PROVIDER NOTIFICATION OF POLICY CRITERIA CHANGE					
POLICY TITLE	**POLICY NUMBER**	**CRITERIA CHANGE**	**MATERIAL AMENDEMENT**	**EFFECTIVE DATE**	**LINK TO FULL POLICY**
Teclistamab-cqyv (e.g., Tecvayli)	2023015	Coverage criteria updated for FDA labeled and off-label indications. **<u>FDA Labeled Indications:</u>** **INITIAL APPROVAL:** 1. Individual has a diagnosis of relapsed or refractory multiple myeloma (MM) (Tecvayli, 2026; NCCN 2A); **AND** 2. Individual is 18 years of age or older (Tecvayli, 2026); **AND** 3. Individual has an ECOG performance status of 0-1* (Moreau, 2022); **AND** 4. Teclistamab-cqyv (e.g., Tecvayli) will be used in combination with daratumumab hyaluronidase-fihj (Tecvayli, 2026; NCCN 1); **AND** a. Individual has received at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent; **OR** 5. Teclistamab-cqyv (e.g., Tecvayli) will be used as monotherapy; **AND** a. Individual has received at least four prior therapies and must have included ALL of the following (Tecvayli, 2026; NCCN 2A): i. An anti-CD38 monoclonal antibody (such as daratumumab, daratumumab-hyaluronidase, or isatuximab); **AND** ii. A proteasome inhibitor (such as bortezomib, carfilzomib, or ixazomib); **AND** iii. An immunomodulatory agent (such as lenalidomide, pomalidomide, or thalidomide); **AND**	No	June 15, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2023015

		6. Individual has not been previously treated with prior BCMA-targeting therapy (such as belantamab) (Moreau, 2022); **AND** 7. Individual does **NOT** have active central nervous system involvement or clinical signs of meningeal involvement of MM (Moreau, 2022); **AND** **CONTINUATION OF THERAPY:** 1. Individual continues to meet the initial approval criteria; **AND** 2. Individual has not experienced disease progression during teclistamab-cqyv treatment (Tecvayli, 2022); **AND** 3. Individual has an ECOG performance status of 0-1* (Moreau, 2022); **AND** 4. Individual does **NOT** have active central nervous system involvement or clinical signs of meningeal involvement of MM (Moreau, 2022). **<u>Off-label Indications</u>** **INITIAL APPROVAL:** 1. Treatment of multiple myeloma in combination with talquetamab-tgvs in those who have received at least 3 prior lines of therapy (NCCN 2A). **CONTINUATION OF THERAPY:** 1. Individual continues to meet the initial approval criteria; **AND** 2. Individual has not experienced disease progression during teclistamab-cqyv treatment (Tecvayli, 2022); **AND** 3. Individual has an ECOG performance status of 0-1* (Moreau, 2022).			
Nab-Paclitaxel (e.g., Abraxane)	2017012	Coverage criteria updated for off-label indications. 1. **Ampullary Adenocarcinoma** (NCCN 2A); **OR** 2. **Kaposi Sarcoma** (NCCN 2A); **OR** 3. **Melanoma**: a. Uveal (NCCN 2A); **OR**	No	June 15, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2017012

		b. Cutaneous (NCCN 2A); **OR** 4. **Pancreatic Adenocarcinoma** (NCCN 1 and 2A); **OR** 5. **Vaginal Cancer** (NCCN 2A); **OR** 6. **Uterine Neoplasms -Endometrial Carcinoma** (NCCN 2A); **OR** 7. **Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer**: a. Epithelia Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer (NCCN 1 and 2A); **OR** b. Carcinosarcoma (Malignant Mixed Mullerian Tumors) (NCCN 1 and 2A); **OR** c. Clear Cell Carcinoma of the Ovary (NCCN 1 and 2A); **OR** d. Mucinous Neoplasms of the Ovary (NCCN 1 and 2A); **OR** e. Grade 1 Endometrioid Carcinoma (NCCN 1 and 2A); **OR** f. Low-Grade Serous Carcinoma (NCCN 2A); **OR** 8. **Biliary Tract Cancers**: a. Gallbladder Cancer (NCCN 2A); **OR** b. Intrahepatic Cholangiocarcinoma (NCCN 2A); **OR** c. Extrahepatic Cholangiocarcinoma (NCCN 2A); **OR** 9. **Cervical Cancer** (NCCN 2A); **OR** 10. **Non-Small Cell Lung Cancer** (NCCN 1 and 2A); **OR** 11. **Breast Cancer**: a. Invasive Breast Cancer (NCCN 1 and 2A); **OR** b. Inflammatory Breast Cancer (NCCN 1 and 2A); **OR** 12. **Small Bowel Adenocarcinoma** (NCCN 2A); **OR** 13. **Non-Small Cell Lung Cancer** (NCCN 1 and 2A).			
Irinotecan Liposomal (e.g., Onivyde)	2021018	Coverage criteria updated for off-label indications. **<u>Off-Label Indications</u>** 1. Individual has a diagnosis of **Ampullary Adenocarcinoma**:	No	June 15, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2021018

