Medical Policy:

Keytruda® (pembrolizumab) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.89	August 12, 2024	

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Length of Authorization

Coverage will be provided for 6 months and may be renewed (unless otherwise specified).

- Biliary Tract Cancer (Gallbladder Cancer or Intra-/Extra-Hepatic Cholangiocarcinoma), Bladder Cancer/Urothelial Carcinoma, Cervical Cancer, cHL, Cutaneous Melanoma (in combination with ipilimumab, lenvatinib, OR trametinib and dabrafenib), cSCC, Endometrial Carcinoma (Uterine Neoplasms), Esophageal and Esophagogastric/Gastroesophageal Junction Cancer (first-line or subsequent therapy), Gastric Cancer (first-line therapy), HCC, MCC, MSI-H/dMMR Cancer, NSCLC (first-line or subsequent therapy), PMBCL, RCC (first-line or subsequent therapy), SCCHN, TMB-H Cancer, and TNBC (recurrent unresectable or metastatic disease) can be authorized up to a maximum of twenty-four (24) months of therapy.
- Therapy for MSI-H/dMMR Esophageal, Esophagogastric/Gastroesophageal Junction, and Gastric Cancer can be authorized for a maximum of 8 weeks of neoadjuvant

therapy (3 doses), followed by a maximum of 48 weeks (16 doses) of postoperative therapy after surgery.

- Adjuvant therapy in Cutaneous Melanoma, NSCLC, and RCC can be authorized up to a maximum of twelve (12) months of therapy.
- Therapy for resectable NSCLC can be authorized for up to a maximum of twelve (12) weeks of neoadjuvant therapy and thirty-nine (39) weeks of adjuvant therapy.
- Neoadjuvant therapy in TNBC can be authorized up to a maximum of twenty-four (24) weeks of therapy.
- Adjuvant therapy in TNBC can be authorized up to a maximum of twenty-seven (27) weeks of therapy.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

Indication	Billable Units (BU)	Per unit time (days)
Biliary Tract Cancer (Gallbladder Cancer or Intra-/Extra- Hepatic Cholangiocarcinoma), Bladder/Urothelial, Cervical, cHL, cSCC, Cutaneous Melanoma, Endometrial Carcinoma (Uterine Neoplasms), Esophageal, Esophagogastric/Gastroesophageal, Gastric, HCC, MCC, MSI-H/dMMR Cancer, NSCLC, PMBCL, RCC, SCCHN, TMB-H Cancer, & TNBC	200 BU	21 days
	400 BU	42 days

Guideline

I. Initial Approval Criteria

Coverage is provided in the following conditions:

1. Patient must be 18 years of age or older (unless otherwise specified); **AND**
2. Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., cemiplimab, avelumab, nivolumab, atezolizumab, durvalumab, dostarlimab, nivolumab/relatlimab, retifanlimab, toripalimab, etc.) unless otherwise specified; **AND**

Cutaneous Melanoma †

A. Used as first-line therapy as a single agent for unresectable or metastatic* disease; **OR**
B. Used as initial treatment of limited resectable disease; **AND**
   i. Used as a single agent; **AND**
      a. Patient has stage III disease with clinical satellite/in-transit metastases; **OR**
      b. Patient has local satellite/in-transit recurrence; **OR**
C. Used as subsequent therapy; **AND**
   i. Used for metastatic or unresectable disease with progression following treatment with anti-PD-1/PD-L1-based therapy, including in combination with anti-CTLA-4 (e.g., ipilimumab) for ≥2 doses; **AND**
      a. Used in combination with lenvatinib; **OR**
   ii. Used for metastatic or unresectable disease with disease progression or intolerance if BRAF/MEK and/or PD(L)-1 checkpoint inhibition not previously used; **AND**
      a. Patient has BRAF V600 activating mutation positive disease; **AND**
      b. Used in combination with trametinib and dabrafenib; **OR**
   iii. Used for disease progression or relapse following treatment with BRAF/MEK + PD(L)-1 checkpoint inhibitor therapy; **AND**

a. Patient has BRAF V600 activating mutation positive disease; **AND**
b. Used in combination with trametinib and dabrafenib; **AND**
c. Used as re-induction therapy in patients who experienced disease control *(i.e., complete response, partial response, or stable disease)* and no residual toxicity from prior combination BRAF/MEK + PD(L)-1 checkpoint inhibitor therapy, but subsequently have disease progression/relapse > 3 months after treatment discontinuation; **OR**

iv. Used for metastatic***** or unresectable disease with progression or relapse following treatment with anti-PD-1 therapy; **AND**
a. Used as a single agent; **AND**
b. Used as re-induction therapy in patients who experienced disease control *(i.e., complete response, partial response, or stable disease)* and no residual toxicity from prior anti-PD-1 therapy, but subsequently have disease progression/relapse > 3 months after treatment discontinuation; **OR**

v. Used for metastatic***** or unresectable disease with progression, intolerance, and/or projected risk of progression with BRAF-targeted therapy (e.g., dabrafenib/trametinib, vemurafenib/cobimetinib, encorafenib/binimetinib, etc.); **AND**
a. Used as a single agent; **AND**
1) Anti-PD-1 therapy was not previously used; **OR**
2) Used as re-induction therapy in patients who experienced disease control *(i.e., complete response, partial response, or stable disease)* and no residual toxicity from prior anti-PD-1 therapy, but subsequently have disease progression/relapse > 3 months after treatment discontinuation; **OR**

b. Used in combination with ipilimumab; **AND**
1) Used after progression on single-agent anti-PD-1 therapy and combination ipilimumab/anti-PD-1 therapy was not previously used; **OR**
2) Used as re-induction therapy in patients who experienced disease control *(i.e., complete response, partial response, or stable disease)* and no residual toxicity from prior combination ipilimumab/anti-PD-1 therapy, but subsequently have disease progression/relapse > 3 months after treatment discontinuation; **OR**

D. Used as a single agent for adjuvant treatment; **AND**
i. Patient has stage IIB or IIC melanoma following complete resection **†**; **AND**
a. Patient is at least 12 years of age; **OR**

ii. Patient has stage III disease; **AND**
a. Used following complete resection **†**; **AND**
1) Patient is at least 12 years of age; **OR**

b. Patient has sentinel node positive disease either during observation without additional nodal surgery and with mandatory radiographic nodal surveillance OR after complete lymph node dissection (CLND); **OR**
c. Patient has clinically positive node(s) following wide excision of the primary tumor and therapeutic lymph node dissection (TLND) OR following neoadjuvant therapy; **OR**
d. Patient has clinical satellite/in-transit metastases and has no evidence of disease (NED) after complete excision to clear margins; **OR**

iii. Patient has local satellite/in-transit recurrence and has NED after complete excision to clear margins; **OR**

iv. Patient has resectable disease limited to nodal recurrence following excision and complete TLND OR following neoadjuvant therapy; **OR**

v. Patient has oligometastatic disease and NED after receiving metastasis-directed therapy (i.e., complete resection, stereotactic ablative therapy, or T-VEC/intralesional therapy) or systemic therapy followed by resection

***Metastatic disease includes stage III unresectable/borderline resectable disease with clinically positive node(s) or clinical satellite/in-transit metastases, as well as unresectable local satellite/in-transit recurrence, unresectable nodal recurrence, and widely disseminated distant metastatic disease.*

Gastric Cancer †

A. Patient is not a surgical candidate or has unresectable locally advanced, recurrent, or metastatic disease; **AND**

B. Used as first-line therapy; **AND**

i. Patient has HER2-positive adenocarcinoma; **AND**

a. Used in combination with trastuzumab, fluoropyrimidine- and platinum containing chemotherapy; **OR**

ii. Patient has HER2-negative adenocarcinoma; **AND**

A. Used in combination with fluoropyrimidine- and platinum-containing chemotherapy.

Merkel Cell Carcinoma †

A. Patient is at least 6 months of age; **AND**

B. Used as a single agent; **AND**

i. Patient has recurrent locally advanced or metastatic disease †

Non-Small Cell Lung Cancer (NSCLC) †

A. Used for stage III disease **†**; **AND**

i. Used as first-line therapy as a single-agent in patients who are not candidates for surgical resection or definitive chemoradiation; **AND**

ii. Used in patients with tumors expressing PD-L1 (TPS ≥1%) as determined by an FDA- approved or CLIA compliant test❖ and with no EGFR or ALK genomic tumor aberrations; **OR**

B. Used as neoadjuvant therapy **†**; **AND**

i. Patient has resectable disease (tumors ≥4 cm or node positive); **AND**

ii. Used in combination with platinum-containing chemotherapy and then continued as a single agent as adjuvant treatment after surgery; **OR**

C. Used as adjuvant therapy; **AND**

i. Used as a single agent; **AND**

ii. Used following resection and previous adjuvant chemotherapy; **AND**

a. Patient has stage IB (T2a ≥4 cm), II, or IIIA disease **†**; **OR**

b. Patient has stage IIIB (T3, N2) disease; **AND**

- Disease is negative for EGFR exon 19 deletion or exon 21 L858R mutations, or ALK rearrangements; **OR**

iii. Used following previous neoadjuvant pembrolizumab plus chemotherapy and resection; **OR**

D. Used for recurrent, advanced, or metastatic disease (excluding locoregional recurrence or

symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**

i. Used as first-line therapy; **AND**
   a. Used for one of the following:
      1) PD-L1 expression-positive (TPS ≥1%) tumors, as detected by an FDA-approved or CLIA compliant test❖, that are negative for actionable molecular biomarkers***¥**
      2) Patients with performance status (PS) 0-1 who have tumors that are negative for actionable molecular biomarkers***¥** and PD-L1 expression <1%
      3) Patients with PS 0-1 who are positive for one of the following molecular biomarkers: EGFR exon 20, BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, RET rearrangement, or ERBB2 (HER2); **AND**
   b. Used in combination with pemetrexed AND either carboplatin or cisplatin for non-squamous cell histology; **OR**
   c. Used in combination with carboplatin AND either paclitaxel or albumin-bound paclitaxel for squamous cell histology; **OR**
   d. Used as a single agent *(for PD-L1 expression-positive tumors ONLY)* **†**; **OR**

ii. Used as subsequent therapy; **AND**
   a. Used in patients with tumors expressing PD-L1 (TPS ≥1%) as determined by an FDA-approved or CLIA compliant test❖; **AND**
      1) Used as a single agent; **OR**
   b. Used for one of the following:
      1) Patients with PS 0-1 who are positive for one of the following molecular biomarkers***** and have received prior targeted therapy**§**: EGFR exon 19 deletion or L858R tumors, EGFR S768I, L861Q and/or G719X, ALK rearrangement, or ROS1 rearrangement
      2) Patients with PS 0-1 who are positive for one of the following molecular biomarkers*****: BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, or RET rearrangement; **AND**
      3) Used in combination with carboplatin AND either paclitaxel or albumin-bound paclitaxel for squamous cell histology; **OR**
      4) Used in combination with pemetrexed AND either carboplatin or cisplatin for non-squamous cell histology; **OR**

iii. Used as continuation maintenance therapy in patients who have achieved tumor response or stable disease following initial systemic therapy; **AND**
   a. Used in combination with pemetrexed following a first-line pembrolizumab/pemetrexed/(carboplatin or cisplatin) regimen for non-squamous cell histology; **OR**
   b. Used as a single agent following a first-line pembrolizumab/carboplatin/ (paclitaxel or albumin-bound paclitaxel) regimen for squamous cell histology; **OR**
   c. Used as a single agent following a first-line pembrolizumab monotherapy regimen

