paclitaxel or paclitaxel protein-bound, for first-line treatment in metastatic squamous NSCLC.
  - In combination with platinum-containing chemotherapy, for the neoadjuvant treatment of resectable (tumors ≥ 4 cm or node positive) NSCLC and then continued as a single agent as adjuvant treatment after surgery.
  - As a single agent, as adjuvant treatment following resection and platinum-based chemotherapy for stage IB, II, or IIIA NSCLC in adults.

- **Primary mediastinal large B-cell lymphoma** (PMBCL), for treatment of refractory disease, or relapsed disease after two or more prior lines of therapy, in adults and pediatric patients.
  Limitation of Use: Keytruda is not recommended for treatment of patients with PMBCL who require urgent cytoreductive therapy.
- **Renal cell carcinoma**, in the following situations:
  - In combination with Inlyta® (axitinib tablets) or Lenvima, for the first-line treatment of advanced disease in adults.
  - For adjuvant treatment of disease that is intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions.
- **Tumor mutational burden-high (TMB-H) cancer**, for treatment of unresectable or metastatic TMB-H (≥ 10 mutations/megabase) disease, as determined by an FDA-approved test, in adults and pediatric patients that have progressed following prior treatment and who have no satisfactory alternative treatment options.*
  Limitation of Use: The safety and effectiveness of Keytruda in pediatric patients with TMB-H central nervous system cancers have not been established.
- **Urothelial carcinoma**, in the following situations:
  - Treatment of locally advanced or metastatic disease in patients who are not eligible for platinum-containing chemotherapy as a single agent.
  - Treatment of locally advanced or metastatic urothelial carcinoma in patients who have disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy as a single agent.
  - Treatment of Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer with carcinoma in situ with or without papillary tumors in patients who are ineligible for or have elected not to undergo cystectomy as a single agent.
  - In combination with Padcev® (enfortumab intravenous infusion), for the treatment of locally advanced or metastatic urothelial carcinoma in adults.

* 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.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Keytruda. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Keytruda as well as the monitoring required for adverse events and long-term efficacy, approval requires the medication to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Keytruda is recommended in those who meet one of the following criteria:
FDA-Approved Indications

1. **Biliary Tract Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, E, and F):
   Note: Biliary tract cancer includes gallbladder cancer, intrahepatic cholangiocarcinoma, and extrahepatic cholangiocarcinoma.

A) Patient is ≥ 18 years of age; AND
B) Disease is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); AND
Note: If the tumor is MSI-H or dMMR, see Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Solid Tumors criteria.
C) Disease is not tumor mutational burden-high (≥ 10 mutations/megabase); AND
Note: If the tumor is mutational burden-high, see Tumor Mutational Burden-High (TMB-H) Cancer criteria.
D) Patient has unresectable, resected gross residual, or metastatic disease; AND
E) Patient meets ONE of the following (i or ii):
i. Medication is used in combination with cisplatin and gemcitabine; OR
ii. If the medication is used in combination with Lenvima (lenvatinib capsules), it is used for subsequent treatment; AND
F) The medication is prescribed by or in consultation with an oncologist.

2. Breast Cancer. Approve for 1 year if the patient meets ALL of the following (A, B, C, D, E, and F):
A) Patient is ≥ 18 years of age; AND
B) Disease is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); AND
Note: If the tumor is MSI-H or dMMR, see Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Solid Tumors criteria.
C) Disease is not tumor mutational burden-high (≥ 10 mutations/megabase); AND
Note: If the tumor is mutational burden-high, see Tumor Mutational Burden-High (TMB-H) Cancer criteria.
D) Patient has triple-negative breast cancer; AND
Note: Triple negative breast cancer is estrogen receptor-negative, progesterone receptor-negative, human epidermal growth factor receptor 2 (HER2)-negative.
E) Patient meets ONE of the following (i or ii):
i. Patient meets ALL of the following (a, b, and c):
a) Patient has recurrent unresectable (local or regional) or metastatic disease; AND
b) The medication is used in combination with chemotherapy; AND
c) Patient's tumor expression for programmed death-ligand 1 (PD-L1) as determined by an approved test has a combined positive score (CPS) ≥ 10; OR
ii. Patient has high-risk, early-stage disease; AND
F) The medication is prescribed by or in consultation with an oncologist.