		a. First-line therapy for pancreatobiliary and mixed type metastatic disease if good performance status [ECOG (PS 0-1, with good biliary drainage and adequate nutritional intake) as a component of Fluorouracil, leucovorin, liposomal irinotecan, and oxaliplatin (NALIRIFOX) regimen (NCCN 2A); **OR** b. Therapy for disease progression in individuals with good performance status (ECOG 0-1, with good biliary drainage and adequate nutritional intake) and pancreatobiliary and mixed type in combination with fluorouracil and leucovorin if previously treated with prior (NCCN 2A): i. Gemcitabine-based therapy; **OR** ii. Fluoropyrimidine-based therapy if no prior irinotecan; **OR** iii. Oxaliplatin-based therapy (e.g., capecitabine, 5-fluorouracil) if no prior irinotecan; **OR** c. Subsequent therapy in combination with fluorouracil and leucovorin (NCCN 1 for metastatic disease if previously treated with gemcitabine-based therapy; 2A for all others): i. Less than 6 months from completion of first-line gemcitabine-based therapy; **OR** ii. Less than 6 months from completion of first-line fluoropyrimidine-based therapy if no prior irinotecan; **OR**			

		iii. Less than 6 months from completion of first-line therapy as alternate therapy not previously used; **OR** iv. Greater than or equal to 6 months from completion of first-line therapy; **OR** 2. Individual has a diagnosis of **Pancreatic Adenocarcinoma**: a. First-line therapy, or as induction therapy followed by chemoradiation for locally advanced disease and good performance status (defined as ECOG PS 0-1, with good biliary drainage and adequate nutritional intake) as a component of fluorouracil, leucovorin, liposomal irinotecan, and oxaliplatin (NALIRIFOX) protocol (NCCN 2A); **OR** b. First-line therapy for metastatic disease with good performance status (defined as ECOG PS 0-1, with good biliary drainage and adequate nutritional intake) as a component of fluorouracil, leucovorin, liposomal irinotecan, and oxaliplatin (NALIRIFOX) (NCCN 1); **OR** c. Subsequent therapy in combination with leucovorin and fluorouracil for metastatic disease with progression if performance status (PS) ECOG 0-2 and previously treated with (NCCN 1 for metastatic disease if previously treated with gemcitabine-based therapy; 2A for all others):			

		i. Fluoropyrimidine-based therapy and no prior irinotecan; **OR** ii. Gemcitabine-based therapy.			
Asparagine Specific Enzymes (e.g., Rylaze, Asparlas, Oncaspar)	2022019	Coverage criteria updated for FDA labeled and off-label indications. **<u>FDA Labeled Indications:</u>** **INITIAL APPROVAL:** 1. Individual has a diagnosis of: a. Acute lymphoblastic leukemia (ALL) (Rylaze, 2025); **OR** b. Lymphoblastic Lymphoma (LBL) (Rylaze, 2025); **AND** 2. Individual is 1 month of age or older(Rylaze, 2025); **AND** 3. Individual has documentation of an allergic reaction to a long-acting E. coli-derived asparaginase OR have silent inactivation (see policy guidelines) (Rylaze, 2025); **AND** 4. Individual has no history of the following contraindications(Rylaze, 2025): a. Serious pancreatitis during previous asparaginase therapy; **OR** b. Serious hemorrhagic events during previous asparaginase therapy; **OR** c. Serious thrombosis during previous asparaginase therapy; **OR** d. Severe hepatic impairment; **AND** 5. Individual is using asparaginase erwinia chrysanthemi (e.g., Rylaze) as a component of multi-agent chemotherapy(Rylaze, 2025) **<u>Off Labeled Indications:</u>** **INITIAL APPROVAL:** 1. **Pediatric Acute Lymphoblastic Leukemia** (NCCN 2A); **OR** 2. **T-Cell Lymphomas** - Extranodal NK/T-Cell Lymphomas (NCCN 2A).	No	June 15, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2022019

