PROVIDER NOTIFICATION OF POLICY CRITERIA CHANGE					
POLICY TITLE	**POLICY NUMBER**	**CRITERIA CHANGE**	**MATERIAL AMENDMENT**	**EFFECTIVE DATE**	**LINK TO FULL POLICY**
Somatic Biomarker Testing (including Liquid Biopsy) for Targeted Treatment in Metastatic Colorectal Cancer (KRAS, NRAS, BRAF, and HER2)	2008027	Coverage criteria for RET testing added: RET testing of tumor tissue for individuals with metastatic colorectal cancer (mCRC) to select individuals for treatment with FDA-approved therapies.	No	11/01/2025	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2008027
Tisagenlecleucel (e.g., Kymriah)	1998109	Coverage criteria revised. Added the following required criteria for B-Cell Acute Lymphoblastic Leukemia: 1. Individual has confirmed CD19 tumor expression: **AND** 2. Individual is using for one of the following types of disease: a. If individual has Philadelphia chromosome positive (Ph+) ALL with refractory disease or ≥ 2 relapses following therapy that has included at least two tyrosine kinase inhibitor (TKI) therapies (NCCN 2A, NCT02228096); **OR** b. If individual has Philadelphia chromosome negative (Ph -) ALL with refractory disease or ≥ 2 relapses ; Off-label indications added: 1. Individual is 18 years of age or older; **AND** 2. Individual has a histologically confirmed diagnosis of one of the following: a. Monomorphic Post-Transplant Lymphoproliferative (B-cell type) Disorders (PTLD) ; **OR** b. HIV-related B cell Lymphomas ; **OR** c. Histologic Transformation of Indolent Lymphomas to DLBCL ; **AND** 3. Individual has relapsed or refractory disease after receiving two or more lines of systemic therapy (which may or may not	Yes	12/01/2025	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=1998109

		include therapy supported by autologous stem cell transplant); **AND** **4.** Individual has adequate organ and bone marrow function as determined by the treating oncologist/hematologist**; AND** **5.** Individual has not received prior treatment with CAR T-cell therapy or other genetically modified T-cell therapy and is not or has not been a subject of a clinical trial for any of the therapies listed in this policy**; AND** 6. There is only one administration of tisagenlecleucel per individual per lifetime. The following was added to Policy Guidelines: *** Relapsed or refractory disease, defined as progression after 2 or more lines of systemic therapy (which may or may not include therapy supported by autologous cell transplant). This can be defined by any of the following: 1. Second or later bone marrow relapse; **OR** 2. Bone marrow relapse after allogeneic stem cell transplant; **OR** 3. Primary refractory disease defined as failure to achieve complete response after two cycles of standard chemotherapy; **OR** 4. Chemo-refractory after relapse defined as failure to achieve complete response after 1 cycle of standard chemotherapy for relapse leukemia.			
Lisocabtagene Maraleucel (e.g., Breyanzi)	2024042	Coverage criteria revised. Added the following required criteria for Large B-Cell Lymphoma: 1. Individual has treatment resistant disease defined as follows: a. Disease refractory to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy including an Anti-CD20 monoclonal body (for example, rituximab) and an anthracycline-containing chemotherapy regimen (Breyanzi, 2025); **OR**	Yes	12/01/2025	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2024042

		b. Disease refractory to or relapsed after first-line chemoimmunotherapy including an Anti-CD20 monoclonal body (for example, rituximab) and an anthracycline-containing chemotherapy regimen and individual is not eligible for hematopoietic stem cell transplantation due to comorbidities or age (Breyanzi, 2025); **OR** c. Relapsed or refractory disease after two or more lines of systemic therapy including an Anti-CD20 monoclonal body (for example, rituximab) and an anthracycline-containing chemotherapy regimen (Breyanzi, 2025) Off-label indications added: 1. Individual meets one of the following options (A&B or C&D): a. Individual is 18 years of age or younger ; **AND** b. Individual is diagnosed with Pediatric Aggressive Mature B-Cell Lymphomas-Primary Mediastinal Large B-cell lymphoma ; **OR** c. Individual is 18 years of age or older; **AND** d. Individual has a histologically confirmed diagnosis of one of the following: i. Monomorphic Post-Transplant Lymphoproliferative (B-cell type) Disorders (PTLD) ; **OR** ii. HIV-related B cell Lymphomas ; **OR** iii. Diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NCCN 1, 2A); **AND** 2. Individual is using in one of the following ways: a. Relapsed or refractory disease after receiving two or more lines of systemic therapy (which may or may not include therapy supported by autologous stem cell transplant), including all of the following: i. An anthracycline-containing chemotherapy regimen; **AND** ii. For CD20-positive disease, anti-CD20 monoclonal antibody, such as rituximab; **OR**			