3. Cervical Cancer. Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
A) Patient is ≥ 18 years of age; AND
B) Disease is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); AND
Note: If the tumor is MSI-H or dMMR, see Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Solid Tumors criteria.
C) Disease is not tumor mutational burden-high (≥ 10 mutations/megabase); AND
Note: If the tumor is mutational burden-high, see Tumor Mutational Burden-High (TMB-H) Cancer criteria.
D) Patient meets ONE of the following (i or ii):
i. Patient meets BOTH of the following (a and b):
a) Patient has persistent, recurrent, or metastatic disease; AND
b) Patient's tumor expression for programmed death-ligand 1 (PD-L1), as determined by an approved test, has a combined positive score (CPS) ≥ 1; OR
ii. Patient has FIGO 2014 stage III to IVA disease; AND
E) The medication is prescribed by or in consultation with an oncologist.

4. Classic Hodgkin Lymphoma. Approve for 1 year if the patient meets BOTH of the following (A and B):
- **A)** Patient meets ONE of the following (i or ii):
  - **i.** Patient meets BOTH of the following (a and b):
    - **a)** Patient is ≥ 18 years of age; AND
    - **b)** Patient has tried at least one systemic regimen; OR
      Note: Examples of systemic regimens are ABVD (doxorubicin, bleomycin, vinblastine, dacarbazine) + rituximab, CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) + rituximab, CVbP (cyclophosphamide, vinblastine, prednisolone) + rituximab, Adcetris (brentuximab vedotin intravenous infusion) + AVD (doxorubicin, vinblastine, dacarbazine).
  - **ii.** Patient meets BOTH of the following (a and b):
    - **a)** Patient is < 18 years of age; AND
    - **b)** Patient has relapsed or refractory disease; AND
- **B)** The medication is prescribed by or in consultation with an oncologist.

5. Colon, Rectal, or Appendiceal Cancer. Approve for duration noted if the patient meets ALL of the following (A, B, C, D, and E):
- **A)** Patient is ≥ 18 years of age; AND
- **B)** Disease is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); AND
  Note: If the tumor is MSI-H or dMMR, see Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Solid Tumors criteria.
- **C)** Patient is DNA polymerase epsilon/delta (POLE/POLD1) mutation positive; AND
- **D)** Patient meets ONE of the following (i or ii):
  - **i.** Approve for 1 year of the patient meets ONE of the following (a or b):
    - **a)** Patient has locally unresectable or medically inoperable disease; OR
    - **b)** Patient has metastatic disease; OR
  - **ii.** Approve for 6 months if the medication is used for neoadjuvant therapy; AND
- **E)** The medication is prescribed by or in consultation with an oncologist.

6. Cutaneous Squamous Cell Carcinoma. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
- **A)** Patient is ≥ 18 years of age; AND
- **B)** Patient has locally advanced, recurrent, or metastatic disease; AND
- **C)** The disease is not curable by surgery or radiation; AND
- **D)** The medication is prescribed by or in consultation with an oncologist.

7. Endometrial Carcinoma. Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
- **A)** Patient is ≥ 18 years of age; AND
- **B)** Disease is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); AND
  Note: If the tumor is MSI-H or dMMR, see Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Solid Tumors criteria.
- **C)** Disease is not tumor mutational burden-high (≥ 10 mutations/megabase); AND
  Note: If the tumor is mutational burden-high, see Tumor Mutational Burden-High (TMB-H) Cancer criteria.
- **D)** Patient meets ONE of the following (i or ii):
  - **i.** Patient meets BOTH of the following (a and b):
    - **a)** Medication is used for primary or adjuvant therapy; AND
    - **b)** Patient meets ONE of the following [(1) or (2)]:
      - **(1)** Medication is used in combination with carboplatin and paclitaxel; OR

(2) Medication is used as a single agent for maintenance therapy; OR

ii. Patient meets BOTH of the following (a and b):
- **a)** Patient has recurrent disease; AND
- **b)** Patient meets ONE of the following [(1), (2), or (3)]:
  - **(1)** Medication is used in combination with Lenvima (lenvatinib capsules); OR
  - **(2)** Medication is used in combination with carboplatin and paclitaxel; OR
  - **(3)** Medication is used as a single agent for maintenance therapy; AND

E) The medication is prescribed by or in consultation with an oncologist.

8. Esophageal and Esophagogastric Junction Cancer. Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):

A) Patient is ≥ 18 years of age; AND

B) Disease is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); AND
Note: If the tumor is MSI-H or dMMR, see Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Solid Tumors criteria.

