Pembrolizumab (Keytruda®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Melanoma

- Keytruda (pembrolizumab) is indicated for the treatment of patients with unresectable or metastatic melanoma.
- 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.

Non-Small Cell Lung Cancer

- 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.
- 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.
- 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-approved test, with no EGFR or ALK genomic tumor aberrations, and is:
  - stage III where patients are not candidates for surgical resection or definitive chemoradiation, or
  - metastatic.
- 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 approved test, 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.
- Keytruda, in combination with platinum-containing chemotherapy, is indicated for the treatment of patients with resectable (tumors ≥4 cm or node positive) NSCLC as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery.
- Keytruda, as a single agent, is indicated for adjuvant treatment following resection and platinum-based chemotherapy for adult patients with stage 1B (T2a ≥ 4cm), II, or IIIA NSCLC.

Malignant Pleural Mesothelioma

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).

Head and Neck Squamous Cell Cancer

- Keytruda is indicated for the treatment of adult patients with resectable locally advanced HNSCC whose tumors express PD-L1 [Combined Positive Score (CPS) ≥1] as determined by an FDA-approved 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.
- Keytruda, in combination with platinum and fluorouracil (FU), is indicated for the first-line treatment of patients with metastatic or with unresectable, recurrent head and neck squamous cell carcinoma (HNSCC).
- 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-approved test.
- 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.

Classical Hodgkin Lymphoma

- Keytruda is indicated for the treatment of adult patients with relapsed or refractory classical Hodgkin lymphoma (cHL).
- Keytruda is indicated for the treatment of pediatric patients with refractory cHL, or cHL that has relapsed after 2 or more prior lines of therapy.

Primary Mediastinal Large B-cell Lymphoma
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.

Urothelial Carcinoma

- Keytruda, as a single agent, is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma:
  - who are not eligible for any platinum-containing chemotherapy, or
  - who have disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.
- 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.
- Keytruda, in combination with enfortumab vedotin, is indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer.

Microsatellite Instability-High Cancer or Mismatch Repair Deficient Cancer
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-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options.

Microsatellite Instability-High or Mismatch Repair Deficient Colorectal Cancer (CRC)
Keytruda is indicated for the treatment of patients with unresectable or metastatic MSI-H or dMMR colorectal cancer (CRC) as determined by an FDA-approved test.

Gastric Cancer

- 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≥1) as determined by an FDA-approved test.
- 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 ≥ 1) as determined by an FDA-approved test.

Esophageal Cancer
Keytruda is indicated for the treatment of patients with locally advanced or metastatic esophageal or gastroesophageal junction (GEJ) (tumors with epicenter 1 to 5 centimeters above the GEJ) carcinoma that is not amenable to surgical resection or definitive chemoradiation either:
- In combination with platinum- and fluoropyrimidine-based chemotherapy for patients with tumors that express PD-L1 (CPS ≥ 1), or
- 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-approved test.

Cervical Cancer
- 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-approved test.
- 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 tumor express PD-L1 (CPS ≥ 1) as determined by an FDA-approved test.
- Keytruda, in combination with chemoradiotherapy (CRT), is indicated for the treatment of patients with FIGO 2014 Stage III-IVA cervical cancer.

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

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

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

Renal Cell Carcinoma
- Keytruda, in combination with axitinib, is indicated for the first-line treatment of adult patients with advanced renal cell carcinoma (RCC).
- Keytruda, in combination with lenvatinib, is indicated for the first-line treatment of adult patients with advanced RCC.
- 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.

Endometrial Carcinoma
- Keytruda, 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.
- 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-

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

Tumor Mutational Burden-High Cancer
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-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options.

Limitations of use:
The safety and effectiveness of Keytruda in pediatric patients with TMB-H central nervous system cancers have not been established.

Cutaneous Squamous Cell Carcinoma
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.

Triple-Negative Breast Cancer
- Keytruda, in combination with chemotherapy, is indicated for the treatment of patients with locally recurrent unresectable or metastatic triple-negative breast cancer (TNBC) whose tumors express PD-L1 [Combined Positive Score (CPS) ≥10] as determined by an FDA approved test.
- 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.

Adult Classical Hodgkin Lymphoma and Adult Primary Mediastinal Large B-Cell Lymphoma

Additional Dosing Regimen of 400mg Every 6 Weeks

Keytruda is indicated for use at an additional recommended dosage of 400mg every 6 weeks for classical Hodgkin lymphoma and primary mediastinal large B-cell lymphoma in adults.

<u>Compendial Uses</u>

- Cutaneous melanoma
- Non-small cell lung cancer
- Head and neck cancer
- Classical Hodgkin Lymphoma
- Urothelial carcinoma
  - Bladder cancer
  - Primary carcinoma of the urethra
  - Upper genitourinary tract tumors
  - Urothelial carcinoma of the prostate
- Anaplastic thyroid carcinoma
- Follicular, Oncocytic (hürthle cell), or papillary thyroid carcinoma
- Colorectal cancer
- Small bowel adenocarcinoma
- Gastric cancer