		b. Relapsed or refractory disease (≤ 12 months) after first-line rituximab and anthracycline-based chemotherapy (Breyanzi 2025); **AND** **c.** Individual has adequate organ and bone marrow function as determined by the treating oncologist/hematologist**; AND** **d.** Individual has not received prior treatment with CAR T-cell therapy or other genetically modified T-cell therapy and is not or has not been a subject of a clinical trial for any of the therapies listed in this policy**; AND** **e.** There is only one administration of lisocabtagene maraleucel per individual per lifetime.			
Idecabtagene vicleucel (e.g., Abecma)	2024041	Policy criteria revised. Multiple Myeloma Removed exclusion criterion point related to prior allogeneic stem cell transplant. Policy guidelines added. Provider is responsible for assessing suitability for CAR-T therapy, including verification of adequate renal function (creatinine clearance is not less than or equal to 45 mL/min), adequate cardiovascular function (left cardiac ejection fraction (EF) is not less than 45%, or other clinically significant cardiac disease has not been present within in the past 6 months), adequate immunological status (no active hepatitis B, active hepatitis C, human immunodeficiency virus (HIV) positive, or other active, uncontrolled infection).	No	11/01/2025	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2024041
Ciltacabtagene autoleucel (e.g., Carvykti)	2024040	Coverage criteria revised. Removed exclusion criterion related to prior allogeneic stem cell transplant. Policy guidelines added. Provider is responsible for assessing suitability for CAR-T therapy, including	No	11/01/2025	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2024040

		verification of adequate renal function (creatinine clearance is not less than or equal to 45 mL/min), adequate cardiovascular function (left cardiac ejection fraction (EF) is not less than 45%, or other clinically significant cardiac disease has not been present within in the past 6 months), adequate immunological status (no active hepatitis B, active hepatitis C, human immunodeficiency virus (HIV) positive, or other active, uncontrolled infection).			
Brexucabtagene Autoleucel (e.g., Tecartus)	2024039	Policy guidelines added. Provider is responsible for assessing suitability for CAR-T therapy, including verification of adequate renal function (creatinine clearance is not less than or equal to 45 mL/min), adequate cardiovascular function (left cardiac ejection fraction (EF) is not less than 45%, or other clinically significant cardiac disease has not been present within in the past 6 months), adequate immunological status (no active hepatitis B, active hepatitis C, human immunodeficiency virus (HIV) positive, or other active, uncontrolled infection).	No	11/01/2025	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2024039
Self-Administered Medication	2020005	CPT codes updated. Garadacimab (e.g., Andembry) added as a self-administered medication. Zuranolone (e.g., Zurzuvae) removed from policy due to discontinuation by manufacturer.	No	11/01/2025	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2020005
NIVOLUMAB (e.g., Opdivo)	2016005	Coverage criteria has been revised. <u>Colorectal Cancer</u> For treatment of adult and pediatric (12 years and older) individuals with **COLORECTAL CANCER** that is microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR), given as a single agent or in combination with ipilimumab: Individual has not received another PD-1 agent (i.e., pembrolizumab); <u>Hepatocellular carcinoma</u>	Yes	12/01/2025	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2016005

		For treatment of individuals in the following circumstances: a. Individual has previously been treated with sorafenib and nivolumab will be used in combination with ipilimumab; **OR** b. Individual has an unresectable or metastatic hepatocellular carcinoma and nivolumab will be used in combination with ipilimumab as a first-line therapy (Opdivo 2025, NCCN 2A); **AND** c. Individual has not received another PD-1 (e.g., pembrolizumab); Continuation criteria added: 1. Individual continues to meet the initial approval criteria; AND 2. Individual experiences objective benefit from continued treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; AND 3. Individual does not have unacceptable toxicity resulting from the treatment including immune-mediated adverse reactions (i.e., pneumonitis, colitis, hepatitis, endocrinopathies, nephritis with renal dysfunction, dermatologic adverse reaction, and solid organ transplant rejection) and severe infusion reactions. <u>Off-label indications added:</u> The following indications are covered when the individual meets the related NCCN category 1 or 2A recommendations specific to the indications below (e.g., histology, cancer staging, surgical status, mono- or combination therapy, and previous lines of therapy): **1.** Ampullary Adenocarcinoma; **OR** **2.** Anal Carcinoma; **OR** **3.** Bone cancer, including osteosarcoma, Ewing Sarcoma, chondrosarcoma, and chordoma; **OR** **4.** Biliary Tract Cancers; **OR** **5.** Cervical Cancer; **OR** **6.** Chronic Lymphocytic Leukemia/Small Lymphocytic Leukemia (CLL/SLL); **OR**			