C) Disease is not tumor mutational burden-high (≥ 10 mutations/megabase); AND
Note: If the tumor is mutational burden-high, see Tumor Mutational Burden-High (TMB-H) Cancer criteria.

D) Patient meets ONE of the following (i, ii, or iii):

i. Patient meets BOTH of the following (a and b):
- **a)** Patient's tumor expression for programmed death-ligand 1 (PD-L1) as determined by an approved test has a combined positive score (CPS) ≥ 1; AND
- **b)** The medication is used in combination with chemotherapy; OR
  Note: Examples of chemotherapy include cisplatin plus fluorouracil or capecitabine; and oxaliplatin plus fluorouracil or capecitabine.

ii. Patient meets ALL of the following (a, b, and c):
- **a)** Patient has squamous cell carcinoma; AND
- **b)** Patient's tumor expression for programmed death-ligand 1 (PD-L1) as determined by an approved test has a combined positive score (CPS) ≥ 10; AND
- **c)** Patient meets ONE of the following [(1) or (2)]:
  - **(1)** The medication is used as monotherapy; OR
  - **(2)** The medication is used in combination with chemotherapy; OR
    Note: Examples of chemotherapy include cisplatin plus fluorouracil or capecitabine; and oxaliplatin plus fluorouracil or capecitabine.

iii. Patient meets ALL of the following (a, b, c, and d):
- **a)** Patient has adenocarcinoma; AND
- **b)** Patient's tumor expression for PD-L1 as determined by an approved test has a CPS ≥ 1; AND
- **c)** Tumor is human epidermal growth factor receptor 2 (HER2) or HER2/neu positive; AND
- **d)** Medication is used in combination with trastuzumab, cisplatin or oxaliplatin, and fluorouracil or capecitabine; AND

E) The medication is prescribed by or in consultation with an oncologist.

9. Gastric Cancer. Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):

A) Patient is ≥ 18 years of age; AND

B) Disease is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); AND
Note: If the tumor is MSI-H or dMMR, see Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Solid Tumors criteria.

C) Disease is not tumor mutational burden-high (≥ 10 mutations/megabase); AND
Note: If the tumor is mutational burden-high, see Tumor Mutational Burden-High (TMB-H) Cancer criteria.

D) Patient meets ONE of the following (i or ii):
- **i.** Patient meets ALL of the following (a, b, and c):
  - **a)** Tumor is human epidermal growth factor receptor 2 (HER2) or HER2/neu positive; AND
  - **b)** Patient's tumor expression for programmed death-ligand 1 (PD-L1) as determined by an approved test has a combined positive score (CPS) ≥ 1; AND
  - **c)** Medication is used in combination with trastuzumab, cisplatin or oxaliplatin, and fluorouracil or capecitabine; OR
- **ii.** Patient meets BOTH of the following (a and b):
  - **a)** Patient's tumor expression for PD-L1 as determined by an approved test has a CPS ≥ 1; AND
  - **b)** Medication is used in combination with cisplatin or oxaliplatin, and fluorouracil or capecitabine; AND

E) The medication is prescribed by or in consultation with an oncologist.

10. Head and Neck Squamous Cell Carcinoma. Approve for 1 year if the patients meets ALL of the following (A, B, C, D, E, and F):

A) Patient is ≥ 18 years of age; AND

B) Disease is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); AND
Note: If the tumor is MSI-H or dMMR, see Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Solid Tumors criteria.

C) Disease is not tumor mutational burden-high (≥ 10 mutations/megabase); AND
Note: If the tumor is mutational burden-high, see Tumor Mutational Burden-High (TMB-H) Cancer criteria.

D) Patient has recurrent, unresectable, or metastatic disease; AND

E) Patient meets ONE of the following (i or ii):
- **i.** If the medication is used for first-line treatment, patient must meet ONE of the following (a or b):
  - **a)** Keytruda is used in combination with chemotherapy; OR
    Note: Examples of chemotherapy are cisplatin, carboplatin, fluorouracil, gemcitabine.
  - **b)** Keytruda is used as a single agent if the tumors are PD-L1-positive (combined positive score ≥ 1), as determined by an approved test.
- **ii.** For subsequent therapy, patient has tried at least one platinum-containing chemotherapy regimen; AND
  Note: Examples of platinum-contain chemotherapy regimens are: cisplatin or carboplatin with Erbitux (cetuximab intravenous infusion), gemcitabine, or 5-fluorouracil (5-FU).

F) The medication is prescribed by or in consultation with an oncologist.