***Note:** Actionable molecular genomic biomarkers include EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, RET, and ERBB2 (HER2). Complete genotyping for EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, RET, and ERBB2 (HER2), via biopsy and/or plasma testing. If a clinically actionable marker is found, it is reasonable to start therapy based on the identified marker. Treatment is guided by available results and, if unknown, these patients are treated as though they do not have driver oncogenes.*
¥ *May also be used for patients with KRAS G12C mutation positive tumors.*

Esophageal Cancer and Esophagogastric Junction Cancer

A. Patient is not a surgical candidate or has unresectable locally advanced, recurrent, or metastatic disease; **AND**
    i. Used as first-line therapy; **AND**
        a. Patient has HER2-positive adenocarcinoma; **AND**
            1) Used in combination with trastuzumab, fluoropyrimidine- and platinum containing chemotherapy; **OR**
        b. Patient has HER2-negative adenocarcinoma; **AND**
            1) Used in combination with platinum- and fluoropyrimidine-based chemotherapy; **OR**
        c. Patient has squamous cell carcinoma; **AND**
            1) Used in combination with platinum- and fluoropyrimidine-based chemotherapy; **AND**
            2) Tumor expresses PD-L1 (CPS ≥ 10) as determined by an FDA-approved or CLIA compliant test; **OR**
    ii. Used as subsequent therapy; **AND**
        a. Used as a single agent; **AND**
        b. Patient has squamous cell carcinoma †; **AND**
        c. Tumor expresses PD-L1 (CPS ≥ 10) as determined by an FDA-approved or CLIA compliant test

Squamous Cell Carcinoma of the Head and Neck (SCCHN) †

A. Patient has Cancer of the Nasopharynx; **AND**
    i. Used in combination with cisplatin and gemcitabine; **AND**
    ii. Used for oligometastatic or metastatic disease; **OR**
B. Patient has Very Advanced Head and Neck Cancer*****; **AND**
    i. Patient has nasopharyngeal cancer; **AND**
        a. Patient has a performance status 0-1; **AND**
        b. Used in combination with cisplatin and gemcitabine; **AND**
        c. Used for one of the following:
            1) Unresectable locoregional recurrence with prior radiation therapy (RT)
            2) Unresectable second primary with prior RT
            3) Unresectable persistent disease with prior RT
            4) Recurrent/persistent disease with distant metastases; **OR**
    ii. Patient has NON-nasopharyngeal cancer; **AND**
        a. Patient is unfit for surgery or has T4b, N0-3, M0 disease; **AND**
            1) Used as a single agent as first-line therapy in patients with a performance status (PS) 3; **AND**
            2) Tumor expresses PD-L1 (CPS ≥1) as determined by an FDA-approved or CLIA-compliant test❖; **OR**
        b. Patient has unresectable, recurrent, persistent, or metastatic disease; **AND**

1) Used as a single agent; **AND**
   - Tumor expresses PD-L1 (CPS ≥1) as determined by an FDA-approved or CLIA-compliant test❖; **OR**
   - Used as subsequent therapy for disease that has progressed on or after platinum-containing chemotherapy; **OR**
2) Used in combination with cetuximab; **AND**
   - Patient has a performance status 0-1; **OR**
3) Used in combination with carboplatin or cisplatin AND either fluorouracil, docetaxel, or paclitaxel; **AND**
   - Patient has a performance status 0-1

***** *Very Advanced Head and Neck Cancer includes: Newly diagnosed locally advanced T4b (M0) disease; newly diagnosed unresectable regional nodal disease (typically N3); metastatic disease at initial presentation (M1); or recurrent or persistent disease.*

Adult Classical Hodgkin Lymphoma (cHL) † ‡ Φ

A. Patient has relapsed or refractory disease; **AND**
   i. Used as a single agent; **OR**
   ii. Used in combination with GVD (gemcitabine, vinorelbine, liposomal doxorubicin) or ICE (ifosfamide, carboplatin, etoposide); **AND**
      a. Patient is ≤ 60 years of age.

Pediatric Classical Hodgkin Lymphoma † ‡ Φ

A. Patient is at least 6 months of age*; **AND**
B. Used as a single agent; **AND**
   i. Patient has refractory disease †; **OR**
   ii. Patient has relapsed disease; **AND**
      a. Used after two (2) or more prior lines of therapy †; **OR**
      b. Used as subsequent therapy in patients heavily pretreated with platinum or anthracycline-based chemotherapy ‡; **OR**
      c. Used as subsequent therapy in patients with an observed decrease in cardiac function ‡

***** *Pediatric Classical Hodgkin Lymphoma may be applicable to adolescent and young adult (AYA) patients up to the age of 39 years.*

Primary Mediastinal Large B-Cell Lymphoma (PMBCL) †

A. Used as single agent; **AND**
   i. Patient is at least 6 months of age; **AND**
   ii. Patient has relapsed or refractory disease; **AND**
   iii. Patient does not require urgent cytoreductive therapy; **OR**
B. Used in combination with brentuximab vedotin; **AND**
   i. Patient is at least 6 months to <39 years of age*; **AND**
   ii. Used as consolidation/additional therapy in patients who achieve a partial response after therapy for relapsed or refractory disease

** Pediatric Primary Mediastinal Large B-Cell Lymphoma may be applicable to adolescent and young adult (AYA) patients older than 18 years of age and less than 39 years of age, who are treated in the pediatric oncology setting*

Bladder Cancer/Urothelial Carcinoma †

A. Used in combination with enfortumab vedotin; **AND**
   i. Patient has locally advanced or metastatic urothelial carcinoma †; **AND**
      a. Used as first-line therapy; **OR**
      b. Used as first-line therapy in cisplatin ineligible patients*; **OR**

B. Used as a single agent; **AND**
   i. Patient has Bacillus Calmette-Guerin (BCG)-unresponsive**, high-risk, non-muscle invasive bladder cancer (NMIBC) †; **AND**
      a. Patient has carcinoma in situ (CIS); **AND**
      b. Patient is ineligible for or has elected not to undergo cystectomy; **OR**
   ii. Patient has one of the following diagnoses:
   - Locally advanced or metastatic urothelial carcinoma †; **AND**
      a. Used for disease that progressed during or following platinum-containing chemotherapy*; **OR**
      b. Used as second-line treatment after chemotherapy other than a platinum; **OR**
      c. Used as first-line therapy in cisplatin-ineligible patients*; **AND**
      d. Patient is not eligible for any platinum-containing chemotherapy (i.e., both cisplatin and carboplatin-ineligible)*

** Note:*

- *If patient was progression free for > 12 months after platinum therapy, consider re-treatment with platinum-based therapy if the patient is still platinum eligible (see below for cisplatin- or platinum-ineligible comorbidities).*
  - *Cisplatin-ineligible comorbidities may include the following: CrCl < 60 mL/min, ECOG PS ≥ 2 or KPS ≤ 70%, hearing loss of ≥ 25 decibels (dB) at two contiguous frequencies, grade ≥ 2 peripheral neuropathy, or NYHA Heart Failure class ≥ 3. Carboplatin may be substituted for cisplatin particularly in those patients with a CrCl <60 mL/min or a PS of 2.*
- *Platinum-ineligible comorbidities may include the following: CrCl < 30 mL/min, ECOG PS ≥ 3, grade ≥ 2 peripheral neuropathy, or NYHA Heart Failure class > 3, etc.*

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

Cervical Cancer †

A. Patient has FIGO 2014 Stage III-IVA disease; **AND**
   i. Used in combination with chemoradiotherapy (CRT); **OR**

B. Tumor expresses PD-L1 (CPS ≥1) as determined by an FDA-approved or CLIA-compliant test❖; **AND**
   i. Used as a single agent; **AND**
      a. Used as subsequent therapy for recurrent or metastatic disease; **OR**
   ii. Used in combination with chemotherapy, with or without bevacizumab; **AND**
      a. Patient has persistent, recurrent, or metastatic disease

Microsatellite Instability-High (MSI-H) Cancer †

A. Patient is at least 6 months of age; **AND**
B. Patient has microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by an FDA-approved or CLIA compliant test❖; **AND**
C. Patient has unresectable or medically inoperable, advanced, recurrent, persistent, or metastatic solid tumors; **AND**

i. Used as a single agent; **AND**
    a. Used for disease progression following prior treatment **†**; **OR**
ii. Used in combination with oxaliplatin AND either fluorouracil or capecitabine; **AND**
    a. Used as first-line therapy; **AND**
    b. Patient has one of the following cancers:
        1) Esophageal or Esophagogastric/Gastroesophageal Junction Cancer
        2) Gastric Cancer

Hepatocellular Carcinoma (HCC) †

A. Used as a single agent; **AND**
B. Patient has Child-Pugh Class A liver impairment *(i.e., excluding Child-Pugh Class B and C)*; **AND**
    i. Disease is secondary to hepatitis B **†**; **AND**
        a. Patient has received prior systemic therapy other than a PD-1/PD-L1-containing regimen

Renal Cell Carcinoma (RCC) †

A. Patient has clear cell histology; **AND**
    i. Used in combination with axitinib or lenvatinib; **AND**
        a. Used as first-line therapy for advanced, relapsed, or stage IV disease; **OR**
        b. Used as subsequent therapy for relapsed or stage IV disease; **OR**
    ii. Used as a single agent; **AND**
        a. Used as adjuvant therapy **†**; **AND**
            1) Patient has undergone a nephrectomy prior to receiving treatment; **AND**
            - Patient has stage II disease with grade 4 tumors (with or without sarcomatoid features); **OR**
            - Patient has stage III disease; **OR**
            2) Patient has undergone a metastasectomy with complete resection of disease within one year of nephrectomy for relapsed or stage IV disease

Endometrial Carcinoma

A. Used in combination with lenvatinib; **AND**
    i. Disease is mismatch repair proficient (pMMR) as determined by an FDA-approved or CLIA-compliant test❖ or NOT microsatellite instability-high (MSI-H); **AND**
        a. Used as first-line therapy for recurrent disease after prior platinum-based therapy (excluding use in patients with isolated metastases); **OR**
        b. Used as subsequent therapy for advanced, recurrent, or metastatic disease; **OR**
B. Used in combination with carboplatin and paclitaxel, followed by single agent maintenance therapy; **AND**
    i. Patient has clear cell carcinoma, endometrioid adenocarcinoma, serous carcinoma, or undifferentiated/dedifferentiated carcinoma *(excluding use in carcinosarcoma)*; **AND**
        a. Used as primary or adjuvant therapy for patients with stage III-IV tumors; **OR**
        b. Used as first-line or subsequent therapy for recurrent disease *(excluding use as first-line therapy in patients with isolated metastases)*; **OR**
C. Used as a single agent as maintenance therapy following treatment with pembrolizumab in

combination with carboplatin and paclitaxel

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

A. Patient is at least 6 months of age; **AND**

B. Patient has tumor mutational burden-high (TMB-H) [≥ 10 mutations/megabase (mut/Mb)] solid tumors, as determined by an FDA-approved or CLIA-compliant test; **AND**

C. Used as a single agent; **AND**

D. Pediatric patients must not have a diagnosis of TMB-H central nervous system cancer; **AND**

E. Patient has unresectable or medically inoperable, advanced, recurrent, persistent, or metastatic solid tumors; **AND**

i. Used for disease progression following prior treatment **†**

Cutaneous Squamous Cell Carcinoma (cSCC)†

A. Used as a single agent; **AND**

B. Patient has locally advanced, recurrent, or metastatic disease that is not curable by surgery or radiation

Triple-Negative Breast Cancer † ‡ Ψ

A. Patient has recurrent unresectable or metastatic disease **OR** inflammatory breast cancer with no response to preoperative systemic therapy; **AND**

i. Used in combination with chemotherapy; **AND**

ii. Tumor expresses PD-L1 (combined positive score [CPS] ≥10) as determined by an FDA-approved or CLIA-compliant test❖; **OR**

B. Patient has high-risk early-stage (i.e., stage II-III) disease; **AND**

i. Used as neoadjuvant therapy in combination with chemotherapy; **OR**

ii. Used as adjuvant therapy as a single agent following use as neoadjuvant therapy in combination with chemotherapy

Biliary Tract Cancers (Gallbladder Cancer or Intra-/Extra-Hepatic Cholangiocarcinoma) † ‡ Φ

A. Patient has unresectable, resected gross residual (R2), or metastatic disease; **AND**

i. Used in combination with gemcitabine and cisplatin

❖ *As confirmed using an immunotherapy assay such as the PD-L1 IHC 22C3 pharmDx*.