- Esophageal cancer and esophagogastric junction cancer
- Cervical cancer
- Epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer
- Uveal melanoma
- Testicular cancer
- Endometrial carcinoma
- Anal carcinoma
- Central Nervous System (CNS) brain metastases
- Primary mediastinal large B-cell lymphoma
- Pancreatic adenocarcinoma
- Biliary Tract cancers
- Hepatocellular carcinoma
- Vulvar cancer
- Renal cell carcinoma
- Thymic carcinoma
- Primary Cutaneous Lymphomas
  - Mycosis Fungoides/Sezary syndrome
  - Anaplastic Large Cell Lymphoma (ALCL)
- Extranodal NK/T-cell lymphoma
- Gestational trophoblastic neoplasia
- Neuroendocrine and Adrenal Tumors
  - Well Differentiated Grade 3 Tumors
  - Adrenal Gland Tumors
  - Extrapulmonary Poorly Differentiated/Large or Small Cell Carcinoma
  - Adrenocortical carcinoma
- Soft tissue sarcomas
  - alveolar soft part sarcoma (ASPS)
  - cutaneous angiosarcoma
  - extremity/body wall sarcoma
  - head/neck sarcoma
  - retroperitoneal/intra-abdominal sarcoma
  - rhabdomyosarcoma
  - dedifferentiated liposarcoma
  - epithelioid hemangioendothelioma
- Occult primary cancer
- Prostate cancer
- Bone Cancer
  - Chondrosarcoma
  - Chordoma
  - Ewing Sarcoma
  - Osteosarcoma
- Breast Cancer
- Salivary Gland Tumors
- Merkel Cell Carcinoma
- Penile Cancer
- Uterine Sarcoma
- Small cell lung cancer
- Ampullary Adenocarcinoma
- Pediatric Diffuse High-Grade Gliomas
- Cutaneous squamous cell skin carcinoma

- Nasopharyngeal Cancer
- Kaposi Sarcoma
- Vaginal Cancer
- Pleural or Peritoneal mesothelioma
- Histologic (Richter) transformation to diffuse large B-cell lymphoma

All other indications are considered experimental/investigational and not medically necessary.

DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

- Documentation of programmed death ligand 1 (PD-L1) tumor expression, where applicable.
- Documentation of laboratory report confirming microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR) or polymerase epsilon/delta (POLE/POLD1) tumor status, where applicable.
- Documentation of laboratory report confirming high tumor mutational burden (≥10 mutations/megabase [mut/Mb]), where applicable.
- Documentation of laboratory report confirming that the cancer cells are negative for the following receptors, where applicable:
  - human epidermal growth factor receptor 2 (HER-2)
  - estrogen
  - progesterone
- Documentation of the presence of EGFR exon 19 deletions or exon 21 L858R mutations or ALK rearrangements, where applicable.

EXCLUSIONS

Coverage will not be provided for members with any of the following exclusions:

- Pediatric members with TMB-H central nervous system cancers.
- Members who have experienced disease progression while on programmed death receptor-1 (PD-1) or PD-L1 inhibitor therapy (other than when used as subsequent therapy for metastatic or unresectable melanoma in combination with ipilimumab or lenvatinib).

COVERAGE CRITERIA

Cutaneous Melanoma

Authorization of 6 months may be granted for treatment of cutaneous melanoma in any of the following settings:

- For unresectable or metastatic disease as a single agent.
- As subsequent therapy for disease progression of metastatic or unresectable tumors, as a single agent or in combination with ipilimumab or lenvatinib.
- As neoadjuvant treatment as a single agent
- As adjuvant treatment following complete lymph node resection or complete resection of stage IIB, IIC, III, or metastatic disease as a single agent.
- As subsequent or re-induction therapy in combination with trametinib and dabrafenib for metastatic or unresectable disease with a BRAF V600 activating mutation.

Non-small Cell Lung Cancer (NSCLC)

Authorization of 6 months may be granted:

- For treatment of recurrent, advanced, or metastatic NSCLC when there are no EGFR exon 19 deletions or exon 21 L858R mutations or ALK rearrangements (unless testing is not feasible due to insufficient tissue) and any of the following criteria are met:
  - The requested medication will be used as a first-line therapy for PDL1 positive disease.
  - The requested medication will be used as single agent or in combination with pemetrexed for maintenance therapy.
  - The requested medication will be used in combination with pemetrexed and either carboplatin or cisplatin for nonsquamous cell histology.
  - The requested medication will be used in combination with carboplatin and either paclitaxel or albumin-bound paclitaxel for squamous cell histology.
  - The requested medication will be used as single agent subsequent treatment of PDL1 positive disease.
- As neoadjuvant treatment when used in combination with platinum containing chemotherapy for resectable (tumors ≥4 cm or node positive) NSCLC, and then continued as single agent adjuvant therapy after surgery when there are no EGFR exon 19 deletions or exon 21 L858R mutations or ALK rearrangements (unless testing is not feasible due to insufficient tissue).

Head and Neck Cancer

Authorization of 6 months may be granted for resectable stage III-IVa non-nasopharyngeal head and neck squamous cell carcinoma when PD-L1 ≥ 1 and the requested medication will be used 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

Authorization of 6 months may be granted for treatment of members with very advanced head and neck squamous cell carcinoma with mixed subtypes (HNSCC) or nasopharyngeal cancer when any of the following criteria is met:

- The requested medication will be used as a single agent for first-line treatment in members whose tumors express PD-L1 (CPS ≥1), are microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR) or tumor mutational burden high (TMB-H [≥ 10 mut/Mb].
- The requested medication will be used as a single agent for subsequent therapy.
- The requested medication will be used in combination with cetuximab or chemotherapy.

Authorization of 6 months may be granted for treatment of MSI-H, dMMR, TMB-H (≥ 10 mut/Mb), or PD-L1 positive recurrent salivary gland tumors as a single agent.