11. Hepatocellular Carcinoma. Approve for 1 year if the patient meets ALL of the following (A, B, C, D, E, and F):

A) Patient is ≥ 18 years of age; AND

B) Disease is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); AND
Note: If the tumor is MSI-H or dMMR, see Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Solid Tumors criteria.

C) Disease is not tumor mutational burden-high (≥ 10 mutations/megabase); AND
Note: If the tumor is mutational burden-high, see Tumor Mutational Burden-High (TMB-H) Cancer criteria.

D) Patient meets ONE of the following (i, ii, or iii):
- **i.** Patient has unresectable disease and is not a transplant candidate; OR
- **ii.** Patient has liver-confined disease, inoperable by performance status, comorbidity, or with minimal or uncertain extrahepatic disease; OR
- **iii.** Patient has metastatic disease or extensive liver tumor burden; AND

E) If medication is used as subsequent therapy, the patient has Child-Pugh Class A disease only; AND
F) The medication is prescribed by or in consultation with an oncologist.

12. Melanoma. Approve for the duration noted below if the patient meets ALL of the following (A and B):
Note: This includes cutaneous melanoma, brain metastases due to melanoma, and uveal melanoma.
A) Patient meets ONE of the following (i, ii, or iii):
- **i.** Approve for 1 year if the patient meets BOTH of the following (a and b):
  - **a)** Patient is ≥ 18 years of age; AND
  - **b)** Patient has unresectable, advanced, or metastatic melanoma; OR
- **ii.** Approve for up to 1 year (total) if patient meets BOTH of the following (a and b):
  - **a)** Patient is ≥ 12 years of age; AND
  - **b)** Keytruda will be used as adjuvant treatment; OR
- **iii.** Approve for 4 months if the patient meets BOTH of the following (a and b):
  - **a)** Patient is ≥ 18 years of age; AND
  - **b)** Keytruda will be used as neoadjuvant treatment; AND

B) The medication is prescribed by or in consultation with an oncologist.

13. Merkel Cell Carcinoma. Approve for 1 year if the patient meets BOTH of the following (A and B):
A) Patient meets ONE of the following (i, ii, or iii):
- **i.** Patient has locally advanced disease, if according to the prescriber curative surgery and curative radiation therapy are not feasible; OR
- **ii.** Patient has recurrent regional disease, if according to the prescriber curative surgery and curative radiation therapy are not feasible; OR
- **iii.** Patient has metastatic disease; AND

B) The medication is prescribed by or in consultation with an oncologist.

14. Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Solid Tumors. Approve for 1 year if the patient meets BOTH of the following (A and B):
Note**:** Examples of solid tumors with MSI-H or dMMR are adrenal gland, biliary tract cancers, breast cancer, cervical cancer, chondrosarcoma, colon or rectal cancer, endometrial carcinoma, esophageal or esophagogastric cancers, Ewing sarcoma, gallbladder carcinoma, gastric cancer, head and neck squamous cell carcinoma, hepatocellular carcinoma, occult primary (cancer of unknown primary), osteosarcoma, ovarian/fallopian tube/primary peritoneal, pancreatic adenocarcinoma, penile cancer, neuroendocrine tumor, prostate cancer, small bowel adenocarcinoma, testicular cancer, vulvar cancer.
A) One of the following conditions applies (i, ii, iii, iv, v, vi, vii, or viii):
- **i.** Patient has advanced or metastatic ampullary cancer; OR
- **ii.** Patient has unresectable or metastatic colon or rectal cancer; OR
- **iii.** Patient has unresectable or metastatic gallbladder cancer (including intra- and extra-hepatic cholangiocarcinoma); OR
- **iv.** Patient has unresectable or metastatic head and neck squamous cell carcinoma; OR
- **v.** Patient has persistent or recurrent ovarian/fallopian tube/primary peritoneal carcinoma; OR
- **vi.** Patient has locally advanced or metastatic pancreatic adenocarcinoma; OR
- **vii.** Patient has advanced or metastatic small bowel carcinoma; OR
- **viii.** Patient meets BOTH of the following (a and b):
  - **a)** Patient has tried at least one prior systemic therapy for an MSI-H or dMMR solid tumor; AND
  - **b)** Patient has unresectable or metastatic disease; AND

B) The medication is prescribed by or in consultation with an oncologist.