† FDA Approved Indication(s); **‡** Compendia Approved Indication(s) **Φ** Orphan Drug

§ Genomic Aberration/Mutational Driver Targeted Therapies (Note: *not all inclusive, refer to guidelines for appropriate use*)			
EGFR exon 19 deletion or exon 21 L858R tumors	*EGFR* S768I, L861Q, and/or G719X mutation positive tumors	*EGFR* exon 20 insertion mutation positive tumors	*NTRK1/2/3* gene fusion positive tumors
Afatinib Erlotinib Dacomitinib Gefitinib Osimertinib Amivantamab	Afatinib Erlotinib Dacomitinib Gefitinib Osimertinib Amivantamab	Amivantamab	Larotrectinib Entrectinib
ALK rearrangement-positive tumors	*ROS1* rearrangement-positive tumors	*BRAF* V600E-mutation positive tumors	*ERBB2 (HER2)* mutation positive tumors

Alectinib Brigatinib Ceritinib Crizotinib Lorlatinib	Ceritinib Crizotinib Entrectinib Lorlatinib Repotrectinib	Dabrafenib ± trametinib Encorafenib + binimetinib Vemurafenib	Fam-trastuzumab deruxtecan-nxki Ado-trastuzumab emtansine
PD-L1 tumor expression ≥ 1%	*MET* exon-14 skipping mutations	*RET* rearrangement-positive tumors	*KRAS G12C* mutation positive tumors
Pembrolizumab Atezolizumab Nivolumab + ipilimumab Cemiplimab Tremelimumab + durvalumab	Capmatinib Crizotinib Tepotinib	Selpercatinib Cabozantinib Pralsetinib	Sotorasib Adagrasib

II. Renewal Criteria

Coverage may be renewed based upon the following criteria:

A. Patient continues to meet the universal and other indication-specific relevant criteria identified in Initial Criteria; **AND**

B. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**

C. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion-related reactions, severe immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis with renal dysfunction, dermatologic adverse reactions/rash, etc.), hepatotoxicity when used in combination with axitinib, complications of allogeneic hematopoietic stem cell transplantation (HSCT), etc.; **AND**

D. For the following indications, patient has not exceeded a maximum of twenty-four (24) months of therapy:

- Biliary Tract Cancer
- Bladder Cancer/Urothelial Carcinoma
- Cervical Cancer
- Classical Hodgkin Lymphoma (cHL)
- Cutaneous Melanoma (in combination with ipilimumab, lenvatinib, OR trametinib and dabrafenib only)
- Cutaneous Squamous Cell Carcinoma (cSCC)
- Endometrial Carcinoma (Uterine Neoplasm)
- Esophageal Cancer and Esophagogastric/Gastroesophageal Junction Cancer (first-line or subsequent therapy)
- Gastric Cancer (first-line therapy)
- Hepatocellular Carcinoma (HCC)
- Merkel Cell Carcinoma (MCC)
- MSI-H/dMMR Cancer (Excluding neoadjuvant and post-operative therapy for MSI-H/dMMR Esophageal, Esophagogastric/Gastroesophageal Junction, & Gastric Cancer)
- Non-Small Cell Lung Cancer (NSCLC) (first-line or subsequent therapy)
- Primary Mediastinal Large B-Cell Lymphoma (PMBCL)
- Renal Cell Carcinoma (RCC) (first-line or subsequent therapy)
- Squamous Cell Carcinoma of the Head and Neck (SCCHN)

- Tumor Mutational Burden-High (TMB-H) Cancer
- Triple Negative Breast Cancer (recurrent unresectable or metastatic disease)

MSI-H/dMMR Esophageal, Esophagogastric/Gastroesophageal Junction, and Gastric Cancer (neoadjuvant and postoperative therapy)

A. Patient has not exceeded a maximum of 8 weeks of neoadjuvant therapy (3 doses), followed by a maximum of 48 weeks (16 doses) of postoperative therapy after surgery

NSCLC (adjuvant treatment)

A. Patient has not exceeded a maximum of twelve (12) months of therapy **NSCLC**

NSCLC (resectable disease)

A. Patient has not exceeded a maximum of twelve (12) weeks of neoadjuvant therapy and thirty-nine (39) weeks of adjuvant therapy

Renal Cell Carcinoma (adjuvant treatment)

A. Patient has not exceeded a maximum of twelve (12) months of therapy

Triple Negative Breast Cancer (neoadjuvant treatment)

A. Patient has not exceeded a maximum of twenty-four (24) weeks of therapy

Triple Negative Breast Cancer (adjuvant treatment)

A. Patient has not exceeded a maximum of twenty-seven (27) weeks of therapy

Cutaneous Melanoma (subsequent treatment after prior anti-PD-1 immunotherapy or BRAF/MEK + anti-PD-1 immunotherapy) ‡

A. Refer to Initial Criteria for criteria

Cutaneous Melanoma (adjuvant treatment)

A. Patient has not exceeded a maximum of twelve (12) months of therapy

NSCLC (continuous maintenance treatment)

A. Refer to Initial Criteria for criteria

Endometrial Carcinoma (continuous maintenance treatment)

A. Refer to Initial Criteria for criteria

Δ Notes:

- Patients responding to therapy who relapse ≥ 6 months after discontinuation due to duration (i.e., receipt of 24 months of therapy) are eligible to re-initiate PD-directed therapy.
  Patients previously presenting with aggressive disease who are exhibiting stable disease on treatment as their best response (or if therapy improved performance status) may beeligible for continued therapy beyond the 24-month limit without interruption or discontinuation.
- Patients who complete adjuvant therapy and progress ≥ 6 months after discontinuation are eligible to re-initiate PD-directed therapy for metastatic disease.
- Patients whose tumors, upon re-biopsy, demonstrate a change in actionable mutation (e.g., MSS initial biopsy; MSI-H subsequent biopsy) may be eligible to re-initiate PD- directed therapy and will be evaluated on a case-by-case basis.
- Patients diagnosed with Renal Cell Carcinoma with clear cell histology who have received previous immuno-oncology therapy may be eligible for treatment with pembrolizumab as subsequent therapy and will be evaluated on a case-by-case basis

Limitations/Exclusions

Keytruda is not considered medically necessary for indications other than those listed above due to insufficient evidence of therapeutic value.

Applicable Procedure Codes

Code	Description
J9271	Injection, pembrolizumab, 1 mg; 1 billable unit = 1 mg

Applicable NDCs

Code	Description
00006-3026-XX	Keytruda 100 mg/4 mL single use vial

ICD-10 Diagnoses

Code	Description
C00.0	Malignant neoplasm of external upper lip
C00.1	Malignant neoplasm of external lower lip
C00.2	Malignant neoplasm of external lip, unspecified
C00.3	Malignant neoplasm of upper lip, inner aspect
C00.4	Malignant neoplasm of lower lip, inner aspect
C00.5	Malignant neoplasm of lip, unspecified, inner aspect
C00.6	Malignant neoplasm of commissure of lip, unspecified
C00.8	Malignant neoplasm of overlapping sites of lip
C01	Malignant neoplasm of base of tongue
C02.0	Malignant neoplasm of dorsal surface of tongue
C02.1	Malignant neoplasm of border of tongue
C02.2	Malignant neoplasm of ventral surface of tongue

C02.3	Malignant neoplasm of anterior two-thirds of tongue, part unspecified
C02.4	Malignant neoplasm of lingual tonsil
C02.8	Malignant neoplasm of overlapping sites of tongue
C02.9	Malignant neoplasm of tongue, unspecified
C03.0	Malignant neoplasm of upper gum
C03.1	Malignant neoplasm of lower gum
C03.9	Malignant neoplasm of gum, unspecified
C04.0	Malignant neoplasm of anterior floor of mouth
C04.1	Malignant neoplasm of lateral floor of mouth
C04.8	Malignant neoplasm of overlapping sites of floor of mouth
C04.9	Malignant neoplasm of floor of mouth, unspecified
C05.0	Malignant neoplasm of hard palate
C05.1	Malignant neoplasm of soft palate
C06.0	Malignant neoplasm of cheek mucosa
C06.2	Malignant neoplasm of retromolar area
C06.80	Malignant neoplasm of overlapping sites of unspecified parts of mouth
C06.89	Malignant neoplasm of overlapping sites of other parts of mouth
C06.9	Malignant neoplasm of mouth, unspecified
C09.0	Malignant neoplasm of tonsillar fossa
C09.1	Malignant neoplasm of tonsillar pillar (anterior) (posterior)
C09.8	Malignant neoplasm of overlapping sites of tonsil
C09.9	Malignant neoplasm of tonsil, unspecified
C10.3	Malignant neoplasm of posterior wall of oropharynx
C11.0	Malignant neoplasm of superior wall of nasopharynx
C11.1	Malignant neoplasm of posterior wall of nasopharynx
C11.2	Malignant neoplasm of lateral wall of nasopharynx
C11.3	Malignant neoplasm of anterior wall of nasopharynx
C11.8	Malignant neoplasm of overlapping sites of nasopharynx
C11.9	Malignant neoplasm of nasopharynx, unspecified
C12	Malignant neoplasm of pyriform sinus
C13.0	Malignant neoplasm of postcricoid region
C13.1	Malignant neoplasm of aryepiglottic fold, hypopharyngeal aspect
C13.2	Malignant neoplasm of posterior wall of hypopharynx
C13.8	Malignant neoplasm of overlapping sites of hypopharynx
C13.9	Malignant neoplasm of hypopharynx, unspecified
C14.0	Malignant neoplasm of pharynx, unspecified
C14.2	Malignant neoplasm of Waldeyer's ring
C14.8	Malignant neoplasm of overlapping sites of lip, oral cavity and pharynx
C15.3	Malignant neoplasm of upper third of esophagus
C15.4	Malignant neoplasm of middle third of esophagus
C15.5	Malignant neoplasm of lower third of esophagus
C15.8	Malignant neoplasm of overlapping sites of esophagus
C15.9	Malignant neoplasm of esophagus, unspecified
C16.0	Malignant neoplasm of cardia
C16.1	Malignant neoplasm of fundus of stomach