		7. Colorectal Cancer, including advanced Appendiceal Adenocarcinoma; **OR** **8.** Endometrial carcinoma; **OR** **9.** Esophageal and Esophagogastric junction cancer; **OR** **10.** Gastric or Esophageal and Esophagogastric Junction Cancers and has microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) tumor; **OR** **11.** Gastric Cancer; **OR** **12.** Multi-agent chemotherapy-resistant gestational trophoblastic neoplasia; **OR** **13.** Pediatric Classic Hodgkin Lymphoma; **OR** **14.** Kaposi Sarcoma; **OR** **15.** Malignant Pleural or Peritoneal Mesothelioma; **OR** **16.** Malignant Pleural Mesothelioma; **OR** **17.** Melanoma (Cutaneous); **OR** **18.** Melanoma with brain metastases; **OR** **19.** NSCLC with brain metastases; **OR** **20.** Primary Mediastinal Large B-Cell Lymphoma; **OR** **21.** Relapsed, recurrent, or advanced RCC; **OR** **22.** Relapsed or metastatic non-clear cell RCC (nccRCC) [including hereditary leiomyomatosis and renal cell carcinoma (HLRCC)]; **OR** **23.** Small Bowel Adenocarcinoma (SBA) ; **OR** **24.** Extra nodal NK/T-cell lymphomas; **OR** **25.** Soft Tissue Sarcoma and Aggressive Soft Tissue Neoplasms; **OR** **26.** Head and Neck cancers; **OR** **27.** Anaplastic Thyroid carcinoma; **OR** **28.** Urothelial carcinoma of the Prostate; **OR** **29.** Central Nervous System Cancers- Pediatric Diffuse High-Grade Gliomas; **OR** **30.** Vaginal Cancer; **OR** **31.** Vulvar Cancer. Continuation criteria added: 1. Individual continues to meet the initial approval criteria; **AND** 2. Individual experiences objective benefit from continued treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**			

		3. Individual does not have unacceptable toxicity resulting from the treatment including immune-mediated adverse reactions (i.e., pneumonitis, colitis, hepatitis, endocrinopathies, nephritis with renal dysfunction, dermatologic adverse reaction, and solid organ transplant rejection) and severe infusion reactions.			
Nivolumab and hyaluronidase (e.g., Opdivo qvantig)	2025024	A new policy has been developed for Nivolumab and hyaluronidase (e.g., Opdivo qvantig)	No	11/01/2025	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2025024
Durvalumab (e.g., Imfinzi)	2025023	Coverage criteria has been revised. Non-Small Cell Lung Cancer (NSCLC) • Adults with resectable (tumors equal or larger than 4 cm and/or node positive) and no known epidermal growth factor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements. Non-Small Cell Lung Cancer **(NSCLC)** in combination with platinum-containing chemotherapy as neoadjuvant treatment followed by single agent adjuvant treatment following surgery. Limited-Stage-Small Cell Lung Cancer (LS-SCLC) • As a single agent in adults with Limited-Stage Small Cell Lung Cancer (LS-SCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy. Muscle Invasive Bladder Cancer (MIBC) • In combination with gemcitabine and cisplatin as a neoadjuvant treatment, followed by single agent durvalumab as adjuvant treatment following radical cystectomy, for adults with Muscle Invasive Bladder Cancer (MIBC). Continuation criteria added: 1. Individual continues to meet the initial approval criteria; **AND** 2. Individual experiences objective benefit from continued treatment as defined by	Yes	12/01/2025	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2025023

		stabilization of disease or decrease in size of tumor or tumor spread; **AND** 3. Individual does not have unacceptable toxicity resulting from the treatment including immune-mediated adverse reactions (i.e., pneumonitis, colitis, hepatitis, endocrinopathies, nephritis with renal dysfunction, dermatologic adverse reaction, and solid organ transplant rejection) and severe infusion reactions. Off-label Indications added: The following indications are covered when the individual meets the related NCCN category 1 or 2A recommendations specific to the indications below (e.g., histology, cancer staging, surgical status, mono- or combination therapy, and previous lines of therapy): **1.** Non-Small Cell Lung Cancer; **OR** **2.** Primary Advanced or Recurrent Endometrial Cancer; **OR** **3.** Limited Stage (LS) Small Cell Lung Cancer (Stage I-III); **OR** 4. Extensive Stage (ES) Small Cell Lung Cancer; **OR** 5. Locally Advanced or Metastatic Biliary Tract Cancer (including Pancreatobiliary and Mixed Type Disease); **OR** 6. Hepatocellular Carcinoma (HCC); **OR** 7. Muscle Invasive Bladder Cancer (MIBC); **OR** 8. Small Cell Neuroendocrine Carcinoma of the Cervix (NECC); **OR** 9. Esophageal and esophagogastric junction cancers or Gastric cancers. Continuation criteria added: 1. Individual continues to meet the initial approval criteria; **AND** 2. Individual experiences objective benefit from continued treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND** 3. Individual does not have unacceptable toxicity resulting from the treatment including immune-mediated adverse			