15. Non-Small Cell Lung Cancer. Approve for the duration noted if the patient meets ALL of the following (A, B, and C):
- **A)** Patient is ≥ 18 years of age; AND
- **B)** Patient meets ONE of the following (i, ii, iii, iv, v, vi, or vii):
  - **i.** Approve for 1 year if the patient meets ALL of the following (a, b, and c):
    - **a)** Patient has recurrent, advanced, or metastatic disease; AND
    - **b)** Keytruda is used as first-line or continuation maintenance therapy; AND
      Note: This is regardless of programmed death-ligand 1 (PD-L1) status.
    - **c)** The tumor is negative for actionable mutations; OR
      Note: Examples of actionable mutations include sensitizing epidermal growth factor receptor (*EGFR*) mutation, anaplastic lymphoma kinase (*ALK*) fusions, *NTRK* gene fusion-positive, *ROS1*, *BRAF V600E*, *MET 14* skipping mutation, *RET* rearrangement. *KRAS G12C* is not considered an actionable mutation (the tumor may be *KRAS G12C* mutation positive).
  - **ii.** Approve for 1 year if the patient meets ALL of the following (a, b, and c):
    - **a)** Patient has advanced or metastatic disease; AND
    - **b)** Keytruda is used as first-line therapy; AND
      Note: This is regardless of the PD-L1 status.
    - **c)** The tumor is positive for one of the following mutations [(1) or (2)]:
      - **(1)** EGFR exon 20 mutation; OR
      - **(2)** ERBB2 (HER2) mutation; OR
  - **iii.** Approve for 1 year if the patient meets ALL of the following (a, b, and c):
    - **a)** Patient has recurrent, advanced, or metastatic disease; AND
    - **b)** Keytruda is used as first-line or subsequent therapy; AND
      Note: This is regardless of the PD-L1 status.
    - **c)** The tumor is positive for one of the following mutations [(1), (2), (3), or (4)]:
      - **(1)** BRAF V600E mutation; OR
      - **(2)** NTRK1/2/3 gene fusion; OR
      - **(3)** MET exon 14 skipping mutation; OR
      - **(4)** RET rearrangement; OR
  - **iv.** Approve for 1 year if the patient meets ALL of the following (a, b, c, and d):
    - **a)** Patient has recurrent, advanced, or metastatic disease; AND
    - **b)** Keytruda is used as subsequent therapy; AND
    - **c)** The tumor is positive for ONE of the following mutations [(1), (2), (3), or (4)]:
      - **(1)** EGFR S768I, L861Q, and/or G719X mutation; OR
      - **(2)** EGFR exon 19 deletion or exon 21 L858R; OR
      - **(3)** ALK rearrangement; OR
      - **(4)** ROS1 rearrangement; AND
    - **d)** The patient has received targeted drug therapy for the specific mutation; OR
      Note: Examples of targeted drug therapy include Gilotrif (afatinib tablets), Tagrisso (osimertinib tablets), erlotinib, Iressa (gefitinib tablets), or Vizimpro (dacomitinib tablets), Xalkori (crizotinib capsules), Rozlytrek (entrectinib capsules), or Zykadia (ceritinib tablets).
  - **v.** Approve for 1 year if the patient meets ALL of the following (a, b, c, d, and e):
    - **a)** Patient has advanced, recurrent, or metastatic disease; AND
    - **b)** Patient has tried systemic therapy; AND
      Note: Examples of systemic chemotherapy include cisplatin, carboplatin, pemetrexed, paclitaxel albumin-bound, gemcitabine, paclitaxel.
    - **c)** The tumor is PD-L1 positive, with tumor proportion score (TPS) ≥ 1%, as determined by an approved test; AND

d) Patient has not progressed on prior therapy with a programmed death receptor-1 (PD-1)/PD-L1 inhibitor; AND
Note: This includes previous therapy with either one of Keytruda, Opdivo (nivolumab intravenous infusion), or Tecentriq (atezolizumab intravenous infusion).

e) If tumor is positive for an actionable mutation, the patient has received targeted drug therapy for the specific mutation; AND
Note: Examples of actionable mutations include sensitizing epidermal growth factor receptor (*EGFR*) mutation, anaplastic lymphoma kinase (*ALK*) fusions, *NTRK* gene fusion positive, *ROS1*, *BRAF V600E*, *MET* exon 14 skipping mutation, *RET* rearrangement.