C16.2	Malignant neoplasm of body of stomach
C16.3	Malignant neoplasm of pyloric antrum
C16.4	Malignant neoplasm of pylorus
C16.5	Malignant neoplasm of lesser curvature of stomach, unspecified
C16.6	Malignant neoplasm of greater curvature of stomach, unspecified
C16.8	Malignant neoplasm of overlapping sites of stomach
C16.9	Malignant neoplasm of stomach, unspecified
C17.0	Malignant neoplasm of duodenum
C17.1	Malignant neoplasm of jejunum
C17.2	Malignant neoplasm of ileum
C17.8	Malignant neoplasm of overlapping sites of small intestine
C17.9	Malignant neoplasm of small intestine, unspecified
C18.0	Malignant neoplasm of cecum
C18.1	Malignant neoplasm of appendix
C18.2	Malignant neoplasm of ascending colon
C18.3	Malignant neoplasm of hepatic flexure
C18.4	Malignant neoplasm of transverse colon
C18.5	Malignant neoplasm of splenic flexure
C18.6	Malignant neoplasm of descending colon
C18.7	Malignant neoplasm of sigmoid colon
C18.8	Malignant neoplasm of overlapping sites of colon
C18.9	Malignant neoplasm of colon, unspecified
C19	Malignant neoplasm of rectosigmoid junction
C20	Malignant neoplasm of rectum
C21.0	Malignant neoplasm of anus, unspecified
C21.1	Malignant neoplasm of anal canal
C21.2	Malignant neoplasm of cloacogenic zone
C21.8	Malignant neoplasm of overlapping sites of rectum, anus and anal canal
C22.1	Intrahepatic bile duct carcinoma
C23	Malignant neoplasm of gallbladder
C24.0	Malignant neoplasm of extrahepatic bile duct
C24.1	Malignant neoplasm of ampulla of Vater
C24.8	Malignant neoplasm of overlapping sites of biliary tract
C24.9	Malignant neoplasm of biliary tract, unspecified
C25.0	Malignant neoplasm of head of pancreas
C25.1	Malignant neoplasm of body of the pancreas
C25.2	Malignant neoplasm of tail of pancreas
C25.3	Malignant neoplasm of pancreatic duct
C25.7	Malignant neoplasm of other parts of pancreas
C25.8	Malignant neoplasm of overlapping sites of pancreas
C25.9	Malignant neoplasm of pancreas, unspecified
C31.0	Malignant neoplasm of maxillary sinus
C31.1	Malignant neoplasm of ethmoidal sinus
C32.0	Malignant neoplasm of glottis
C32.1	Malignant neoplasm of supraglottis

C32.2	Malignant neoplasm of subglottis
C32.3	Malignant neoplasm of laryngeal cartilage
C32.8	Malignant neoplasm of overlapping sites of larynx
C32.9	Malignant neoplasm of larynx, unspecified
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C38.4	Malignant neoplasm of pleura
C40.00	Malignant neoplasm of scapula and long bones of unspecified upper limb
C40.01	Malignant neoplasm of scapula and long bones of right upper limb
C40.02	Malignant neoplasm of scapula and long bones of left upper limb
C40.10	Malignant neoplasm of short bones of unspecified upper limb
C40.11	Malignant neoplasm of short bones of right upper limb
C40.12	Malignant neoplasm of short bones of left upper limb
C40.20	Malignant neoplasm of long bones of unspecified lower limb
C40.21	Malignant neoplasm of long bones of right lower limb
C40.22	Malignant neoplasm of long bones of left lower limb
C40.30	Malignant neoplasm of short bones of unspecified lower limb
C40.31	Malignant neoplasm of short bones of right lower limb
C40.32	Malignant neoplasm of short bones of left lower limb
C40.80	Malignant neoplasm of overlapping sites of bone and articular cartilage of unspecified limb
C40.81	Malignant neoplasm of overlapping sites of bone and articular cartilage of right limb
C40.82	Malignant neoplasm of overlapping sites of bone and articular cartilage of left limb
C40.90	Malignant neoplasm of unspecified bones and articular cartilage of unspecified limb
C40.91	Malignant neoplasm of unspecified bones and articular cartilage of right limb
C40.92	Malignant neoplasm of unspecified bones and articular cartilage of left limb
C41.0	Malignant neoplasm of bones of skull and face
C41.1	Malignant neoplasm of mandible
C41.2	Malignant neoplasm of vertebral column
C41.3	Malignant neoplasm of ribs, sternum and clavicle
C41.4	Malignant neoplasm of pelvic bones, sacrum and coccyx

C41.9	Malignant neoplasm of bone and articular cartilage, unspecified
C43.0	Malignant melanoma of lip
C43.10	Malignant melanoma of unspecified eyelid, including canthus
C43.11	Malignant melanoma of right eyelid, including canthus
C43.12	Malignant melanoma of left eyelid, including canthus
C43.20	Malignant melanoma of unspecified ear and external auricular canal
C43.21	Malignant melanoma of right ear and external auricular canal
C43.22	Malignant melanoma of left ear and external auricular canal
C43.30	Malignant melanoma of unspecified part of face
C43.31	Malignant melanoma of nose
C43.39	Malignant melanoma of other parts of face
C43.4	Malignant melanoma of scalp and neck
C43.51	Malignant melanoma of anal skin
C43.52	Malignant melanoma of skin of breast
C43.59	Malignant melanoma of other part of trunk
C43.60	Malignant melanoma of unspecified upper limb, including shoulder
C43.61	Malignant melanoma of right upper limb, including shoulder
C43.62	Malignant melanoma of left upper limb, including shoulder
C43.70	Malignant melanoma of unspecified lower limb, including hip
C43.71	Malignant melanoma of right lower limb, including hip
C43.72	Malignant melanoma of left lower limb, including hip
C43.8	Malignant melanoma of overlapping sites of skin
C43.9	Malignant melanoma of skin, unspecified
C44.00	Unspecified malignant neoplasm of skin of lip
C44.02	Squamous cell carcinoma of skin of lip
C44.09	Other specified malignant neoplasm of skin of lip
C44.92	Squamous cell carcinoma of skin, unspecified
C45.0	Mesothelioma of pleura
C48.1	Malignant neoplasm of specified parts of peritoneum
C48.2	Malignant neoplasm of peritoneum, unspecified
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum
C4A.0	Merkel cell carcinoma of lip
C4A.10	Merkel cell carcinoma of eyelid, including canthus
C4A.11	Merkel cell carcinoma of right eyelid, including canthus
C4A.12	Merkel cell carcinoma of left eyelid, including canthus
C4A.20	Merkel cell carcinoma of unspecified ear and external auricular canal
C4A.21	Merkel cell carcinoma of right ear and external auricular canal
C4A.22	Merkel cell carcinoma of left ear and external auricular canal
C4A.30	Merkel cell carcinoma of unspecified part of face
C4A.31	Merkel cell carcinoma of nose
C4A.39	Merkel cell carcinoma of other parts of face
C4A.4	Merkel cell carcinoma of scalp and neck
C4A.51	Merkel cell carcinoma of anal skin
C4A.52	Merkel cell carcinoma of skin of breast
C4A.59	Merkel cell carcinoma of other part of trunk

C4A.60	Merkel cell carcinoma of unspecified upper limb, including shoulder
C4A.61	Merkel cell carcinoma of right upper limb, including shoulder
C4A.62	Merkel cell carcinoma of left upper limb, including shoulder
C4A.70	Merkel cell carcinoma of unspecified lower limb, including hip
C4A.71	Merkel cell carcinoma of right lower limb, including hip
C4A.72	Merkel cell carcinoma of left lower limb, including hip
C4A.8	Merkel cell carcinoma of overlapping sites
C4A.9	Merkel cell carcinoma, unspecified
C53.0	Malignant neoplasm of endocervix
C53.1	Malignant neoplasm of exocervix
C53.8	Malignant neoplasm of overlapping sites of cervix uteri
C53.9	Malignant neoplasm of cervix uteri, unspecified
C54.0	Malignant neoplasm of isthmus uteri
C54.1	Malignant neoplasm of endometrium
C54.2	Malignant neoplasm of myometrium
C54.3	Malignant neoplasm of fundus uteri
C54.8	Malignant neoplasm of overlapping sites of corpus uteri
C54.9	Malignant neoplasm of corpus uteri, unspecified
C55	Malignant neoplasm of uterus, part unspecified
C56.1	Malignant neoplasm of right ovary
C56.2	Malignant neoplasm of left ovary
C56.9	Malignant neoplasm of unspecified ovary
C57.00	Malignant neoplasm of unspecified fallopian tube
C57.01	Malignant neoplasm of right fallopian tube
C57.02	Malignant neoplasm of left fallopian tube
C57.10	Malignant neoplasm of unspecified broad ligament
C57.11	Malignant neoplasm of right broad ligament
C57.12	Malignant neoplasm of left broad ligament
C57.20	Malignant neoplasm of unspecified round ligament
C57.21	Malignant neoplasm of right round ligament
C57.22	Malignant neoplasm of left round ligament
C57.3	Malignant neoplasm of parametrium
C57.4	Malignant neoplasm of uterine adnexa, unspecified
C57.7	Malignant neoplasm of other specified female genital organs
C57.8	Malignant neoplasm of overlapping sites of female genital organs
C57.9	Malignant neoplasm of female genital organ, unspecified
C60.0	Malignant neoplasm of prepuce
C60.1	Malignant neoplasm of glans penis
C60.2	Malignant neoplasm of body of penis
C60.8	Malignant neoplasm of overlapping sites of penis
C60.9	Malignant neoplasm of penis, unspecified
C61	Malignant neoplasm of prostate
C62.00	Malignant neoplasm of unspecified undescended testis
C62.01	Malignant neoplasm of undescended right testis
C62.02	Malignant neoplasm of undescended left testis

C62.10	Malignant neoplasm of unspecified descended testis
C62.11	Malignant neoplasm of descended right testis
C62.12	Malignant neoplasm of descended left testis
C62.90	Malignant neoplasm of unspecified testis, unspecified whether descended or undescended
C62.91	Malignant neoplasm of right testis, unspecified whether descended or undescended
C62.92	Malignant neoplasm of left testis, unspecified whether descended or undescended
C63.7	Malignant neoplasm of other specified male genital organs
C63.8	Malignant neoplasm of overlapping sites of male genital organs
C65.1	Malignant neoplasm of right renal pelvis
C65.2	Malignant neoplasm of left renal pelvis
C65.9	Malignant neoplasm of unspecified renal pelvis
C66.1	Malignant neoplasm of right ureter
C66.2	Malignant neoplasm of left ureter
C66.9	Malignant neoplasm of unspecified ureter
C67.0	Malignant neoplasm of trigone of bladder
C67.1	Malignant neoplasm of dome of bladder
C67.2	Malignant neoplasm of lateral wall of bladder
C67.3	Malignant neoplasm of anterior wall of bladder
C67.4	Malignant neoplasm of posterior wall of bladder
C67.5	Malignant neoplasm of bladder neck
C67.6	Malignant neoplasm of ureteric orifice
C67.7	Malignant neoplasm of urachus
C67.8	Malignant neoplasm of overlapping sites of bladder
C67.9	Malignant neoplasm of bladder, unspecified
C68.0	Malignant neoplasm of urethra
C69.30	Malignant neoplasm of unspecified choroid
C69.31	Malignant neoplasm of right choroid
C69.32	Malignant neoplasm of left choroid
C69.40	Malignant neoplasm of unspecified ciliary body
C69.41	Malignant neoplasm of right ciliary body
C69.42	Malignant neoplasm of left ciliary body
C69.60	Malignant neoplasm of unspecified orbit
C69.61	Malignant neoplasm of right orbit
C69.62	Malignant neoplasm of left orbit
C69.90	Malignant neoplasm of unspecified site of unspecified eye
C69.91	Malignant neoplasm of unspecified site of right eye
C69.92	Malignant neoplasm of unspecified site of left eye
C74.00	Malignant neoplasm of cortex of unspecified adrenal gland
C74.01	Malignant neoplasm of cortex of right adrenal gland
C74.02	Malignant neoplasm of cortex of left adrenal gland
C74.90	Malignant neoplasm of unspecified part of unspecified adrenal gland
C74.91	Malignant neoplasm of unspecified part of right adrenal gland
C74.92	Malignant neoplasm of unspecified part of left adrenal gland
C76.0	Malignant neoplasm of head, face and neck
C77.0	Secondary and unspecified malignant neoplasm of lymph nodes of head, face and neck