Ado-Trastuzumab Emtansine (e.g., Kadcyla (Trastuzumab-DM1) for Treatment of HER-2 Positive Malignancies	2013014	Coverage criteria updated for off-label indications. 1. Individual has a diagnosis of **CENTRAL NERVOUS SYSTEM CANCERS:** a. Limited Brain Metastases (NCCN 2A) i. Used as a single-agent treatment for limited brain metastases in HER2 positive brain cancer: 1. May be considered as initial treatment in select cases (e.g., small asymptomatic brain metastases) for newly diagnosed or stable systemic disease or if reasonable systemic treatment options exist; **OR** 2. Recurrent brain metastases; **OR** b. Extensive Brain Metastases (NCCN 2A) i. Single agent treatment or in combination with neratinib for extensive brain metastases in HER2 positive breast cancer: 1. Primary treatment in select cases (e.g., small asymptomatic brain metastases); **OR** 2. As treatment for recurrent disease with stable systemic disease or reasonable systemic treatment options; **OR** 2. Individual has a diagnosis of **HEAD AND NECK CANCERS** a. Salivary Gland Tumors (NCCN 2A) i. Single-agent systemic therapy for human epidermal growth factor receptor 2	No	June 15, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2013014

		(HER2)-positive recurrent disease with a: 1. Distant metastases in individuals with a performance status (PS) of 0-3; **OR** 2. Unresectable locoregional recurrence or second primary disease with prior radiation therapy; **OR** 3. Individual has a diagnosis of **NON-SMALL CELL LUNG CANCER** a. Subsequent therapy as a single agent for ERBB2 (HER2) mutation positive recurrent, advanced, or metastatic disease (following progression on first-line systemic therapy with a non-ERBB2 (HER2)-targeted regimen; other recommended option following progression on first-line zongertinib or progression on subsequent therapy if not previously given (NCCN 2A); **OR** 4. Individual has a diagnosis of **BREAST CANCER**: a. Invasive Breast Cancer: i. Adjuvant systemic therapy for HER2-positive tumors and locally advanced disease following completion of planned chemotherapy and following mastectomy or breast-conserving surgery with surgical axillary staging if ypT1-4N0 or ypN ≧ greater than or equal to 1 (NCCN 1); **OR** ii. Adjuvant systemic therapy for HER2-positive tumors and pT1-3 and pN0 or pN+ disease (NCCN 2A); **OR** iii. Third line and beyond (or second line in fam-trastuzumab deruxtecan is not			

		able to be used) single-agent therapy for recurrent unresectable (local or regional) or stage IV (M1) HER2-positive disease that is HR-negative or HR-positive with or without endocrine therapy (NCCN 2A); **OR** b. Inflammatory Breast Cancer i. Adjuvant systemic therapy in residual disease following preoperative therapy for HER2-positive tumors (NCCN 1); **OR** ii. Third line and beyond (or second line in fam-trastuzumab deruxtecan is not able to be used) single-agent therapy for recurrent unresectable (local or regional) or stage IV (M1) HER2-positive disease that is HR-negative or HR-positive with or without endocrine therapy (NCCN 2A) iii. Adjuvant systemic therapy for individuals who had a response to preoperative systemic therapy, followed by surgery, and need to complete planned chemotherapy, with human epidermal growth factor receptor 2 (HER2)-positive tumors (NCCN 2A).			
Isatuximab-irfc (e.g., Sarclisa)	2020008	Coverage criteria updated for off-label indications. 1. Primary therapy for symptomatic **multiple myeloma** in combination with bortezomib, lenalidomide and dexamethasone for: a. Transplant candidates (NCCN 2A); **OR** b. Non-transplant candidates less than 80 years old who are not frail (NCCN 1); **OR** 2. Primary therapy for symptomatic **multiple myeloma** in combination with carfilzomib,	No	June 15, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2020008