Classic Hodgkin Lymphoma

Authorization of 6 months may be granted for treatment of relapsed or refractory classic Hodgkin lymphoma in any of the following regimens:

- As a single agent
- In combination with GVD (gemcitabine, vinorelbine, liposomal doxorubicin)
- In combination with ICE (ifosfamide, carboplatin, etoposide)
- In combination with decitabine or vorinostat if refractory to at least 3 prior lines of therapy

Urothelial Carcinoma

Authorization of 6 months may be granted as a single agent for treatment of urothelial carcinoma when used in any of the following subtypes:

- Urothelial carcinoma of the bladder in any of the following settings:
  - First line therapy for stage II, locally advanced or metastatic disease in members who are not eligible for any platinum containing chemotherapy

  - Subsequent therapy for stage II, locally advanced or metastatic disease
  - Adjuvant therapy
  - For the treatment of members with high risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) when disease is Bacillus Calmette Guerin (BCG) unresponsive, and member will not undergo cystectomy
- Primary carcinoma of the urethra in any of the following settings:
  - Locally advanced, recurrent or metastatic disease for members who are not eligible for any platinum-containing chemotherapy
  - Locally advanced, recurrent or metastatic disease post-platinum or other chemotherapy
  - Adjuvant therapy
- Urothelial carcinoma of the upper genitourinary tract in any of the following settings:
  - Metastatic disease for members who are not eligible for any platinum-containing chemotherapy
  - Metastatic disease post-platinum or other chemotherapy
  - Adjuvant therapy if platinum-based neoadjuvant chemotherapy was given
- Urothelial carcinoma of the prostate in any of the following settings:
  - Metastatic disease for members who are not eligible for any platinum-containing chemotherapy
  - Metastatic disease post-platinum or other chemotherapy
  - Adjuvant therapy if platinum-based neoadjuvant chemotherapy was not given

Authorization of 6 months may be granted in combination with enfortumab vedotin-ejfv for treatment of stage II, recurrent, locally advanced or metastatic urothelial carcinoma.

Solid Tumors

Authorization of 6 months may be granted as a single agent for treatment of solid tumors in members with unresectable or metastatic disease that has progressed following prior treatment and who have no satisfactory alternative treatment options when either of the following criteria is met:

- The requested medication will be used for microsatellite instability-high or mismatch repair deficient solid tumors.
- The requested medication will be used for tumor mutational burden-high (≥10 mutations/megabase [mut/Mb]) solid tumors.

Anaplastic Thyroid Carcinoma

Authorization of 6 months may be granted:

- As a single agent for treatment of metastatic anaplastic thyroid carcinoma for tumor mutational burden-high (≥10 mutations/megabase [mut/Mb]) tumors.
- In combination with lenvatinib (Lenvima) for treatment of stage IVC anaplastic thyroid carcinoma.

Follicular or Papillary Thyroid Carcinoma

Authorization of 6 months may be granted for treatment of unresectable or metastatic follicular or papillary thyroid carcinoma not amenable to radioactive iodine therapy when any of the following criteria are met:

- Disease is microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR) or tumor mutational burden-high (≥10 mutations/megabase [mut/Mb]) (TMB-H)
- The member experienced disease progression on single agent lenvatinib and the requested medication will be used in combination with lenvatinib

Oncocytic (Hürthle Cell) Thyroid Carcinoma

Authorization of 6 months may be granted for treatment of unresectable or metastatic oncocytic (hürthle cell) thyroid carcinoma when any of the following criteria are met:

- Disease is microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR) or tumor mutational burden-high (≥10 mutations/megabase [mut/Mb]) (TMB-H)
- The member experienced disease progression on single agent lenvatinib and the requested medication will be used in combination with lenvatinib

Colorectal Cancer

Authorization of 6 months may be granted as a single agent for the treatment of colorectal cancer, including appendiceal carcinoma, for microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1) tumors with ultra-hypermutated phenotype (TMB > 50 mut/Mb).

Small Bowel Adenocarcinoma

Authorization of 6 months may be granted as a single agent for treatment of unresectable, medically inoperable, advanced or metastatic small bowel adenocarcinoma for microsatellite instability-high (MSI-H), or mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1) tumors with ultra-hypermutated phenotype (TMB > 50 mut/Mb).

Merkel Cell Carcinoma

Authorization of 6 months may be granted as a single agent for treatment of Merkel cell carcinoma in members with locally advanced, recurrent or metastatic disease.

Gastric Cancer

Authorization of 6 months may be granted:

- For treatment of gastric cancer in members who are not surgical candidates or have unresectable locally advanced, recurrent, or metastatic disease when any of the following criteria are met:
  - The requested medication will be used as subsequent therapy as a single agent for microsatellite instability-high (MSI-H), or deficient mismatch repair (dMMR), or tumor mutational burden (TMB) high (≥10 mutations/megabase (mut/Mb)) tumors.
  - The requested medication will be used as first line therapy as a single agent or in combination with chemotherapy for microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) tumors.
  - The requested medication will be used in combination with trastuzumab and chemotherapy for HER2 overexpression positive adenocarcinoma with PD-L1 ≥ 1.
  - The requested medication will be used in combination with chemotherapy for the first-line treatment of HER2-negative adenocarcinoma with PD-L1 ≥ 1.
- For treatment of gastric cancer in members who are medically fit for surgery when any of the following criteria are met:
  - The requested medication will be used as a single agent or in combination with chemotherapy to treat microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) tumors.
  - The requested medication will be used in combination with trastuzumab and chemotherapy for surgically unresectable locoregional adenocarcinoma that is HER2 overexpression positive and PD-L1 ≥ 1.
  - The requested medication will be used in combination with chemotherapy for surgically unresectable locoregional adenocarcinoma that is HER2 overexpression negative with PD-L1 tumor expression by CPS ≥ 1.