C78.00	Secondary malignant neoplasm of unspecified lung
C78.01	Secondary malignant neoplasm of right lung
C78.02	Secondary malignant neoplasm of left lung
C78.6	Secondary malignant neoplasm of retroperitoneum and peritoneum
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct
C78.89	Secondary malignant neoplasm of other digestive organs
C79.31	Secondary malignant neoplasm of brain
C7B.00	Secondary carcinoid tumors unspecified site
C7B.01	Secondary carcinoid tumors of distant lymph nodes
C7B.02	Secondary carcinoid tumors of liver
C7B.03	Secondary carcinoid tumors of bone
C7B.04	Secondary carcinoid tumors of peritoneum
C7B.1	Secondary Merkel cell carcinoma
C7B.8	Other secondary neuroendocrine tumors
C79.89	Secondary malignant neoplasm of other specified sites
C79.9	Secondary malignant neoplasm of unspecified site
C80.0	Disseminated malignant neoplasm, unspecified
C80.1	Malignant (primary) neoplasm, unspecified
C81.10	Nodular sclerosis Hodgkin lymphoma, unspecified site
C81.11	Nodular sclerosis Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.12	Nodular sclerosis Hodgkin lymphoma, intrathoracic lymph nodes
C81.13	Nodular sclerosis Hodgkin lymphoma, intra-abdominal lymph nodes
C81.14	Nodular sclerosis Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.15	Nodular sclerosis Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.16	Nodular sclerosis Hodgkin lymphoma, intrapelvic lymph nodes
C81.17	Nodular sclerosis Hodgkin lymphoma, spleen
C81.18	Nodular sclerosis Hodgkin lymphoma, lymph nodes of multiple sites
C81.19	Nodular sclerosis Hodgkin lymphoma, extranodal and solid organ sites
C81.20	Mixed cellularity Hodgkin lymphoma, unspecified site
C81.21	Mixed cellularity Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.22	Mixed cellularity Hodgkin lymphoma, intrathoracic lymph nodes
C81.23	Mixed cellularity Hodgkin lymphoma, intra-abdominal lymph nodes
C81.24	Mixed cellularity Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.25	Mixed cellularity Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.26	Mixed cellularity Hodgkin lymphoma, intrapelvic lymph nodes
C81.27	Mixed cellularity Hodgkin lymphoma, spleen
C81.28	Mixed cellularity Hodgkin lymphoma, lymph nodes of multiple sites
C81.29	Mixed cellularity Hodgkin lymphoma, extranodal and solid organ sites
C81.30	Lymphocyte depleted Hodgkin lymphoma, unspecified site
C81.31	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.32	Lymphocyte depleted Hodgkin lymphoma, intrathoracic lymph nodes
C81.33	Lymphocyte depleted Hodgkin lymphoma, intra-abdominal lymph nodes
C81.34	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.35	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.36	Lymphocyte depleted Hodgkin lymphoma, intrapelvic lymph nodes

C81.37	Lymphocyte depleted Hodgkin lymphoma, spleen
C81.38	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of multiple sites
C81.39	Lymphocyte depleted Hodgkin lymphoma, extranodal and solid organ sites
C81.40	Lymphocyte-rich Hodgkin lymphoma, unspecified site
C81.41	Lymphocyte-rich Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.42	Lymphocyte-rich Hodgkin lymphoma, intrathoracic lymph nodes
C81.43	Lymphocyte-rich Hodgkin lymphoma, intra-abdominal lymph nodes
C81.44	Lymphocyte-rich Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.45	Lymphocyte-rich Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.46	Lymphocyte-rich Hodgkin lymphoma, intrapelvic lymph nodes
C81.47	Lymphocyte-rich Hodgkin lymphoma, spleen
C81.48	Lymphocyte-rich Hodgkin lymphoma, lymph nodes of multiple sites
C81.49	Lymphocyte-rich Hodgkin lymphoma, extranodal and solid organ sites
C81.70	Other Hodgkin lymphoma unspecified site
C81.71	Other Hodgkin lymphoma lymph nodes of head, face, and neck
C81.72	Other Hodgkin lymphoma intrathoracic lymph nodes
C81.73	Other Hodgkin lymphoma intra-abdominal lymph nodes
C81.74	Other Hodgkin lymphoma lymph nodes of axilla and upper limb
C81.75	Other Hodgkin lymphoma lymph nodes of inguinal region and lower limb
C81.76	Other Hodgkin lymphoma intrapelvic lymph nodes
C81.77	Other Hodgkin lymphoma spleen
C81.78	Other Hodgkin lymphoma lymph nodes of multiple sites
C81.79	Other Hodgkin lymphoma extranodal and solid organ sites
C81.90	Hodgkin lymphoma, unspecified, unspecified site
C81.91	Hodgkin lymphoma, unspecified, lymph nodes of head, face, and neck
C81.92	Hodgkin lymphoma, unspecified, intrathoracic lymph nodes
C81.93	Hodgkin lymphoma, unspecified, intra-abdominal lymph nodes
C81.94	Hodgkin lymphoma, unspecified, lymph nodes of axilla and upper limb
C81.95	Hodgkin lymphoma, unspecified, lymph nodes of inguinal region and lower limb
C81.96	Hodgkin lymphoma, unspecified, intrapelvic lymph nodes
C81.97	Hodgkin lymphoma, unspecified, spleen
C81.98	Hodgkin lymphoma, unspecified, lymph nodes of multiple sites
C81.99	Hodgkin lymphoma, unspecified, extranodal and solid organ sites
C84.90	Mature T/NK-cell lymphomas, unspecified site
C84.91	Mature T/NK-cell lymphomas, lymph nodes of head, face, and neck
C84.92	Mature T/NK-cell lymphomas, intrathoracic lymph nodes
C84.93	Mature T/NK-cell lymphomas, intra-abdominal lymph nodes
C84.94	Mature T/NK-cell lymphomas, lymph nodes of axilla and upper limb
C84.95	Mature T/NK-cell lymphomas, lymph nodes of inguinal region and lower limb
C84.96	Mature T/NK-cell lymphomas, intrapelvic lymph nodes
C84.97	Mature T/NK-cell lymphomas, spleen
C84.98	Mature T/NK-cell lymphomas, lymph nodes of multiple sites
C84.99	Mature T/NK-cell lymphomas, extranodal and solid organ sites
C84.Z0	Other mature T/NK-cell lymphomas, Unspecified site
C84.Z1	Other mature T/NK-cell lymphomas, lymph nodes of head, face, and neck

C84.Z2	Other mature T/NK-cell lymphomas, intrathoracic lymph nodes
C84.Z3	Other mature T/NK-cell lymphomas, intra-abdominal lymph nodes
C84.Z4	Other mature T/NK-cell lymphomas, lymph nodes of axilla and upper limb
C84.Z5	Other mature T/NK-cell lymphomas, lymph nodes of inguinal region and lower limb
C84.Z6	Other mature T/NK-cell lymphomas, intrapelvic lymph nodes
C84.Z7	Other mature T/NK-cell lymphomas, spleen
C84.Z8	Other mature T/NK-cell lymphomas, lymph nodes of multiple sites
C84.Z9	Other mature T/NK-cell lymphomas, extranodal and solid organ sites
C85.20	Mediastinal (thymic) large B-cell lymphoma, unspecified site
C85.21	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of head, face and neck
C85.22	Mediastinal (thymic) large B-cell lymphoma, intrathoracic lymph nodes
C85.23	Mediastinal (thymic) large B-cell lymphoma, intra-abdominal lymph nodes
C85.24	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of axilla and upper limb
C85.25	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C85.26	Mediastinal (thymic) large B-cell lymphoma, intrapelvic lymph nodes
C85.27	Mediastinal (thymic) large B-cell lymphoma, spleen
C85.28	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of multiple sites
C85.29	Mediastinal (thymic) large B-cell lymphoma, extranodal and solid organ sites
C86.0	Other specified types of T/NK-cell lymphoma
D09.0	Carcinoma in situ of bladder
D37.01	Neoplasm of uncertain behavior of lip
D37.02	Neoplasm of uncertain behavior of tongue
D37.05	Neoplasm of uncertain behavior of pharynx
D37.09	Neoplasm of uncertain behavior of other specified sites of the oral cavity
D37.1	Neoplasm of uncertain behavior of stomach
D37.8	Neoplasm of uncertain behavior of other specified digestive organs
D37.9	Neoplasm of uncertain behavior of digestive organ, unspecified
D38.0	Neoplasm of uncertain behavior of larynx
D38.5	Neoplasm of uncertain behavior of other respiratory organs
D38.6	Neoplasm of uncertain behavior of respiratory organ, unspecified
Z80.49	Family history of malignant neoplasm of other genital organs
Z85.00	Personal history of malignant neoplasm of unspecified digestive organ
Z85.01	Personal history of malignant neoplasm of esophagus
Z85.028	Personal history of other malignant neoplasm of stomach
Z85.038	Personal history of other malignant neoplasm of large intestine
Z85.068	Personal history of other malignant neoplasm of small intestine
Z85.07	Personal history of malignant neoplasm of pancreas
Z85.118	Personal history of other malignant neoplasm of bronchus and lung
Z85.21	Personal history of malignant neoplasm of larynx
Z85.22	Personal history of malignant neoplasm of nasal cavities, middle ear, and accessory sinuses
Z85.43	Personal history of malignant neoplasm of ovary
Z85.47	Personal history of malignant neoplasm of testis
Z85.49	Personal history of malignant neoplasm of other male genital organs
Z85.51	Personal history of malignant neoplasm of bladder
Z85.59	Personal history of malignant neoplasm of other urinary tract organ

Z85.71	Personal history of Hodgkin Lymphoma
Z85.810	Personal history of malignant neoplasm of tongue
Z85.818	Personal history of malignant neoplasm of other sites of lip, oral cavity and pharynx
Z85.819	Personal history of malignant neoplasm of unspecified site of lip, oral cavity and pharynx
Z85.820	Personal history of malignant melanoma of skin
Z85.821	Personal history of Merkel cell carcinoma
Z85.830	Personal history of malignant neoplasm of bone
Z85.858	Personal history of malignant neoplasm of other endocrine glands
Z85.59	Personal history of malignant neoplasm of other urinary tract organ
C22.0	Liver cell carcinoma
C22	Malignant neoplasm of liver and intrahepatic bile ducts
Z85.05	Personal history of malignant neoplasm of liver