vi. Approve for 1 year (total) if the patient meets ONE of the following (a or b):
- **a)** Patient meets ALL of the following [(1), (2), and (3)]:
  - **(1)** Patient has completely resected stage II or III disease; AND
  - **(2)** Tumor is negative for *EGFR* exon 19 deletion, exon 21 *L858R* mutation, and *ALK* rearrangements; AND
  - **(3)** Patient has received adjuvant chemotherapy; OR
- **b)** Patient has received neoadjuvant treatment with Keytruda; AND

iv. Approve for 4 months if the patient meets ALL of the following (a, b, and c):
- **a)** Patient has resectable disease; AND
  Note: Resectable disease is defined as tumors ≥ 4 cm or node positive.
- **b)** Keytruda is used as neoadjuvant therapy; AND
- **c)** Keytruda is used in combination with platinum-doublet chemotherapy; AND
  Note: Examples of platinum-doublet chemotherapy include cisplatin plus pemetrexed and cisplatin plus gemcitabine.

C) The medication is prescribed by or in consultation with an oncologist.

16. Primary Mediastinal Large B-Cell Lymphoma. Approve for 1 year if the patient meets BOTH of the following (A and B):

A) Patient has relapsed after, or is refractory to, at least two previous regimens; AND
Note: Examples of previous regimens include autologous hematopoietic stem cell transplant (auto-HSCT), EPOCH-R (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin, rituximab), RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone], RCEPP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone).

B) The medication is prescribed by or in consultation with an oncologist.

17. Renal Cell Carcinoma. Approve for the duration noted below if the patient meets ALL of the following (A, B, and C):

A) Patient is ≥ 18 years of age; AND

B) Patient meets ONE of the following (i, ii, or iii):

i. Approve for 1 year if the patient meets ALL of the following (a, b, and c):
- **a)** The tumor has clear cell histology; AND
- **b)** Patient has relapsed or metastatic disease; AND
- **c)** The medication is used in combination with Inlyta (axitinib tablets) or Lenvima (lenvatinib capsules); OR

ii. Approve for 1 year if the patient meets ALL of the following (a, b, and c):
- **a)** The tumor has non-clear cell histology; AND
- **b)** Patient has relapsed or metastatic disease; AND
- **c)** The medication is used as single-agent therapy; OR

iii. Approve for up to 1 year (total) if patient meets ALL of the following (a, b, c, and d):
- **a)** Keytruda is used as adjuvant therapy; AND
- **b)** The tumor has clear cell histology; AND
- **c)** Patient has advanced disease; AND

d) The medication is used as single-agent therapy; AND

C) The medication is prescribed by or in consultation with an oncologist.

18. Tumor Mutational Burden-High (TMB-H) Cancer. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):

A) Patient has unresectable or metastatic tumor mutational burden-high (≥ 10 mutations/megabase) solid tumor; AND

Note: Examples of solid tumors are adrenal cancer, ampullary adenocarcinoma, breast cancer, cervical cancer, cholangiocarcinoma (intrahepatic and extrahepatic), chondrosarcoma, chordoma, endometrial carcinoma, esophageal carcinoma, esophagogastric junction carcinoma, Ewing sarcoma, gallbladder cancer, gastric cancer, head and neck cancer, neuroendocrine cancer, osteosarcoma, ovarian/fallopian tube/primary peritoneal carcinoma, pancreatic adenocarcinoma, penile cancer, primary occult, prostate cancer, salivary gland tumors, testicular cancer, thyroid cancer, uterine sarcoma, vulvar cancer.

B) Patient has progressed on prior therapy; AND

C) Patient has no satisfactory alternative treatment options; AND

D) The medication is prescribed by or in consultation with an oncologist.

19. Urothelial Carcinoma. Approve for 1 year if the patient meets ALL of the following (A, B, and C):

A) Patient is ≥ 18 years of age; AND

B) Patient meets ONE of the following conditions (i, ii, iii, or iv):

i. Patient has locally advanced or metastatic disease; OR

ii. Patient has tried at least one platinum-based chemotherapy; OR
Note: Cisplatin and carboplatin are platinum-based chemotherapies.

iii. According to the prescriber, patient is not eligible for platinum-based chemotherapy; OR
Note: This is regardless of PD-L1 status. Cisplatin and carboplatin are platinum-based chemotherapies.

iv. Patient meets both of the following (a and b):

a) Patient has non-muscle invasive bladder cancer; AND

b) Patient has tried Bacillus Calmette-Guerin (BCG) or intravesical chemotherapy; AND
Note: Examples of agents used as intravesical chemotherapy include mitomycin and gemcitabine.

C) The medication is prescribed by or in consultation with an oncologist.