Esophageal Cancer and Esophagogastric Junction (EGJ) Cancer

Authorization of 6 months may be granted:

- In combination with platinum and fluoropyrimidine-based chemotherapy for treatment of esophageal and EGJ cancer with PD-L1 tumor expression by CPS ≥ 1 in members who are surgical candidates.
- As a single agent or in combination with platinum and fluoropyrimidine-based chemotherapy for treatment of esophageal and EGJ cancer in members who are surgical candidates when the requested medication will be used to treat microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) tumors.
- For treatment of esophageal cancer (including EGJ cancer) in members who are not surgical candidates or have unresectable locally advanced, recurrent, or metastatic disease when any of the following criteria are met:
  - The requested medication will be used as subsequent therapy as a single agent for microsatellite instability-high (MSI-H), deficient mismatch repair (dMMR) or tumor mutational burden (TMB) high (≥10 mutations/megabase (mut/Mb)) tumors.
  - The requested medication will be used as first line therapy as a single agent or in combination with platinum and fluoropyrimidine- based chemotherapy for microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) tumors.
  - The requested medication will be used as single agent subsequent therapy for squamous cell carcinoma with PD-L1 tumor expression by CPS ≥ 10.
  - The requested medication will be used in combination with platinum and fluoropyrimidine-based chemotherapy for squamous cell carcinoma or HER2 overexpression negative adenocarcinoma with PD-L1 tumor expression by CPS ≥ 1.
  - The requested medication will be used in combination with trastuzumab and platinum and fluoropyrimidine-based chemotherapy for HER2 overexpression positive adenocarcinoma with PD-L1 tumor expression by CPS ≥ 1.

Cervical Cancer

Authorization of 6 months may be granted for the treatment of cervical cancer when any of the following criteria are met:

- Persistent, recurrent or metastatic disease in combination with chemotherapy with or without bevacizumab in members whose tumors express PD-L1 (CPS ≥1).
- Recurrent or metastatic disease as single agent or in combination with tisotumab vedotin-tftv subsequent therapy in members whose tumors express PD-L1 (CPS ≥1) or are microsatellite instability-high or mismatch repair deficient.
- FIGO stage III-IVA disease in combination with chemoradiation.

Epithelial Ovarian Cancer, Fallopian Tube Cancer, Primary Peritoneal Cancer

Authorization of 6 months may be granted:

- As a single agent for treatment of epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, carcinosarcoma (malignant mixed Mullerian tumors), clear cell carcinoma of the ovary, mucinous carcinoma of the ovary, grade 1 endometrioid carcinoma, low-grade serous carcinoma, or malignant germ cell tumors for recurrent or persistent microsatellite instability-high or mismatch repair deficient tumors or tumor mutational burden-high (TMB-H) (tumors ≥10 mutations/megabase [mut/Mb]).
- In combination with oral cyclophosphamide and bevacizumab for treatment of recurrent or persistent epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, carcinosarcoma (malignant mixed Mullerian tumors), clear cell carcinoma of the ovary, mucinous carcinoma of the ovary, grade 1 endometrioid carcinoma, low-grade serous carcinoma.

Uveal Melanoma

Authorization of 6 months may be granted as a single agent for treatment of unresectable or metastatic uveal melanoma.

Testicular Cancer

Authorization of 6 months may be granted as a single agent for third-line treatment of testicular cancer in members with microsatellite instability-high or mismatch repair deficient or tumor mutational burden-high (TMB-H) (≥10 mutations/megabase [mut/Mb]) tumors.

Endometrial Carcinoma

Authorization of 6 months may be granted:

- In combination with lenvatinib for treatment of advanced, metastatic or recurrent endometrial carcinoma when either of the following criteria are met:
  - The disease is mismatch repair proficient (pMMR)
  - The disease is mismatch repair deficient (dMMR) and has progressed following prior platinum-based chemotherapy
- As a single agent for treatment of endometrial carcinoma in members with recurrent unresectable or metastatic microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or tumor mutational burden high (TMB-H) [≥ 10 mut/Mb] tumors.
- For treatment of endometrial carcinoma in combination with carboplatin and paclitaxel and continued as single agent maintenance therapy (for up to 20 cycles total) in members with stage III-IV or recurrent disease.

Anal Carcinoma

Authorization of 6 months may be granted as a single agent for subsequent treatment of metastatic anal carcinoma.

CNS Brain Metastases

Authorization of 6 months may be granted as a single agent for treatment of CNS brain metastases in members with melanoma or PD-L1 positive non-small cell lung cancer.

Primary Mediastinal Large B-Cell Lymphoma

Authorization of 6 months may be granted as a single agent or in combination with brentuximab vedotin for treatment of primary mediastinal large B-cell lymphoma in members with relapsed or refractory disease.

Pancreatic Adenocarcinoma

Authorization of 6 months may be granted as a single agent for treatment of recurrent, locally advanced or metastatic pancreatic adenocarcinoma in members with microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or tumor mutational burden high (TMB-H) [≥ 10 mut/Mb] tumors.

Biliary Tract Cancers

Authorization of 6 months may be granted:

- In combination with gemcitabine and cisplatin or carboplatin for unresectable, resected gross residual (R2) disease or metastatic biliary tract cancers.
- As a single agent for unresectable, resected gross residual (R2) disease, or metastatic biliary tract cancers, including intrahepatic and extrahepatic cholangiocarcinoma and gallbladder cancer that is microsatellite

instability-high (MSI-H), mismatch repair deficient (dMMR), or tumor mutational burden high (TMB-H) [≥ 10 mut/Mb].