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	8/12/2024	Annual Review: Updated Length of Authorization, billing units, updated PD-1 examples in Initial approval criteria. Melanoma †Deleted the following to reword criteria: "Patient has unresectable or metastatic disease; OR Keytruda is being used as Adjuvant treatment of patients 12 years and older with Stage IIB, IIC, or III melanoma following complete resection." Added all of the other criteria. Gastric Cancer † Reworded the following: "Patient meets one of the following (i or ii) Patient meets ALL of the following (a, b, 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) ≥ 1; AND Patient has tried at least two previous chemotherapy regimens; AND If the patient's tumor is human epidermal growth factor receptor 2 (HER2) or HER2/neu positive, targeted therapy with trastuzumab has been tried; OR Patient meets ALL of the following (a, b, and c): Patient has locally advanced unresectable or metastatic disease; AND Tumor is human epidermal growth factor receptor 2 (HER2) or HER2/neu positive; AND Medication is used in combination with trastuzumab, cisplatin or oxaliplatin, and fluorouracil or capecitabine" to read the following: "Patient is not a surgical candidate or has unresectable locally advanced, recurrent, or metastatic disease; AND Used as first-line therapy; AND Patient has HER2-positive adenocarcinoma; AND Used in combination with trastuzumab, fluoropyrimidine- and platinum containing chemotherapy; OR Patient has HER2-negative adenocarcinoma; AND Used in combination with fluoropyrimidine- and platinum-containing chemotherapy" Merkel Cell Carcinoma Reworded to update criteria as follows: "Patient is at least 6 months of age; AND Used as a single agent; AND Patient has primary locally advanced disease ‡; AND Both curative surgery and curative radiation therapy are not feasible; OR Patient has had disease progression on neoadjuvant nivolumab therapy; OR Patient has recurrent locally advanced or metastatic disease † Non-Small Cell Lung Cancer (NSCLC) † Updated and removed to reword: "Patient has recurrent, advanced, or metastatic disease; AND Patient meets ONE of the following (i, ii, or iii): Patient meets BOTH of the following (a and b): Keytruda is used as first-line or continuation maintenance therapy; AND The tumor is negative for actionable mutations; OR Patient meets BOTH of

		the following (a and b): Keytruda is used as first-line or subsequent therapy; AND The tumor is positive for one of the following mutations [(1), (2), (3), (4), (5), or (6)]: Epidermal growth factor receptor (EGFR) exon 20 mutation; OR KRAS G12C mutation; OR BRAF V600E mutation; OR NTRK1/2/3 gene fusion; OR MET exon 14 skipping mutation; OR RET rearrangement; OR Keytruda is used as subsequent therapy and the patient meets ONE of the following (a, b, or c): Patient meets BOTH of the following [(1) and (2)]: The tumor is epidermal growth factor receptor (EGFR) S768I, L861Q, and/or G719X mutation positive; AND The patient has received targeted drug therapy for the specific mutation; OR Patient meets BOTH of the following [(1) and (2)]: The tumor is ROS1 rearrangement positive; AND The patient has received targeted drug therapy for the specific mutation; OR Patient meets ALL of the following [(1), (2), and (3)]: Patient has tried systemic therapy; AND Patient has not progressed on prior therapy with a programmed death-1 (PD-1)/PD-ligand 1 (PD-L1) inhibitor; AND If tumor is positive for an actionable mutation, the patient has received targeted drug therapy for the specific mutation" updated to: Used for stage III disease †; AND Used as first-line therapy as a single-agent in patients who are not candidates for surgical resection or definitive chemoradiation; AND Used in patients with tumors expressing PD-L1 (TPS ≥1%) as determined by an FDA- approved or CLIA compliant test and with no EGFR or ALK genomic tumor aberrations; OR Used as neoadjuvant therapy †; AND Patient has resectable disease (tumors ≥4 cm or node positive); AND Used in combination with platinum-containing chemotherapy and then continued as a single agent as adjuvant treatment after surgery; OR Used as adjuvant therapy; AND Used as a single agent; AND Used following resection and previous adjuvant chemotherapy; AND Patient has stage IB (T2a ≥4 cm), II, or IIIA disease †; OR Patient has stage IIIB (T3, N2) disease; AND Disease is negative for EGFR exon 19 deletion or exon 21 L858Rb mutations, or ALK rearrangements; OR Used following previous neoadjuvant pembrolizumab plus chemotherapy and resection; OR Used for recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; AND Used as first-line therapy; AND Used for one of the following: PD-L1 expression-positive (TPS ≥1%) tumors, as detected by an FDA- approved or CLIA compliant test, that are negative for actionable molecular biomarkers*¥ Patients with performance status (PS) 0-1 who have tumors that are negative for actionable molecular biomarkers*¥ and PD-L1 expression <1% Patients with PS 0-1 who are positive for one of the following molecular biomarkers: EGFR exon 20, BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, RET rearrangement, or ERBB2 (HER2); AND Used in combination with pemetrexed AND either carboplatin or cisplatin for non-squamous cell histology; ORUsed in combination with carboplatin AND either paclitaxel or albumin-bound paclitaxel for squamous cell histology; OR Used as a single agent *(for PD-L1 expression-positive tumors ONLY)* †; OR Used as subsequent therapy; AND Used in patients with tumors expressing PD-L1 (TPS ≥1%) as determined by an FDA-approved or CLIA compliant test; AND Used as a single agent; OR Used for one of the following: Patients with PS 0-1 who are positive for one of the following molecular biomarkers* and have received prior targeted therapy§: EGFR exon 19 deletion or L858R tumors, EGFR S768I, L861Q and/or G719X, ALK rearrangement, or ROS1 rearrangement Patients with PS 0-1 who are positive for one of the following molecular biomarkers*: BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, or RET rearrangement; AND Used in combination with carboplatin AND either paclitaxel or albumin-bound paclitaxel for squamous cell histology; OR Used

		in combination with pemetrexed AND either carboplatin or cisplatin for non-squamous cell histology; OR Used as continuation maintenance therapy in patients who have achieved tumor response or stable disease following initial systemic therapy; AND Used in combination with pemetrexed following a first-line pembrolizumab/pemetrexed/(carboplatin or cisplatin) regimen for non-squamous cell histology; OR Used as a single agent following a first-line pembrolizumab/carboplatin/ (paclitaxel or albumin-bound paclitaxel) regimen for squamous cell histology; OR Used as a single agent following a first-line pembrolizumab monotherapy regimen Esophageal Cancer and Esophagogastric Junction Cancer Removed the following to update: "Patient meets ONE of the following (i or ii): According to the prescriber, the patient is not a surgical candidate; OR Patient has unresectable, recurrent, or metastatic disease; AND Patient meets ONE of the following (i, ii, iii, or iv):Patient meets ALL of the following (a, b, 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; AND The medication is used first-line; AND The medication is used in combination with chemotherapy; OR Patient meets ALL of the following (a, b, and c): Patient has squamous cell carcinoma; AND 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 Patient has tried at least one previous chemotherapy regimen; OR Patient meets BOTH of the following (a and b): Tumor is human epidermal growth factor receptor 2 (HER2) or HER2/neu positive; AND Medication is used in combination with trastuzumab, cisplatin or oxaliplatin, and fluorouracil or capecitabine; OR Patient meets ALL of the following (a, b, 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) ≥ 1; AND Patient has tried at least two previous chemotherapy regimens; AND If the patient's tumor is human epidermal growth factor receptor 2 (HER2) or HER2/neu positive, targeted therapy with trastuzumab has been tried" Updated to: "Patient is not a surgical candidate or has unresectable locally advanced, recurrent, or metastatic disease; AND Used as first-line therapy; AND Patient has HER2-positive adenocarcinoma; AND Used in combination with trastuzumab, fluoropyrimidine- and platinum containing chemotherapy; OR Patient has HER2-negative adenocarcinoma; AND Used in combination with platinum- and fluoropyrimidine-based chemotherapy; OR Patient has squamous cell carcinoma; AND Used in combination with platinum- and fluoropyrimidine-based chemotherapy; AND Tumor expresses PD-L1 (CPS ≥ 10) as determined by an FDA-approved or CLIA compliant test; OR Used as subsequent therapy; AND Used as a single agent; AND Patient has squamous cell carcinoma †; AND Tumor expresses PD-L1 (CPS ≥ 10) as determined by an FDA-approved or CLIA compliant test" mous Cell Carcinoma of the Head and Neck (SCCHN) Updated criteria, removed: "Patient has recurrent, unresectable, or metastatic disease; AND Patient meets ONE of the following (i or ii): If the medication is used for first-line treatment, patient must meet ONE of the following (a or b): Keytruda is used in combination with chemotherapy; OR Keytruda is used as a single agent if the tumors are PD-L1-positive (combined positive score ≥ 1), as determined by an approved test.For subsequent therapy, patient has tried at least one platinum-containing chemotherapy regimen" and added: "Patient has Cancer of the Nasopharynx; AND Used in combination with cisplatin and gemcitabine; AND Used for oligometastatic or metastatic disease; OR Patient has Very Advanced Head and Neck Cancer*; AND Patient has nasopharyngeal cancer; AND Patient has a performance status 0-1; AND

		Used in combination with cisplatin and gemcitabine; AND Used for one of the following: Unresectable locoregional recurrence with prior radiation therapy (RT) Unresectable second primary with prior RT, Unresectable persistent disease with prior RT, Recurrent/persistent disease with distant metastases; OR Patient has NON-nasopharyngeal cancer; AND Patient is unfit for surgery or has T4b, N0-3, M0 disease; AND Used as a single agent as first-line therapy in patients with a performance status (PS) 3; AND Tumor expresses PD-L1 (CPS ≥1) as determined by an FDA-approved or CLIA-compliant test; OR Patient has unresectable, recurrent, persistent, or metastatic disease; AND Used as a single agent; AND Tumor expresses PD-L1 (CPS ≥1) as determined by an FDA-approved or CLIA-compliant test; OR Used as subsequent therapy for disease that has progressed on or after platinum-containing chemotherapy; OR Used in combination with cetuximab; AND Patient has a performance status 0-1; OR Used in combination with carboplatin or cisplatin AND either fluorouracil, docetaxel, or paclitaxel; AND Patient has a performance status 0-1" Updated Classical Hodgkin Lymphoma (cHL) † to break into Adult and pediatric; Removed: "Adult patients Patient has relapsed or refractory disease Pediatric patients Patient has a refractory disease; OR Patient has cHL that has relapsed after 2 or more lines of therapy. Added: " Adult Classical Hodgkin Lymphoma (cHL) † ‡ Φ Patient has relapsed or refractory disease; AND Used as a single agent; OR Used in combination with GVD (gemcitabine, vinorelbine, liposomal doxorubicin) or ICE (ifosfamide, carboplatin, etoposide); AND Patient is ≤ 60 years of age Pediatric Classical Hodgkin Lymphoma † ‡ Φ Patient is at least 6 months of age*; AND Used as a single agent; AND Patient has refractory disease †; OR Patient has relapsed disease; AND Used after two (2) or more prior lines of therapy †; OR Used as subsequent therapy in patients heavily pretreated with platinum or anthracycline-based chemotherapy ‡; OR Used as subsequent therapy in patients with an observed decrease in cardiac function ‡" Primary Mediastinal Large B-Cell Lymphoma (PMBCL) † Removed the following and updated: " Patient has relapsed or refractory disease; AND Patient must be at least 2 years old; AND Used after two or more prior lines of therapy " Added: " Used as single agent; AND Patient is at least 6 months of age; AND Patient has relapsed or refractory disease; AND Patient does not require urgent cytoreductive therapy; OR Used in combination with brentuximab vedotin; AND Patient is at least 6 months to <39 years of age*; AND Used as consolidation/additional therapy in patients who achieve a partial response after therapy for relapsed or refractory disease" Bladder Cancer/Urothelial Carcinoma ‡ † Removed to update: "Patient meets ONE of the following conditions (i, ii, or iii): Patient has tried at least one platinum-based chemotherapy; OR According to the prescriber, patient is not eligible for platinum-based chemotherapy (i.e., with cisplatin and carboplatin); OR Patient meets both of the following (a and b): Patient has non-muscle invasive bladder cancer; AND Patient has tried Bacillus Calmette-Guerin (BCG) or intravesical chemotherapy" Updated to: "Used in combination with enfortumab vedotin; AND Patient has locally advanced or metastatic urothelial carcinoma †; AND Used as first-line therapy; OR R Used as a single agent; AND Patient has Bacillus Calmette-Guerin (BCG)-unresponsive**, high-risk, non-muscle invasive bladder cancer (NMIBC) †; AND Patient has carcinoma in situ (CIS); AND