Other Uses with Supportive Evidence

20. Adrenal Gland Tumor. Approve for 1 year if the patient meets ALL of the following (A, B, and C):

A) Patient is ≥ 18 years of age; AND

B) Patient has unresectable or metastatic adrenocortical carcinoma; AND

C) The medication is prescribed by or in consultation with an oncologist.

21. Anal Carcinoma. Approve for 1 year if the patient meets ALL of the following (A, B, and C):

A) Patient is ≥ 18 years of age; AND

B) Patient meets ONE of the following (i or ii):

i. Patient has locally recurrent, persistent disease; OR

ii. Patient has metastatic disease; AND

C) Medication is used for subsequent therapy; AND

D) The medication is prescribed by or in consultation with an oncologist.

22. Extranodal NK/T-Cell Lymphoma, Nasal Type. Approve for 1 year if the patient meets ALL of the following (A, B, and C):

A) Patient is ≥ 18 years of age; AND
B) Patient has received an asparaginase-based chemotherapy regimen; AND
Note: Examples of asparaginase-based chemotherapy are dexamethasone, ifosfamide, pegaspargase, etoposide; and gemcitabine, pegaspargase, oxaliplatin.
C) The medication is prescribed by or in consultation with an oncologist.

23. Gestational Trophoblastic Neoplasia. Approve for 1 year if the patient meets ALL of the following (A, B, and C):
A) Patient is ≥ 18 years of age; AND
B) Patient meets ONE of the following (i or ii):
i. Patient has tried at least one previous chemotherapy regimen for recurrent or progressive disease; OR
Note: Examples of chemotherapy regimens contain etoposide, cisplatin/carboplatin, paclitaxel, bleomycin, ifosfamide, methotrexate.
ii. Patient has high-risk disease; AND
C) The medication is prescribed by or in consultation with an oncologist.

24. Glioma. Approve for duration noted if the patient meets ALL of the following (A, B, C, D, and E):
A) Patient is < 18 years of age; AND
B) Patient has diffuse high-grade disease; AND
C) Tumor is hypermutant; AND
D) Patient meets ONE of the following (i or ii):
i. Approve for 1 year (total) if the patient meets BOTH of the following (a and b):
a) Medication is used for adjuvant treatment; AND
b) Patient does NOT have diffuse midline glioma, H3 K27-altered, or pontine location; OR
ii. Approve for 1 year of the patient has meets BOTH of the following (a and b):
a) Patient has recurrent or progressive; AND
b) Patient does NOT have either of the following [(1) or (2)]:
(1) Oligodendroglioma isocitrate dehydrogenase (IDH)-mutant and 1p/19q co-deleted; OR
(2) Astrocytoma, IDH-mutant; AND
E) The medication is prescribed by or in consultation with an oncologist.

25. Kaposi Sarcoma. Approve for 6 months if the patient meets ALL of the following (A, B, C, and D):
A) Patient is ≥ 18 years of age; AND
B) Patient has endemic or classic Kaposi sarcoma; AND
C) Patient has relapsed or refractory advanced cutaneous, oral, visceral, or nodal disease; AND
D) The medication is prescribed by or in consultation with an oncologist.

26. Mycosis Fungoides/Sezary Syndrome. Approve for 1 year if the patient meets BOTH of the following (A and B):
A) Patient is ≥ 18 years of age; AND
B) The medication is prescribed by or in consultation with an oncologist.

27. Ovarian/Fallopian Tube/Peritoneal Cancer. Approve for 1 year if the patient meets ALL of the following (A, B, C, D, E, F, and G):
A) Patient is ≥ 18 years of age; AND
B) Disease is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); AND
Note: If the tumor is MSI-H or dMMR, see Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Solid Tumors criteria.
C) Disease is not tumor mutational burden-high (≥ 10 mutations/megabase); AND

Note: If the tumor is mutational burden-high, see Tumor Mutational Burden-High (TMB-H) Cancer criteria.

D) Patient has platinum-resistant disease; AND
E) Medication is used for the treatment of recurrence; AND
F) Medication is used in combination with cyclophosphamide and bevacizumab; AND
G) The medication is prescribed by or in consultation with an oncologist.

28. Primary Cutaneous Anaplastic Large Cell Lymphoma. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
A) Patient is ≥ 18 years of age; AND
B) Patient has relapsed or refractory disease; AND
C) Patient meets ONE of the following (i or ii):
ii. Patient has disease with multifocal lesions; OR
iii. Patient has disease with regional node; AND
D) The medication is prescribed by or in consultation with an oncologist.