		lenalidomide and dexamethasone for transplant candidates (not covered when used for transplant-deferred or transplant not indicated scenarios) (NCCN 2A); **OR** 3. Primary for symptomatic multiple myeloma in combination with lenalidomide and dexamethasone if transplant-deferred or if transplant not indicated (NCCN 2A); **OR** 4. Therapy for previously treated multiple myeloma for relapse or progressive disease in combination with: a. pomalidomide and dexamethasone for individuals who have received two prior therapies including lenalidomide and a proteasome inhibitor if lenalidomide-or bortezomib-refractory (NCCN 1); **OR** b. dexamethasone and carfilzomib if lenalidomide-or bortezomib-refractory (NCCN 1).			
Elotuzumab (e.g., Empliciti)	2017013	Coverage criteria updated for off-label indications. 1. Therapy for previously treated **multiple myeloma** for relapse or progressive disease in combination with bortezomib and dexamethasone (NCCN 1 for combination with lenalidomide and dexamethasone; NCCN 2A for all others): a. Pomalidomide and dexamethasone after two prior therapies including lenalidomide and a proteasome inhibitor; **OR** b. Lenalidomide and dexamethasone; **OR** c. Bortezomib and dexamethasone.	No	June 15, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2017013
Pembrolizumab (e.g., Keytruda)	2019005	Coverage criteria for FDA labeled indications updated. **MELANOMA** 1. Individual has a diagnosis of melanoma: a. For the treatment of individuals with unresectable or metastatic melanoma (Keytruda, 2026; NCCN 2A); **OR** b. For the adjuvant treatment of adult and pediatric (12 years and older)	No	June 15, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2019005

		individuals with Stage IIB, IIC, or III melanoma following complete resection (Keytruda, 2026); **AND** 2. Pembrolizumab (e.g., Keytruda) will not be used: a. For adult individuals who have received another PD-1 agent (i.e., nivolumab); **OR** b. In combination with any other drug except as listed above. **<u>NON-SMALL CELL LUNG CANCER (NSCLC)</u>** 1. Individual has a diagnosis of non-small cell lung cancer (NSCLC): a. In combination with pemetrexed and platinum chemotherapy, as first-line treatment of individuals with metastatic nonsquamous NSCLC, with no EGFR or ALK genomic tumor aberrations (Keytruda, 2026); **OR** b. In combination with carboplatin and either paclitaxel or paclitaxel protein-bound, as first-line treatment of individuals with metastatic squamous NSCLC (Keytruda, 2026); **OR** c. As a single agent for the first-line treatment of individuals with NSCLC expressing PD-L1 [Tumor Proportion Score (TPS) greater than or equal to 1%] as determine by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations, and is: i. Stage III where individuals are not candidates for surgical resection or definitive chemoradiation (Keytruda, 2026); **OR** ii. Metastatic(Keytruda, 2026); **OR** d. As a single agent for the treatment of individuals with metastatic NSCLC hose tumors express PD-L1 (TPS greater than or equal to 1%) as determined by an FDA-approved test, with disease progression on or after			

		platinum-containing chemotherapy. Individuals with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving pembrolizumab (Keytruda, 2026); **OR** e. For the treatment of individuals with resectable tumors(greater than or equal to 4 cm or node positive) NSCLC in combination with platinum-containing chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery (Keytruda, 2024); **OR** f. As a single agent , for adjuvant treatment following resection and platinum-based chemotherapy for adult individuals with Stage IB (T2a greater than or equal to 4 cm), II, or IIIA NSCLC (Keytruda, 2024; **AND** b. Pembrolizumab (e.g., Keytruda) will not be used: a. For adult individuals who have received another PD-1 agent (i.e., nivolumab); **OR** b. In combination with any other drug except as listed above. **<u>MALIGNANT PLEURAL MESOTHELIOMA (MPM)</u>** 1. Individual has a diagnosis of malignant pleural mesothelioma (MPM) (Keytruda, 2026; NCCN 1): a. In combination with pemetrexed and platinum chemotherapy, as first-line treatment of adult individuals with unresectable advanced or metastatic MPM; **AND** 2. Pembrolizumab (e.g., Keytruda) will not be used: a. For adult individuals who have received another PD-1 agent (i.e., nivolumab); **OR** b. In combination with any other drug except as listed above.			