		Patient is ineligible for or has elected not to undergo cystectomy; OR Patient has one of the following diagnoses: Locally advanced or metastatic urothelial carcinoma † AND Used for disease that progressed during or following platinum-containing chemotherapy*; OR Used as second-line treatment after chemotherapy other than a platinum; OR Used as first-line therapy in cisplatin-ineligible patients*; AND Patient is not eligible for any platinum-containing chemotherapy (i.e., both cisplatin and carboplatin-ineligible)*" Cervical Cancer † Updated criteria, reworded: " Patient has recurrent or metastatic disease; AND Tumor expresses PD-L1 (CPS ≥1%) as determined by an FDA-approved test; AND Disease progressed on or after chemotherapy" Updated to: "Patient has FIGO 2014 Stage III-IVA disease; AND Used in combination with chemoradiotherapy (CRT); OR Tumor expresses PD-L1 (CPS ≥1) as determined by an FDA-approved or CLIA-compliant test; AND Used as a single agent; AND Used as subsequent therapy for recurrent or metastatic disease; OR Used in combination with chemotherapy, with or without bevacizumab; AND Patient has persistent, recurrent, or metastatic disease" Microsatellite Instability-High (MSI-H) Cancer † Removed to update: "Patient must be at least 2 years old; AND One of the following conditions applies (i, ii, iii, iv, v, vi, vii, or viii):Patient has advanced or metastatic ampullary cancer; OR Patient has unresectable or metastatic colon or rectal cancer; OR Patient has unresectable or metastatic gallbladder cancer (including intra- and extra-hepatic cholangiocarcinoma); OR Patient has unresectable or metastatic head and neck squamous cell carcinoma; OR Patient has persistent or recurrent ovarian/fallopian tube/primary peritoneal carcinoma; OR Patient has locally advanced or metastatic pancreatic adenocarcinoma; OR Patient has advanced or metastatic small bowel carcinoma; OR Patient meets BOTH of the following (a and b): Patient has tried at least one prior systemic therapy for an MSI-H or dMMR solid tumor; AND Patient has unresectable or metastatic disease" Updated to: "Patient is at least 6 months of age; AND Patient has microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by an FDA-approved or CLIA compliant test; AND Patient has unresectable or medically inoperable, advanced, recurrent, persistent, or metastatic solid tumors; AND Used as a single agent; AND Used for disease progression following prior treatment †; OR Used in combination with oxaliplatin AND either fluorouracil or capecitabine; AND Used as first-line therapy; AND Patient has one of the following cancers: Esophageal or Esophagogastric/Gastroesophageal Junction Cancer Gastric Cancer" Hepatocellular Carcinoma (HCC) †Removed:" Patient has tried at least one tyrosine kinase inhibitor" Updated to: "Used as a single agent; AND Patient has Child-Pugh Class A liver impairment *(i.e., excluding Child-Pugh Class B and C)*; AND Disease is secondary to hepatitis B †; AND Patient has received prior systemic therapy other than a PD-1/PD-L1- containing regimen" Renal Cell Carcinoma (RCC) † removed: "Patient meets ONE of the following (i, ii, or iii): Approve if the patient meets ALL of the following (a, b, and c): The tumor has clear cell histology; AND Patient has relapsed or metastatic disease; AND The medication is used in combination with Inlyta (axitinib tablets) or Lenvima (lenvatinib capsules); OR Approve for 1 year if the patient meets ALL of the following (a, b, and c): The tumor has non-clear cell histology; AND Patient has relapsed or metastatic disease; AND The medication is used as single-agent therapy; OR Approve for up to 1 year (total) if patient meets ALL of the following (a, b, c, and d): Keytruda is used as adjuvant therapy; AND The tumor has clear cell histology; AND Patient has advanced disease; AND The medication is used as single-agent therapy"

		Updated to: "Patient has clear cell histology; AND Used in combination with axitinib or lenvatinib; AND Used as first-line therapy for advanced, relapsed, or stage IV disease; OR Used as subsequent therapy for relapsed or stage IV disease Δ; OR Used as a single agent; AND Used as adjuvant therapy †; AND Patient has undergone a nephrectomy prior to receiving treatment; AND Patient has stage II disease with grade 4 tumors (with or without sarcomatoid features); OR Patient has stage III disease; OR Patient has undergone a metastasectomy with complete resection of disease within one year of nephrectomy for relapsed or stage IV disease" Endometrial Carcinoma Updated to reword: "The medication is used in combination with Lenvima (lenvatinib capsules); AND Patient has progressed on at least one prior systemic therapy; ANDPatient is not a candidate for curative surgery or radiation" Updated to: "Used in combination with lenvatinib; AND Disease is mismatch repair proficient (pMMR) as determined by an FDA-approved or CLIA-compliant test or NOT microsatellite instability-high (MSI-H); AND Used as first-line therapy for recurrent disease after prior platinum-based therapy (excluding use in patients with isolated metastases); OR Used as subsequent therapy for advanced, recurrent, or metastatic disease; OR Used in combination with carboplatin and paclitaxel, followed by single agent maintenance therapy; AND Patient has clear cell carcinoma, endometrioid adenocarcinoma, serous carcinoma, or undifferentiated/dedifferentiated carcinoma *(excluding use in carcinosarcoma)*; AND Used as primary or adjuvant therapy for patients with stage III-IV tumors; OR Used as first-line or subsequent therapy for recurrent disease *(excluding use as first-line therapy in patients with isolated metastases)*; OR Used as a single agent as maintenance therapy following treatment with pembrolizumab in combination with carboplatin and paclitaxel" Tumor Mutational Burden-High Cancer † Updated to reword: " Patient has unresectable or metastatic tumor mutational burden-high (TMB-H) [≥10 mutations/megabase (mut/Mb)] solid tumors, as determined by an FDA-approved test; AND Patient has progressed following prior treatment or have no satisfactory alternative treatment options; AND Pediatric patients do not have a diagnosis of TMB-H central nervous system cancer" Updated to: "Patient is at least 6 months of age; AND Patient has tumor mutational burden-high (TMB-H) [≥ 10 mutations/megabase (mut/Mb)] solid tumors, as determined by an FDA-approved or CLIA-compliant test; AND Used as a single agent; AND Pediatric patients must not have a diagnosis of TMB-H central nervous system cancer; AND Patient has unresectable or medically inoperable, advanced, recurrent, persistent, or metastatic solid tumors; AND Used for disease progression following prior treatment †;" Cutaneous Squamous Cell Carcinoma (cSCC)† Removed to reword: " Patient has recurrent or metastatic disease; AND Patient is not a candidate for surgical or radiation therapy" Updated to: "Used as a single agent; AND Patient has locally advanced, recurrent, or metastatic disease that is not curable by surgery or radiation" Triple-Negative Breast CancerRemoved: "Disease is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); AND Disease is not tumor mutational burden-high (≥ 10 mutations/megabase); AND Patient has triple-negative breast cancer (i.e., estrogen receptor-negative, progesterone receptor-negative, human epidermal growth factor receptor 2 [HER2]-negative); AND Patient meets ONE of the following (i or ii): Patient meets ALL of the following (a, b, and c): Patient has recurrent unresectable

		(local or regional) or metastatic disease; AND The medication is used in combination with chemotherapy; AND 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 Patient has high-risk, early-stage disease" Updated to: "Patient has recurrent unresectable or metastatic disease OR inflammatory breast cancer with no response to preoperative systemic therapy; AND Used in combination with chemotherapy; AND Tumor expresses PD-L1 (combined positive score [CPS] ≥10) as determined by an FDA- approved or CLIA-compliant test; OR Patient has high-risk early-stage (i.e., stage II-III) disease; AND Used as neoadjuvant therapy in combination with chemotherapy; OR Used as adjuvant therapy as a single agent following use as neoadjuvant therapy in combination with chemotherapy" Added: Biliary Tract Cancers (Gallbladder Cancer or Intra-/Extra-Hepatic Cholangiocarcinoma indication
EmblemHealth & ConnectiCare	6/20/2023	Annual Review: Melanoma: Initial Criteria: Removed "Used as a single agent; **AND** a. Used as re-treatment therapy; **OR** b. Patient has unresectable or metastatic Uveal Melanoma: OR c. Patient has melanoma with involvement of lymph node(s) " Added "Adjuvant treatment of patients 12 years and older with Stage IIB, IIC, or III melanoma following complete resection." Gastric Cancer: Initial Criteria: Removed "1. Used as a single agent: AND a. Patient has gastric or gastro-esophageal junction adenocarcinoma; AND b. Patient has recurrent locally advanced or metastatic disease; AND c. Tumor expresses PD-L1 (CPS ≥1%) as determined by an FDA-approved test; AND d. Patient progressed on or after at least two prior systemic treatments which must have included a fluoropyrimidine and platinum-containing regimen; AND e. Patients with HER2 positive disease must have previously failed on HER2 directed therapy; OR" Added: "1. Patient meets one of the following (i or ii): i. Patient meets ALL of the following (a, b, and c): 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. Patient has tried at least two previous chemotherapy regimens; AND Note: Examples of chemotherapy regimens are fluoropyrimidine (fluorouracil or capecitabine) and oxaliplatin, fluoropyrimidine and cisplatin, paclitaxel with cisplatin or carboplatin, docetaxel with cisplatin. c. If the patient's tumor is human epidermal growth factor receptor 2 (HER2) or HER2/neu positive, targeted therapy with trastuzumab has been tried; OR ii. Patient meets ALL of the following (a, b, and c): a. Patient has locally advanced unresectable or metastatic disease; AND b. Tumor is human epidermal growth factor receptor 2 (HER2) or HER2/neu positive; AND c. Medication is used in combination with trastuzumab, cisplatin or oxaliplatin, and fluorouracil or capecitabine"

		Merkel Cell Carcinoma: Initial Criteria: Removed "1. Used as a single agent; AND Patient has disseminated metastatic disease" Added: "1. Keytruda is approved for both Adult and pediatric patients; AND 2. Patient has recurrent, locally advanced, or metastatic Merkel cell carcinoma (MCC)." NSCLC: Initial Criteria: removed "1.Tumor has high PD-L1 expression [(Tumor Proportion Score (TPS) ≥50%)] as determined by an FDA-approved test; AND a. Used as a single agent for metastatic or disseminated recurrent disease; AND i. Used as first-line therapy for genomic tumor aberration (e.g., EGFR, ALK, ROS1, and BRAF) negative or unknown; OR 2. Tumor expresses PD-L1 (TPS ≥1%) as determined by an FDA-approved test; AND a. Used as a single agent for metastatic disease; AND i. Disease must have progressed during or following cytotoxic therapy; AND ii. Patients with genomic tumor aberrations must have progressed following systemic therapy for those aberrations (e.g., EGFR, ALK, etc.); OR 3.Used in combination with one of the following regimens for metastatic or disseminated recurrent disease: a. In combination with pemetrexed and either carboplatin or cisplatin for nonsquamous cell histology; OR b. In combination with carboplatin and paclitaxel for squamous cell histology; AND i. Used as first-line therapy for genomic tumor aberration (e.g., EGFR, ALK, ROS1 and BRAF) negative or unknown**, and PD-L1 expression <50% or unknown; OR ii. Used as first-line therapy for BRAF V600E-mutation positive tumors; OR iii. Used as subsequent therapy for genomic tumor aberration (e.g., EGFR, BRAF V600E, ALK, and ROS1) positive and prior targeted therapy§; OR iv. Used as subsequent therapy if PD-L1 expression-positive (≥50%) and genomic tumor aberration (e.g., EGFR, ALK, ROS1 and BRAF) negative or unknown**; OR 4. Used as continuation maintenance therapy; AND a. Patient has a performance status of 0-2; AND b. Patient achieved tumor response or stable disease following initial therapy; AND i. Used in combination with pemetrexed; AND □ Pembrolizumab was given first-line in combination with pemetrexed and either carboplatin or cisplatin for disease of non-squamous cell histology; OR ii. Used as a single agent; AND □ Pembrolizumab was given first-line in combination with carboplatin and paclitaxel for disease of squamous cell histology" Added "A. Patient has recurrent, advanced, or metastatic disease; AND B. Patient meets ONE of the following (i, ii, or iii): i. Patient meets BOTH of the following (a and b): a. Keytruda is used as first-line or continuation maintenance therapy; AND Note: This is regardless of PD-L1 status.