- For neoadjuvant treatment of resectable locoregionally advanced gallbladder cancer that does not present as jaundice when either of the following criteria are met:
  - The requested medication will be used in combination with cisplatin and gemcitabine.
  - The requested medication will be used as a single agent and member has microsatellite instability-high (MSI-H) and/or mismatch repair deficient (dMMR) tumors.

Hepatocellular Carcinoma

Authorization of 6 months may be granted for treatment of hepatocellular carcinoma when any of the following criteria are met:

- The member has disease secondary to hepatitis B and has received prior systemic therapy other than a PD-1/PD-L1- containing regimen and will use the requested medication as a single agent.
- The member has unresectable or extrahepatic/metastatic disease and will use the requested medication as a single agent.

Vulvar Cancer

Authorization of 6 months may be granted for treatment of advanced, recurrent or metastatic vulvar cancer as a single agent or in combination with chemotherapy with or without bevacizumab.

Renal Cell Carcinoma

Authorization of 6 months may be granted for treatment of renal cell carcinoma, when any of the following criteria are met:

- The requested medication will be used as first-line treatment in combination with axitinib or lenvatinib for advanced, relapsed or stage IV disease.
- The requested medication will be used as subsequent therapy in combination with axitinib or lenvatinib for relapsed or stage IV disease with clear cell histology.
- The requested medication will be used as a single agent for relapsed or stage IV disease with non-clear cell histology.
- The requested medication will be used as a single agent for the adjuvant treatment of members with RCC at intermediate-high or high risk of recurrence following nephrectomy or following nephrectomy and resection of metastatic lesions.

Thymic Carcinoma

Authorization of 6 months may be granted as a single agent for treatment of thymic carcinoma for recurrent, unresectable, advanced, or metastatic disease, or as pre or postoperative therapy in members who cannot tolerate first-line combination regimens.

Primary Cutaneous Lymphomas

Authorization of 6 months may be granted for treatment of primary cutaneous lymphomas when either of the following is met:

- Member has a diagnosis of mycosis fungoides/Sezary syndrome.
- Member has a diagnosis of relapsed or refractory anaplastic large cell lymphoma (ALCL) and the requested medication will be used as a single agent.

Extranodal NK/T-cell lymphoma

Authorization of 6 months may be granted for treatment of extranodal NK/T-cell lymphoma, in members with relapsed or refractory disease.

Gestational Trophoblastic Neoplasia

Authorization of 6 months may be granted as a single agent for treatment of gestational trophoblastic neoplasia for multi-agent chemotherapy-resistant disease when either of the following criteria are met:

- Member has recurrent or progressive intermediate trophoblastic tumor (placental site trophoblastic tumor or epithelioid trophoblastic tumor)
- Member has high-risk disease.

Neuroendocrine and Adrenal Tumors

Authorization of 6 months may be granted for treatment of unresectable, locally advanced or metastatic neuroendocrine and adrenal tumors.

Cutaneous Squamous Cell Skin Carcinoma

Authorization of 6 months may be granted as a single agent for treatment of locally advanced, recurrent or metastatic cutaneous squamous cell carcinoma that is not curable by surgery or radiation.

Soft Tissue Sarcoma

Authorization of 6 months may be granted for treatment of the following types of soft tissue sarcoma when any of the following criteria are met:

- The requested medication will be used as a single agent or in combination with axitinib (Inlyta) for the treatment of alveolar soft part sarcoma (ASPS).
- The requested medication will be used as a single agent for the treatment of cutaneous angiosarcoma or dedifferentiated liposarcoma.
- The requested medication will be used as a single agent for the subsequent treatment of extremity/body wall sarcoma, head/neck sarcoma, retroperitoneal/intra-abdominal sarcoma, and rhabdomyosarcoma.

Occult Primary Cancer

Authorization of 6 months may be granted as a single agent for treatment of occult primary cancer in members with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumors or tumor mutational burden-high (TMB-H) (≥10 mutations/megabase (mut/Mb) tumors).

Breast Cancer

- Authorization of 6 months may be granted for treatment in members with no response to preoperative systemic therapy or for recurrent unresectable or metastatic triple-negative breast cancer (TNBC) when all of the following criteria are met:
  - The diagnosis of triple-negative breast cancer is confirmed by the cancer cells testing negative for ALL of the following receptors:
    - Human epidermal growth factor receptor 2 (HER-2)
    - Estrogen
    - Progesterone
  - Tumor must express PD-L1.
  - The requested medication will be used as a single agent or in combination with chemotherapy.

- Authorization of 6 months may be granted for treatment of locally advanced or high-risk triple-negative breast cancer (TNBC) when all of the following criteria are met:
  - The diagnosis of triple-negative breast cancer is confirmed by the cancer cells testing negative for ALL of the following receptors:
    - Human epidermal growth factor receptor 2 (HER-2)
    - Estrogen
    - Progesterone
  - The requested medication will be used as either:
    - Neoadjuvant treatment in combination with chemotherapy; or
    - Continued adjuvant treatment after surgery, as a single agent.

Prostate Cancer

Authorization of 6 months may be granted as single agent subsequent therapy for treatment of castration-resistant distant metastatic prostate cancer in members with microsatellite instability-high, mismatch repair deficient, or tumor mutational burden (TMB) ≥10 mutations/megabase tumors.

Small Cell Lung Cancer

Authorization of 6 months may be granted as a single agent for subsequent therapy of relapsed or progressive disease.

Pediatric Diffuse High-Grade Gliomas

Authorization of 6 months may be granted as adjuvant treatment for hypermutant tumor pediatric diffuse high-grade glioma or for recurrent or progressive disease.