		HEAD AND NECK SQUAMOUS CELL CANCER (HNSCC) 1. Individual has a diagnosis of head and neck squamous cell cancer (HNSCC): a. For the treatment of adult individuals with resectable locally advanced HNSCC whose tumors express PD-L1 as determined by an FDA-authorized test, as a single agent as neoadjuvant treatment in combination with radiotherapy with or without cisplatin and then as a single agent (Keytruda, 2026); **OR** b. In combination with platinum and FU for the first-line treatment of individuals with metastatic or with unresectable, recurrent HNSCC (Keytruda, 2026); **OR** c. As a single agent for the first-line treatment of individuals with metastatic or with unresectable, recurrent HNSCCC whose tumors express PD-L1 [Combine Positive Score (CPS) greater than or equal to 1] as determined by an FDA-approved test (Keytruda, 2026; NCCN 1 and 2A); **OR** d. As a single agent for the treatment of individuals with recurrent or metastatic HNSCC with disease progression on or after platinum-containing chemotherapy (Keytruda, 2026); **AND** 2. Pembrolizumab (e.g., Keytruda) will not be used: a. For adult individuals who have received another PD-1 agent (i.e., nivolumab); **OR** b. In combination with any other drug except as listed above. **CLASSICAL HODGKIN LYMPHOMA (cHL)** 1. Individual has a diagnosis of classical Hodgkin lymphoma (cHL):			

		a. For the treatment of adult individuals with relapsed or refractory cHL (Keytruda, 2026; NCCN 2A); **OR** b. For the treatment of pediatric individuals with refractory cHL, or cHL that has relapsed after 2 or more lines of therapy (Keytruda, 2026; NCCN 2A); **AND** 2. Pembrolizumab (e.g., Keytruda) will not be used: a. For adult individuals who have received another PD-1 agent (i.e., nivolumab); **OR** b. In combination with any other drug except as listed above. **PRIMARY MEDIASTINAL LARGE B-CELL LYMPHOMA (PMBCL)** 1. Individual has a diagnosis of primary mediastinal large b-cell lymphoma (PMBCL): a. For the treatment of adult and pediatric individuals with refractory PMBCL, or who have relapsed after 2 or more prior lines of therapy (Keytruda, 2026; NCCN 2A); **OR** *Limitations of Use: Pembrolizumab is not recommended for treatment of individuals with PMBCL who require urgent cytoreductive therapy (Keytruda, 2026); **AND** 2. Pembrolizumab (e.g., Keytruda) will not be used: a. For adult individuals who have received another PD-1 agent (i.e., nivolumab); **OR** b. In combination with any other drug except as listed above. **UROTHELIAL CANCER** 1. Individual has a diagnosis of urothelial cancer: a. In combination with enfortumab vedotin, for the treatment of adult individuals with locally advanced or			

		metastatic urothelial cancer (Keytruda, 2026; NCCN 1); **OR** b. As a single agent for the treatment of individuals with locally advanced or metastatic urothelial carcinoma who: i. Are not eligible for any platinum-containing chemotherapy(Keytruda, 2024; NCCN 1 and 2A); **OR** ii. Who have disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy (Keytruda, 2026; NCCN 2A); **OR** c. In combination with enfortumab vedotin, as neoadjuvant treatment and then continued after cystectomy as adjuvant treatment of adult individuals with muscle invasive bladder cancer (MIBC) who are ineligible for cisplatin-containing chemotherapy (Keytruda, 2026); **OR** d. As a single agent for the treatment of individuals with Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy (Keytruda, 2026); **AND** 2. Pembrolizumab (e.g., Keytruda) will not be used: a. For adult individuals who have received another PD-1 agent (i.e., nivolumab); **OR** b. In combination with any other drug except as listed above. **<u>MICROSATELLITE INSTABILITY-HIGH OR MISMATCH REPAIR DEFICIENT CANCER</u>**			