		b. 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. ii. Patient meets BOTH of the following (a and b): a. Keytruda is used as first-line or subsequent therapy; AND Note: This is regardless of the PD-L1 status. b. The tumor is positive for one of the following mutations [(1), (2), (3), (4), (5), or (6)]: (1) Epidermal growth factor receptor (EGFR) exon 20 mutation; OR (2) KRAS G12C mutation; OR (3) BRAF V600E mutation; OR (4) NTRK1/2/3 gene fusion; OR (5) MET exon 14 skipping mutation; OR (6) RET rearrangement; OR iii. Keytruda is used as subsequent therapy and the patient meets ONE of the following (a, b, or c): a. Patient meets BOTH of the following [(1) and (2)]: (1) The tumor is epidermal growth factor receptor (EGFR) S768I, L861Q, and/or G719X mutation positive; AND (2) The patient has received targeted drug therapy for the specific mutation; OR Note: Examples of targeted drug therapy include Gilotrif (afatinib tablet), Tagrisso (osimertinib tablet), erlotinib, Iressa (gefitinib tablet), or Vizimpro (dacomitinib tablet). b. Patient meets BOTH of the following [(1) and (2)]: (1) The tumor is ROS1 rearrangement positive; AND (2) The patient has received targeted drug therapy for the specific mutation; OR Note: Examples of targeted drug therapy include Xalkori (crizotinib capsule), Rozlytrek (entrectinib capsule), or Zykadia (ceritinib tablet). c. Patient meets ALL of the following [(1), (2), and (3)]: (1) Patient has tried systemic therapy; AND Note: Examples of systemic chemotherapy include cisplatin, carboplatin, Alimta (pemetrexed intravenous infusion), Abraxane (paclitaxel albumin-bound intravenous infusion), gemcitabine, paclitaxel. (2) Patient has not progressed on prior therapy with a programmed death-1 (PD-1)/PD-ligand 1 (PD-L1) inhibitor; AND Note: This includes previous therapy with either one of Keytruda, Opdivo (nivolumab intravenous infusion), or Tecentriq (atezolizumab intravenous infusion). (3) 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." Added Esophageal Cancer indication. Removed Small Cell Lung Cancer Indication and Criteria "Small Cell Lung Cancer (SCLC) † 1. For the treatment of patients with metastatic SCLC with disease progression on or after platinum-based chemotherapy and at least one other prior line of therapy" Squamous Cell Carcinoma of the Head and Neck (SCCHN) Initial Criteria: Removed

		"1. Used in combination with platinum and FU for the first-line treatment of patients with metastatic or with unresectable, recurrent SCCHN; OR 2. Used as a single agent; AND 1. Patient has unresectable, recurrent, persistent or metastatic disease; AND 2. Patient has non-nasopharyngeal disease; AND 3. Disease progressed on or after platinum-containing chemotherapy" Added "A. Patient has recurrent, unresectable, or metastatic disease; AND B. 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). " <u>Bladder Cancer/Urothelial Carcinoma Initial Criteria: Removed</u> "1. Must be used as a single agent; AND 2. Patient has one of the following diagnoses: a. Locally advanced or metastatic Urothelial Carcinoma b. Disease recurrence post-cystectomy c. Recurrent or metastatic Primary Carcinoma of the Urethra; AND i. Patient does not have recurrent stage T3-4 disease or palpable inguinal lymph nodes d. Metastatic Upper GU Tract Tumors e. Metastatic Urothelial Carcinoma of the Prostate; AND 3. Used as first-line therapy in cisplatin-ineligible patients; AND a. Patient is carboplatin-ineligible; OR b. Patient has a PD-L1 expression of ≥10%; OR 4. Used as subsequent therapy after previous platinum treatment" Added "A. Patient meets ONE of the following conditions (i, ii, or iii): i. Patient has tried at least one platinum-based chemotherapy; OR Note: Cisplatin and carboplatin are platinum-based chemotherapies. ii. According to the prescriber, patient is not eligible for platinum-based chemotherapy (i.e., with cisplatin and carboplatin); OR Note: This is regardless of PD-L1 status. iii. 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." <u>Cervical Cancer</u>: Initial Criteria: Removed "used as a single agent" <u>Microsatellite Instability-High or Mismatch Repair Deficient Solid Tumor</u>: Initial Criteria: removed "2. Used as a single agent; AND 3. Patient's disease must be microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); AND 4. Pediatric patients must not have a diagnosis of MSI-H central nervous

		system cancer; AND 5. Patient has one of the following cancers: a. Colorectal Cancer † i. Initial therapy in patients with unresectable or metastatic disease who are not candidates for intensive therapy; OR ii. Used as primary treatment in patients with unresectable or metastatic disease who failed adjuvant treatment with FOLFOX (fluorouracil, leucovorin and oxaliplatin) or CapeOX (capecitabine-oxaliplatin) in the previous 12 months; OR iii. Used for unresectable or metastatic disease that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan † b. Pancreatic Adenocarcinoma ‡ i. Second-line therapy for locally advanced, recurrent, or metastatic disease after progression for patients with good performance status c. Bone Cancer (Ewing Sarcoma, Mesenchymal Chondrosarcoma, Osteosarcoma, Dedifferentiated Chondrosarcoma, or High-Grade Undifferentiated Pleomorphic Sarcoma) ‡ i. Used for unresectable or metastatic disease after progression following prior treatment and patient has no satisfactory alternative treatment options d. Gastric adenocarcinoma OR esophageal/esophagogastric junction adenocarcinoma or squamous cell carcinoma ‡ i. Subsequent therapy for unresectable (or not a candidate) locally advanced, recurrent, or metastatic disease e. Ovarian Cancer (included epithelial ovarian, fallopian tube and primary peritoneal cancers) ‡ i. Used for patients with persistent or recurrent disease; AND ii. Patient is not experiencing an immediate biochemical relapse f. Uterine Cancer (Endometrial Carcinoma) ‡ i. Used for patients with high risk tumors, or recurrent or metastatic disease, that have progressed following prior cytotoxic chemotherapy g. Penile Cancer ‡ i. Used as subsequent treatment of unresectable or metastatic disease that is progressive and there are no other satisfactory treatment options h. Testicular Cancer ‡ i. Used as third-line therapy or after progression with high-dose chemotherapy i. Hepatobiliary Cancer (Gall bladder cancer; intra-/extra-hepatic cholangiocarcinoma) ‡ i. Used as initial therapy for unresectable or metastatic disease j. Cervical Cancer † i. Used for recurrent or metastatic disease k. Other Solid Tumor (e.g., adrenal gland tumors, etc.) i. Used for unresectable or metastatic disease that progressed following prior treatment and there are no satisfactory alternative treatment options" Added "2. 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" Removed Malignant Pleural Mesothelioma ‡, Central Nervous System Cancer ‡, T-Cell Lymphoma/Extranodal NK ‡, Anal Carcinoma ‡ Criteria. Hepatocelluar Carcinoma: Initial Criteria: Removed "Patient has previously been treated with Nexavar® (sorafenib)" replaced with "Patient has tried at least one tyrosine kinase inhibitor; AND Note: Examples of tyrosine kinase inhibitors include Nexavar (sorafenib tablets), Lenvima (lenvatinib capsules)." Renal Cell Carcinoma (RCC) † Iniital Criteria: Removed "In combination with axitinib, for the first-line treatment of patients with advanced RCC" Added "A. Patient meets ONE of the following (i, ii, or iii): i. Approve 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" Added Endometrial Carcinoma Indication and criteria Tumor Mutational Burden-High: Initial Criteria: Removed "Keytruda is being used as monotherapy" Added: Triple Negative Breast Cancer Indication Updated Length of Authorization: Removed: • cSCC, SCCHN, cHL, NSCLC, Urothelial Carcinoma, MPM, MSI-H/dMMR, PMBCL, Cervical, Anal & Gastric Cancers can be authorized up to a maximum of 24 months of therapy." Added "• Adrenal Gland Tumors, Anal Carcinoma, Bladder Cancer/Urothelial Carcinoma, Cervical Cancer, cHL, CNS Cancer, Cutaneous Melanoma (in combination with ipilimumab), cSCC, Endometrial Carcinoma, Esophageal/GEJ Cancer, Gastric Cancer, HCC, MCC, MSIH/dMMR Cancer, NSCLC (first-line or subsequent therapy), PMBCL, Primary Cutaneous Lymphomas, RCC (first-line or subsequent therapy), SCCHN, SCLC, Thymic Carcinoma, TMB-H Cancer, TNBC (recurrent unresectable or metastatic disease), Uveal Melanoma, and Vulvar Cancer can be authorized up to a maximum of twenty-four (24) months of therapy. • Adjuvant therapy in Cutaneous Melanoma, NSCLC, and RCC can be authorized up to a maximum of twelve (12) months of therapy. • Neoadjuvant therapy in TNBC can be authorized up to a maximum of twenty-four (24) weeks of therapy.

		• Adjuvant therapy in TNBC can be authorized up to a maximum of twenty-seven (27) weeks of therapy." Updated Max Units: removed "cSCC, SCCHN, cHL, NSCLC, Melanoma, Urothelial, Gastric, CNS metastases, PMBCL, Cervical, MSI-H/dMMR Cancer, & TMB-H Cancer: • 200 billable units every 21 days MPM & Uterine Cancer: • 1150 billable units every 14 days Merkel Cell Carcinoma & NK/T-Cell Lymphoma: • 250 billable units every 21 days" Added chart
EmblemHealth & ConnectiCare	08/11/2022	Transferred policy to new template.
EmblemHealth & ConnectiCare	10/23/2020	Updated FDA approval indication for Classical Hodgkin Lymphoma
EmblemHealth & ConnectiCare	7/15/2020	FDA approval indication for MSI-H or mismatch repair deficient colorectal cancer
EmblemHealth & ConnectiCare	6/29/2020	Added indication, criteria, dosing max, icd 10 code for Cutaneous Squamous cell carcinoma
EmblemHealth & ConnectiCare	6/23/2020	Added indication and criteria for Tumor Mutational Burden-High Cancer
EmblemHealth & ConnectiCare	01/1/2020	-Under Guidelines, Melanoma – added for the adjuvant treatment of patients with melanoma with involvement of lymph node(s) following complete resection -Under Guidelines, added Small Cell Lung Cancer (SCLC) indication. For the treatment of patients with metastatic SCLC with disease progression on or after platinum-based chemotherapy and at least one other prior line of therapy -Under Guidelines, Squamous Cell Carcinoma of the Head and Neck (SCCHN), added in combination with platinum and FU for the first-line treatment of patients with metastatic or with unresectable, recurrent SCCHN -Under Guidelines, added Renal Cell Carcinoma indication, in combination with axitinib, for the first-line treatment of patients with advanced RCC

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