Ampullary Adenocarcinoma

Authorization of 6 months may be granted as a single agent for microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or tumor mutational burden-high (TMB-H ≥ 10 mut/Mb) ampullary adenocarcinoma.

Kaposi Sarcoma

Authorization of 6 months may be granted as a single agent for subsequent treatment of relapsed/refractory Kaposi Sarcoma.

Vaginal Cancer

Authorization of 6 months may be granted for treatment of vaginal cancer when any of the following criteria are met:

- The requested medication will be used in combination with cisplatin or carboplatin, paclitaxel, and with or without bevacizumab for recurrent or metastatic disease.
- The requested medication will be used as single agent subsequent treatment for recurrent or metastatic disease that is PD-L1 positive or disease with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumors.
- The requested medication will be used as subsequent treatment for unresectable or metastatic tumor mutational burden-high (TMB-H ≥ 10 mut/Mb) tumors.

Pleural or Peritoneal Mesothelioma

Authorization of 6 months may be granted for first-line treatment of pleural or peritoneal mesothelioma, including pericardial mesothelioma and tunica vaginalis testis mesothelioma, when used in combination with pemetrexed and platinum chemotherapy.

Histologic (Richter) transformation to diffuse large B-cell lymphoma

Authorization of 6 months may be granted for treatment of Histologic (Richter) transformation to diffuse large B-cell lymphoma as a single agent or in combination with ibrutinib.

Penile Cancer

Authorization of 6 months may be granted for the treatment of penile cancer when either of the following criteria are met:

- The requested medication will be used in combination with fluorouracil and either cisplatin or carboplatin followed by single agent maintenance therapy for recurrent or metastatic disease.
- The requested medication will be used as single agent subsequent therapy for unresectable or metastatic disease with microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or tumor mutational burden-high (TMB-H ≥ 10 mut/Mb) tumors.

CONTINUATION OF THERAPY

Adjuvant treatment of melanoma, HNSCC, TNBC, RCC, or NSCLC

Authorization of 6 months may be granted (up to 12 months total) for continued treatment in members requesting reauthorization for adjuvant treatment of cutaneous melanoma, HNSCC, TNBC, RCC or NSCLC who have not experienced disease recurrence or an unacceptable toxicity.

NSCLC, HNSCC, cHL, PMBCL, MSI-H or dMMR Cancers, Gastric Cancer, Esophageal Cancer, Cervical Cancer, HCC, MCC, RCC, Endometrial carcinoma, cSCC, recurrent unresectable or metastatic TNBC, TMB-H Cancer, Biliary Tract Cancer, pleural or peritoneal mesothelioma, Histologic (Richter) transformation to diffuse large B-cell lymphoma, penile cancer

Authorization of 6 months may be granted (up to 24 months of continuous use) for continued treatment in members requesting reauthorization for NSCLC, HNSCC, cHL, PMBCL, MSI-H or dMMR cancers, gastric cancer, esophageal cancer, cervical cancer, HCC, MCC, RCC, endometrial carcinoma, cSCC, recurrent unresectable or metastatic TNBC, TMB-H, biliary tract cancers, pleural or peritoneal mesothelioma, including pericardial mesothelioma and tunica vaginalis testis mesothelioma subtypes, Histologic (Richter) transformation to diffuse large B-cell lymphoma, and penile cancer who have not experienced disease progression or unacceptable toxicity.

Urothelial Carcinoma

Authorization of 6 months may be granted:

- For continued treatment in members requesting reauthorization for urothelial carcinoma when the requested medication is used in combination with enfortumab vedotin-ejfv who have not experienced disease progression or an unacceptable toxicity.
- Up to 24 months of continuous use for continued treatment in members requesting reauthorization for urothelial carcinoma when both of the following criteria are met:
  - Member has not experienced disease progression or unacceptable toxicity.
  - For high-risk BCG-unresponsive non-muscle invasive bladder cancer only: disease is not persistent or recurrent.

All other indications

- Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section who have not experienced disease progression or an unacceptable toxicity.

MEDICATION QUANTITY LIMITS

Drug Name	Diagnosis	Maximum Dosing Regimen
Keytruda (Pembrolizumab)	Ampullary Adenocarcinoma	Route of Administration: Intravenous 200mg every 3 weeks 400mg every 6 weeks
Keytruda (Pembrolizumab)	Anal Carcinoma	Route of Administration: Intravenous 200mg every 3 weeks 400mg every 6 weeks 2mg/kg every 3 weeks
Keytruda (Pembrolizumab)	Biliary Tract Cancer: Gallbladder Cancer, Intrahepatic/Extrahepatic Cholangiocarcinoma	Route of Administration: Intravenous 200mg every 3 weeks 400mg every 6 weeks
Keytruda (Pembrolizumab)	Bone Cancer: Chondrosarcoma, Ewing Sarcoma, Osteosarcoma, or Chordoma	Route of Administration: Intravenous 200mg every 3 weeks 400mg every 6 weeks
Keytruda (Pembrolizumab)	Breast Cancer	Route of Administration: Intravenous 200mg every 3 weeks 400mg every 6 weeks
Keytruda (Pembrolizumab)	Cervical Cancer	Route of Administration: Intravenous 200mg every 3 weeks 400mg every 6 weeks
Keytruda (Pembrolizumab)	Classical Hodgkin Lymphoma	Route of Administration: Intravenous ≥18 year(s) 200mg every 3 weeks 400mg every 6 weeks <18year(s) 2mg/kg every 3 weeks (up to a maximum of 200 mg)
Keytruda (Pembrolizumab)	CNS Cancer: Brain Metastases	Route of Administration: Intravenous 200mg every 3 weeks 400mg every 6 weeks