		1. Individual has a diagnosis of microsatellite instability-high or mismatch repair deficient cancer: a. For the treatment of adult and pediatric individuals with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options (Keytruda, 2026); **AND** 2. Pembrolizumab (e.g., Keytruda) will not be used: a. For adult individuals who have received another PD-1 agent (i.e., nivolumab); **OR** b. In combination with any other drug except as listed above. **MICROSATELLITE INSTABILITY-HIGH OR MISMATCH REPAIR DEFICIENT COLORECTAL CANCER (CRC)** 1. Individual has a diagnosis of microsatellite instability-high or mismatch repair deficient colorectal cancer (CRC): a. For the treatment of individuals with unresectable or metastatic MSI-H or dMMR colorectal cancer (CRC) as determined by an FDA-approved test(Keytruda, 2026); **AND** 2. Pembrolizumab (e.g., Keytruda) will not be used: a. For adult individuals who have received another PD-1 agent (i.e., nivolumab); **OR** b. In combination with any other drug except as listed above. **GASTRIC CANCER** 1. Individual has a diagnosis of gastric cancer: a. In combination with trastuzumab, fluoropyrimidine- and platinum-			

		containing chemotherapy, for the first-line treatment of adults with locally advanced unresectable or metastatic HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma whose tumors express PD-L1 (CPS greater than or equal to 1) as determined by an FDA-approved test (Keytruda, 2026; NCCN 1); **OR** b. In combination with fluoropyrimidine- and platinum-containing chemotherapy, for the first-line treatment of adults with locally advanced unresectable or metastatic HER2-negative gastric or gastroesophageal junction (GEJ) adenocarcinoma (Keytruda, 2026; NCCN 1 and 2A); **AND** 2. Pembrolizumab (e.g., Keytruda) will not be used: a. For adult individuals who have received another PD-1 agent (i.e., nivolumab); **OR** b. In combination with any other drug except as listed above. **ESOPHAGEAL CANCER** 1. Individual has a diagnosis of esophageal cancer: a. For the treatment of individuals with locally advanced or metastatic esophageal or gastroesophageal junction (GEJ) (tumors with epicenter 1 to 5 centimeters above the GEJ) carcinoma that is not amenable to surgical resection or definitive chemoradiation either: i. In combination with platinum- and fluoropyrimidine-based chemotherapy(Keytruda, 2026; NCCN 1 and 2A); **OR**			

		ii. As a single agent after one or more prior lines of systemic therapy for individuals with tumors of squamous cell histology that express PD-L1 (CPS greater than or equal to 10) as determined by an FDA-approved test (Keytruda, 2026; NCCN 1 and 2A); **AND** 2. Pembrolizumab (e.g., Keytruda) will not be used: a. For adult individuals who have received another PD-1 agent (i.e., nivolumab); **OR** b. In combination with any other drug except as listed above. **CERVICAL CANCER** 1. Individual has a diagnosis of cervical cancer: a. In combination with chemoradiotherapy, for the treatment of individuals with International Federation of Gynecology and Obstetrics (FIGO) 2014 Stage III-IVA cervical cancer; **OR** b. In combination with chemotherapy, with or without bevacizumab, for the treatment of individuals with persistent, recurrent, or metastatic cervical cancer whose tumors express PD-L1 (CPS greater than or equal to 1) as determined by an FDA-approved test (Keytruda, 2026; NCCN 2A); **OR** c. As a single agent for the treatment of individuals with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy whose tumors express PD-L1 (CPS greater than or equal to 1) as determined by an FDA-approved test (Keytruda, 2026; NCCN 2A); **AND** 2. Pembrolizumab (e.g., Keytruda) will not be used:			