29. Small Bowel Adenocarcinoma. Approve for 1 year if the patient meets ALL of the following (A, B, C, D, E, and F):
A) Patient is ≥ 18 years of age; AND
B) Disease is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); AND
Note: If the tumor is MSI-H or dMMR, see Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Solid Tumors criteria.
C) Disease is not tumor mutational burden-high (≥ 10 mutations/megabase); AND
Note: If the tumor is mutational burden-high, see Tumor Mutational Burden-High (TMB-H) Cancer criteria.
D) Disease is DNA polymerase epsilon/delta 1 (POLE/POLD1) mutation positive; AND
E) Patient has advanced or metastatic disease; AND
F) The medication is prescribed by or in consultation with an oncologist.

30. Small Cell Lung Cancer. Approve for 1 year if the patient meets ALL of the following (A, B, and C):
A) Patient is ≥ 18 years of age; AND
B) Keytruda is used as subsequent therapy; AND
C) The medication is prescribed by or in consultation with an oncologist.

31. Soft Tissue Sarcoma. Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
A) Patient is ≥ 18 years of age; AND
B) Disease is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); AND
Note: If the tumor is MSI-H or dMMR, see Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Solid Tumors criteria.
C) Disease is not tumor mutational burden-high (≥ 10 mutations/megabase); AND
Note: If the tumor is mutational burden-high, see Tumor Mutational Burden-High (TMB-H) Cancer criteria.
D) Patient has ONE of the following (i, ii, iii, iv, or v):
i. Alveolar soft part sarcoma; OR
ii. Cutaneous angiosarcoma; OR
iii. Extremity, body wall, or head and neck sarcoma; OR
iv. Retroperitoneal or intra-abdominal sarcoma;
v. Rhabdomyosarcoma; AND
E) The medication is prescribed by or in consultation with an oncologist.

32. Squamous Cell Skin Cancer. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
- **A)** Patient is ≥ 18 years of age; AND
- **B)** Patient has locally advanced, recurrent, or metastatic disease; AND
- **C)** According to the prescriber, curative surgery and curative radiation therapy are not feasible; AND
- **D)** The medication is prescribed by or in consultation with an oncologist.

33. Thymic Carcinoma. Approve for 1 year if the patient meets BOTH of the following (A and B):
- **A)** Patient is ≥ 18 years of age; AND
- **B)** The medication is prescribed by or in consultation with an oncologist.

34. Thyroid Carcinoma. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
- **A)** Patient is ≥ 18 years of age; AND
- **B)** Patient has metastatic anaplastic carcinoma; AND
- **C)** The medication is used in combination with Lenvima (lenvatinib capsules); AND
- **D)** The medication is prescribed by or in consultation with an oncologist.

35. Vaginal Cancer. Approve for 1 year if the patient meets ALL of the following (A, B, C, D, E, and F):
- **A)** Patient is ≥ 18 years of age; AND
- **B)** Disease is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); AND
  Note: If the tumor is MSI-H or dMMR, see Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Solid Tumors criteria.
- **C)** Disease is not tumor mutational burden-high (≥ 10 mutations/megabase); AND
  Note: If the tumor is mutational burden-high, see Tumor Mutational Burden-High (TMB-H) Cancer criteria.
- **D)** Patient has recurrent or metastatic disease; AND
- **E)** Patient's tumor expression for programmed death-ligand 1 (PD-L1), as determined by an approved test, has a combined positive score (CPS) ≥ 1; AND
- **F)** The medication is prescribed by or in consultation with an oncologist.

36. Vulvar Cancer. Approve for 1 year if the patient meets ALL of the following (A, B, C, D, E, and F):
- **A)** Patient is ≥ 18 years of age; AND
- **B)** Disease is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); AND
  Note: If the tumor is MSI-H or dMMR, see Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Solid Tumors criteria.
- **C)** Disease is not tumor mutational burden-high (≥ 10 mutations/megabase); AND
  Note: If the tumor is mutational burden-high, see Tumor Mutational Burden-High (TMB-H) Cancer criteria.
- **D)** The tumor is PD-L1-positive (combined positive score ≥ 1), as determined by an approved test; AND
- **E)** Patient has tried at least one other chemotherapy regimen; AND
  Note: Examples of chemotherapy regimen are cisplatin, carboplatin, fluorouracil, paclitaxel.
- **F)** The medication is prescribed by or in consultation with an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Keytruda is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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