Keytruda (Pembrolizumab)	Colorectal Cancer, including Appendiceal Adenocarcinoma and Anal Adenocarcinoma	Route of Administration: Intravenous 200mg every 3 weeks 400mg every 6 weeks 2mg/kg every 3 weeks
Keytruda (Pembrolizumab)	Cutaneous Squamous Cell Carcinoma	Route of Administration: Intravenous 200mg every 3 weeks 400mg every 6 weeks
Keytruda (Pembrolizumab)	Endometrial Carcinoma, Uterine Sarcoma	Route of Administration: Intravenous 200mg every 3 weeks 400mg every 6 weeks
Keytruda (Pembrolizumab)	Esophageal Cancer, Gastroesophageal Junction Cancer, Gastric Cancer	Route of Administration: Intravenous 200mg every 3 weeks 400mg every 6 weeks
Keytruda (Pembrolizumab)	Extranodal NK/T-Cell Lymphomas, Primary Cutaneous Lymphoma, including Mycosis Fungoides/ Sezary Syndrome or Anaplastic Large Cell Lymphoma (ALCL)	Route of Administration: Intravenous 200mg every 3 weeks 400mg every 6 weeks
Keytruda (Pembrolizumab)	Gestational Trophoblastic Neoplasia	Route of Administration: Intravenous 200mg every 3 weeks 400mg every 6 weeks
Keytruda (Pembrolizumab)	Head and Neck Squamous Cell Carcinoma, Nasopharyngeal Cancer, Salivary Gland Tumors	Route of Administration: Intravenous 200mg every 3 weeks 400mg every 6 weeks
Keytruda (Pembrolizumab)	Hepatocellular Carcinoma	Route of Administration: Intravenous 200mg every 3 weeks 400mg every 6 weeks
Keytruda (Pembrolizumab)	Histologic (Richter) Transformation to Diffuse Large B-cell Lymphoma	Route of Administration: Intravenous 200mg every 3 weeks 400mg every 6 weeks
Keytruda (Pembrolizumab)	Kaposi Sarcoma	Route of Administration: Intravenous 200mg every 3 weeks
Keytruda (Pembrolizumab)	Malignant Pleural Mesothelioma, Malignant Peritoneal Mesothelioma, Pericardial Mesothelioma, or Tunica Vaginalis Testis Mesothelioma	Route of Administration: Intravenous 200mg every 3 weeks 400mg every 6 weeks
Keytruda (Pembrolizumab)	Melanoma or Uveal Melanoma	Route of Administration: Intravenous 200mg every 3 weeks 400mg every 6 weeks
Keytruda (Pembrolizumab)	Melanoma, Adjuvant	Route of Administration: Intravenous ≥12 to <18 year(s)

		2mg/kg every 3 weeks (up to a maximum of 200 mg)
Keytruda (Pembrolizumab)	Merkel Cell Carcinoma	Route of Administration: Intravenous 200mg every 3 weeks 400mg every 6 weeks <18year(s) 2mg/kg every 3 weeks (up to a maximum of 200 mg)
Keytruda (Pembrolizumab)	Microsatellite Instability-High or Mismatch Repair Deficient Cancer	Route of Administration: Intravenous ≥18 year(s) 200mg every 3 weeks 400mg every 6 weeks <18year(s) 2mg/kg every 3 weeks (up to a maximum of 200 mg)
Keytruda (Pembrolizumab)	Neuroendocrine Tumor or Adrenal Gland Tumor (Adrenocortical Carcinoma)	Route of Administration: Intravenous 200mg every 3 weeks 400mg every 6 weeks
Keytruda (Pembrolizumab)	Non-Small Cell Lung Cancer or Small Cell Lung Cancer	Route of Administration: Intravenous 200mg every 3 weeks 400mg every 6 weeks
Keytruda (Pembrolizumab)	Occult Primary Cancer	Route of Administration: Intravenous 200mg every 3 weeks 400mg every 6 weeks
Keytruda (Pembrolizumab)	Ovarian, Fallopian, Primary Peritoneal Cancer	Route of Administration: Intravenous 200mg every 3 weeks 400mg every 6 weeks
Keytruda (Pembrolizumab)	Pancreatic Adenocarcinoma	Route of Administration: Intravenous 200mg every 3 weeks 400mg every 6 weeks
Keytruda (Pembrolizumab)	Pediatric Diffuse High-Grade Gliomas	Route of Administration: Intravenous <18year(s) 200mg every 3 weeks
Keytruda (Pembrolizumab)	Penile Cancer	Route of Administration: Intravenous 200mg every 3 weeks 400mg every 6 weeks
Keytruda (Pembrolizumab)	Primary Mediastinal Large B-cell Lymphoma	Route of Administration: Intravenous 200mg every 3 weeks 400mg every 6 weeks <18year(s)