		a. For adult individuals who have received another PD-1 agent (i.e., nivolumab); **OR** b. In combination with any other drug except as listed above. **HEPATOCELLULAR CARCINOMA (HCC)** 1. Individual has a diagnosis of hepatocellular carcinoma (HCC): a. For the treatment of individuals with HCC secondary to hepatitis B who have received prior systemic therapy other than a PD-1/PD-L1-containing regimen(Keytruda, 2026; NCCN 2A); **AND** 2. Pembrolizumab (e.g., Keytruda) will not be used: a. For adult individuals who have received another PD-1 agent (i.e., nivolumab); **OR** b. In combination with any other drug except as listed above. **BILIARY TRACT CANCER (BTC)** 1. Individual has a diagnosis of biliary tract cancer (BTC): a. In combination with gemcitabine and cisplatin, for the treatment of individuals with locally advanced unresectable or metastatic biliary tract cancer (Keytruda, 2024; NCCN 2A); **AND** 2. Pembrolizumab (e.g., Keytruda) will not be used: a. For adult individuals who have received another PD-1 agent (i.e., nivolumab); **OR** b. In combination with any other drug except as listed above. **MERKEL CELL CARCINOMA (MCC)**			

		1. Individual has a diagnosis of merkel cell carcinoma (MCC): a. For the treatment of adult and pediatric individuals with recurrent locally advanced or metastatic Merkel cell carcinoma(Keytruda, 2026; NCCN 2A); **AND** 2. Pembrolizumab (e.g., Keytruda) will not be used: a. For adult individuals who have received another PD-1 agent (i.e., nivolumab); **OR** b. In combination with any other drug except as listed above. **RENAL CELL CARCINOMA (RCC)** 1. Individual has a diagnosis of renal cell carcinoma (RCC): a. In combination with axitinib, for the first-line treatment of adult individuals with advanced RCC (Keytruda, 2026; NCCN 1); **OR** b. In combination with Lenvatinib, for the first-line treatment of adult individuals with RCC; **OR** c. For the adjuvant treatment of individuals with RCC at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions (Keytruda, 2026; NCCN 1); **AND** 2. Pembrolizumab (e.g., Keytruda) will not be used: a. For adult individuals who have received another PD-1 agent (i.e., nivolumab); **OR** b. In combination with any other drug except as listed above. **ENDOMETRIAL CARCINOMA** 1. Individual has a diagnosis of endometrial carcinoma:			

		a. In combination with carboplatin and paclitaxel, followed by pembrolizumab as a single agent, for the treatment of adult individuals with primary advanced or recurrent endometrial carcinoma; **OR** b. In combination with Lenvatinib, for the treatment of individuals with advanced endometrial carcinoma that is mismatch repair proficient (pMMR) as determined by an FDA-approved test or not MSI-H, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation (Keytruda, 2026; NCCN 1); **OR** c. As a single agent, for the treatment of individuals with advanced endometrial carcinoma that is MSI-H or dMMR, as determined by an FDA-approved test, who have disease progression following prior systemic therapy in any setting and not candidates for curative surgery or radiation (Keytruda, 2026; NCCN 2A); **AND** 2. Pembrolizumab (e.g., Keytruda) will not be used: a. For adult individuals who have received another PD-1 agent (i.e., nivolumab); **OR** b. In combination with any other drug except as listed above. **<u>TUMOR MUTATIONAL BURDEN-HIGH (TMB-H) CANCER</u>** 1. Individual has a diagnosis of tumor mutational burden-high (TMB-H) cancer: a. For the treatment of adult and pediatric individuals with unresectable or metastatic tumor mutational burden-high (TMB-H) (greater than or equal to 10 mutations/megabase (mut/Mb) solid tumors that have progressed following prior treatment and who have no			

		satisfactory alternative treatment options (NCCN 2A); **AND** *Limitations of Use: The safety and effectiveness of pembrolizumab in pediatric individuals with TMB-H central nervous systems cancers have not been established (Keytruda, 2026). 2. Pembrolizumab (e.g., Keytruda) will not be used: a. For adult individuals who have received another PD-1 agent (i.e., nivolumab); **OR** b. In combination with any other drug except as listed above. **CUTANEOUS SQUAMOUS CELL CARCINOMA (CSCC)** 1. Individual has a diagnosis of cutaneous squamous cell carcinoma (CSCC): a. For the treatment of individuals with recurrent or locally advanced cSCC that is not curable by surgery or radiation (Keytruda, 2026; NCCN 2A); **AND** 2. Pembrolizumab (e.g., Keytruda) will not be used: a. For adult individuals who have received another PD-1 agent (i.e., nivolumab); **OR** b. In combination with any other drug except as listed above. **TRIPLE-NEGATIVE BREAST CANCER (TNBC)** 1. Individual has a diagnosis of triple-negative breast cancer (TNBC): a. For the treatment of individuals with high-risk early-stage TNBC in combination with chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery (Keytruda, 2026; NCCN 2A); **OR** b. In combination with chemotherapy, for the treatment of individuals with locally			

		recurrent unresectable or metastatic TNBC whose tumors express PD-L1 (CPS greater than or equal to 10) as determined by an FDA approved test (Keytruda, 2026; NCCN 1 and 2A); **AND** 2. Pembrolizumab (e.g., Keytruda) will not be used: a. For adult individuals who have received another PD-1 agent (i.e., nivolumab); **OR** b. In combination with any other drug except as listed above. **OVARIAN CANCER** 1. In combination with paclitaxel, with or without bevacizumab, for the treatment of adult individuals with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal carcinoma whose tumors express PD-L1 (CPS greater than or equal to 1) as determined by an FDA0authorized test, and who have received one or two prior systemic treatment regimens (Keytruda, 2026); **OR** **ADULT CLASSICAL HODGKIN LYMPHOMA AND ADULT PRIMARY MEDIASTINAL LARGE B-CELL LYMPHOMA** 1. Individual has a diagnosis of adult classical Hodgkin lymphoma and adult primary mediastinal large b-cell lymphoma: Additional Dosing Regimen of 400 mg every 6 Weeks: a. For use at an additional recommended dosage of 400 mg every 6 weeks for Classical Hodgkin Lymphoma and Primary Mediastinal Large B-Cel Lymphoma in adults (Keytruda, 2026); **AND** 2. Pembrolizumab (e.g., Keytruda) will not be used: a. For adult individuals who have received another PD-1 agent (i.e., nivolumab); **OR**			

		b. In combination with any other drug except as listed above.			
Trastuzumab (e.g., Herceptin) and Biosimilars and Trastuzumab/Hyaluronidase-oysk (e.g., Herceptin Hylecta)	1998158	Coverage criteria updated for off-label indications. 1. **Biliary Tract Cancers:** a. Gallbladder Cancer (NCCN 2A); **OR** b. Intrahepatic Cholangiocarcinoma (NCCN 2A); **OR** c. Extrahepatic Cholangiocarcinoma (NCCN 2A); **OR** 2. **Breast Cancer:** a. Invasive Breast Cancer (NCCN 1 and 2A); **OR** b. Inflammatory Breast Cancer (NCCN 1 and 2A); **OR** 3. **Central Nervous System Cancers:** a. Limited Brain Metastases (NCCN1 and 2A); **OR** b. Extensive Brain Metastases (NCCN 1 and 2A); **OR** c. Leptomeningeal Metastases (NCCN 2A); **OR** 4. **Colon Cancer** (NCCN 2A); **OR** 5. **Esophageal and Esophagogastric Junction Cancer** (NCCN 1 and 2A); **OR** 6. **Gastric Cancer** (NCCN 1 and 2A); **OR** 7. **Head and Neck Cancers:** a. Salivary Gland Tumors (NCCN 2A); **OR** 8. **Rectal Cancer** (NCCN 2A); **OR** 9. **Uterine Neoplasms:** a. Endometrial Carcinoma (NCCN 2A); **OR** 10. **Appendiceal Neoplasms and Cancers** (NCCN 2A); **OR** 11. **Gastric Cancer** (NCCN 1 and 2A); **OR** 12. **Small Bowel Adenocarcinoma** (NCCN 2A)	No	June 15, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=1998158
Zenocutuzumab-zbco (e.g., Bizengri)	2025009	Coverage criteria for off-label indications updated. 1. **Biliary Tract Cancers**: a. Intrahepatic Cholangiocarcinoma (NCCN 2A); **OR**	No	June 15, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2025009

		b. Extrahepatic Cholangiocarcinoma (NCCN 2A); **OR** 2. **Non-Small Cell Lung Cancer** (NCCN 2A); **OR** 3. **Pancreatic Adenocarcinoma** (NCCN 2A).			