		2mg/kg every 3 weeks (up to a maximum of 200 mg)
Keytruda (Pembrolizumab)	Prostate Cancer	Route of Administration: Intravenous 200mg every 3 weeks 400mg every 6 weeks
Keytruda (Pembrolizumab)	Renal Cell Carcinoma	Route of Administration: Intravenous 200mg every 3 weeks 400mg every 6 weeks
Keytruda (Pembrolizumab)	Small Bowel Adenocarcinoma	Route of Administration: Intravenous 200mg every 3 weeks 400mg every 6 weeks 2mg/kg every 3 weeks
Keytruda (Pembrolizumab)	Soft Tissue Sarcoma	Route of Administration: Intravenous 200mg every 3 weeks 400mg every 6 weeks
Keytruda (Pembrolizumab)	Testicular Cancer	Route of Administration: Intravenous 200mg every 3 weeks 400mg every 6 weeks
Keytruda (Pembrolizumab)	Thymic Carcinoma	Route of Administration: Intravenous 200mg every 3 weeks 400mg every 6 weeks
Keytruda (Pembrolizumab)	Thyroid Carcinoma: Anaplastic, Follicular, Hurthle Cell, or Papillary	Route of Administration: Intravenous 200mg every 3 weeks 400mg every 6 weeks
Keytruda (Pembrolizumab)	Tumor Mutational Burden-High Cancer	Route of Administration: Intravenous ≥18 year(s) 200mg every 3 weeks 400mg every 6 weeks <18year(s) 2mg/kg every 3 weeks (up to a maximum of 200 mg)
Keytruda (Pembrolizumab)	Urothelial Cancer/Bladder Cancer, including Primary Carcinoma of the Urethra, Upper Genitourinary Tract Tumor, or Urothelial Carcinoma of the Prostate	Route of Administration: Intravenous 200mg every 3 weeks 400mg every 6 weeks
Keytruda (Pembrolizumab)	Vaginal Cancer	Route of Administration: Intravenous 200mg every 3 weeks 400mg every 6 weeks
Keytruda (Pembrolizumab)	Vulvar Cancer	Route of Administration: Intravenous 200mg every 3 weeks

		400mg every 6 weeks

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Keytruda [package insert]. Rahway, NJ: Merck Sharp & Dohme LLC; July 2025.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed August 19, 2025.
3. Makker V, Colombo N, Casado Herraez A, et al: Lenvatinib plus Pembrolizumab for Advanced Endometrial Cancer. N Engl J Med 2022; 386(5):437-448.

EFFECTIVE DATE	9/18/2014	(9/18/14 - Approved and implemented via executive decision)
	11/18/2015	(9/14/15 - Approved by MPRC)
	6/18/2016	(4/11/16 - Approved by MPRC)
	8/17/2016	(8/17/16 - Annual P&T Committee Review)
	12/1/2016	(12/1/16 - Approved and implemented via executive decision)
	6/6/2017	(6/6/17 - Approved by Corporate P&T Subcommittee)
	8/11/2017	(8/11/17 - Approved and implemented via executive decision)
	5/8/2018	(5/8/18 - Approved by P&T Corporate Subcommittee)
	9/11/2018	(9/11/18 - Approved by P&T Corporate Subcommittee)
	1/31/2019	(11/13/18 - Approved by P&T Corporate Subcommittee)
	5/31/2019	(3/12/19 - Approved by P&T Corporate Subcommittee)
	7/31/2019	(5/14/19 - Approved by P&T Corporate Subcommittee)
	9/30/2019	(7/9/19 - Approved by P&T Corporate Subcommittee)
	10/31/2019	(8/13/19 - Approved by P&T Corporate Subcommittee)
	12/31/2019	(10/8/19 - Approved by P&T Corporate Subcommittee)
	4/1/2020	(1/14/20 - Approved by P&T Corporate Subcommittee)
	6/30/2020	(4/14/20 - Approved by P&T Corporate Subcommittee)
	12/31/2020	(10/13/20 - Approved by P&T Corporate Subcommittee)
	4/30/2021	(2/9/21 - Approved by P&T Corporate Subcommittee)

6/30/2021	(4/13/21 - Approved by P&T Corporate Subcommittee)
8/31/2021	(6/8/21 - Approved by P&T Corporate Subcommittee)
11/2/2021	(8/10/21 - Approved by P&T Corporate Subcommittee)
12/31/2021	(10/12/21 - Approved by P&T Corporate Subcommittee)
3/2/2022	(12/14/21 - Approved by P&T Corporate Subcommittee)
4/30/2022	(2/8/22 - Approved by P&T Corporate Subcommittee)
6/30/2022	(4/12/22 - Approved by P&T Corporate Subcommittee)
8/30/2022	(6/14/22 - Approved by P&T Corporate Subcommittee)
11/1/2022	(8/9/22 - Approved by P&T Corporate Subcommittee)
12/31/2022	(10/11/22 - Approved by P&T Corporate Subcommittee)
5/2/2023	(2/14/23 - Approved by P&T Corporate Subcommittee)
6/30/2023	(4/11/23 - Approved by P&T Corporate Subcommittee)
8/30/2023	(6/13/23 - Approved by P&T Corporate Subcommittee)
1/1/2024	(10/10/23 - CHS - Approved by P&T Corporate Subcommittee)
4/1/2024	(3/12/24 –Maintenance CHS Dosing/ Approved by P&T Corporate Subcommittee)
4/30/2024	(2/13/24 - Approved by P&T Corporate Subcommittee)
5/31/2024	(3/12/24 - Approved by P&T Corporate Subcommittee)
10/31/2024	(8/13/24 - Approved by P&T Corporate Subcommittee)
12/31/2024	(12/10/24 – Approved Maintenance CHS Dosing/ P&T Corporate Subcommittee)
3/4/2025	(12/10/24 - Approved by P&T Corporate Subcommittee)
4/30/2025	(2/11/25 - Approved by P&T Corporate Subcommittee)
10/31/2025	(8/12/25 - Approved by P&T Corporate Subcommittee)
1/30/2026	(11/11/25 - Approved by P&T Corporate Subcommittee)
4/30/2026	(2/10/26 - Approved by P&T Corporate Subcommittee)

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