		reactions (i.e., pneumonitis, colitis, hepatitis, endocrinopathies, nephritis with renal dysfunction, dermatologic adverse reaction, and solid organ transplant rejection) and severe infusion reactions.			
Cemiplimab (e.g., Libtayo)	2025022	Coverage criteria revised. Continuation criteria added: 1. Individual continues to meet the initial approval criteria; **AND** 2. Individual experiences objective benefit from continued treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND** 3. Individual does not have unacceptable toxicity resulting from the treatment including immune-mediated adverse reactions (i.e., pneumonitis, colitis, hepatitis, endocrinopathies, nephritis with renal dysfunction, dermatologic adverse reaction, and solid organ transplant rejection) and severe infusion reactions. Off-label Indications added: The following indications are covered when the individual meets the related NCCN category 1 or 2A recommendations specific to the indications below (e.g., histology, cancer staging, surgical status, mono- or combination therapy, and previous lines of therapy): 1. Basal Cell Carcinoma (BCC); OR 2. Squamous Cell Carcinoma (CSCC) OR 3. Non-Small Cell Lung Cancer NSCLC; OR 4. Cervical or Vulvar or Vaginal Cancer; OR 5. Anal Carcinoma, Rectal Cancer, Colon Cancer; OR 6. Small Bowel Adenocarcinoma; OR 7. Appendiceal Adenocarcinoma. Continuation criteria added: 1. Individual continues to meet the initial approval criteria; **AND** 2. Individual experiences objective benefit from continued treatment as defined by	Yes	12/01/2025	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2025022

		stabilization of disease or decrease in size of tumor or tumor spread; **AND** 3. Individual does not have unacceptable toxicity resulting from the treatment including immune-mediated adverse reactions (i.e., pneumonitis, colitis, hepatitis, endocrinopathies, nephritis with renal dysfunction, dermatologic adverse reaction, and solid organ transplant rejection) and severe infusion reactions.			
Fam-trastuzumab deruxtecan-mxki (e.g., Enhertu)	2020015	Coverage criteria revised. HER-2 Positive Breast Cancer 1. Treatment of individual with unresectable or metastatic breast cancer with: a. Hormone receptor (HR)-positive, HER2-low (IHC 1+ or IHC 2+/ISH-) or HER2-ultralow (IHC 0 with membrane staining) breast cancer, as determined by an FDA-approved test, that has progressed on one or more endocrine therapies in the metastatic setting; **OR** b. HER2-low (IHC 1+ or IHC 2+/ISH-) breast cancer, as determined by an FDA-approved test, who have received a prior chemotherapy in the metastatic setting; or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy. Off-label Indications added: **The following indications are covered when the individual meets the related NCCN category 1 or 2A recommendations specific to the indications below (e.g., histology, cancer staging, surgical status, mono- or combination therapy, and previous lines of therapy):** 1. Ampullary cancer 2. Pancreatic cancer 3. Bladder cancer a. Urothelial cancer of prostate	No	11/01/2025	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2020015

		b. Primary cancer of urethra 4. Cervical cancer 5. Vaginal cancer 6. Occult primary 7. Small bowel cancer 8. Rectal cancer 9. Head and neck cancer a. Very advanced head and neck cancer b. Salivary gland tumors 10. Gastric cancer 11. Colon cancer a. Appendiceal cancer 12. Biliary tract cancer a. Gallbladder cancer b. Intrahepatic cholangiocarcinoma c. Extrahepatic cholangiocarcinoma 13. Vulvar cancer 14. Non-small cell lung cancer 15. Ovarian Cancer a. Fallopian tube cancer b. Primary peritoneal cancer i. Malignant mixed mullerian tumors ii. Clear cell carcinoma of the ovary iii. Mucinous neoplasms of the ovary iv. Grade 1 endometrioid cancer v. Low-grade serous cancer c. Epithelial ovarian cancer 16. Breast cancer a. Invasive breast cancer b. Inflammatory breast cancer 17. Esophageal and esophagogastric junction cancer 18. Uterine neoplasms a. Endometrial cancer 19. Central nervous system cancer a. Limited brain metastases b. Extensive brain metastases c. Leptomeningeal metastases			
Eladocagene exuparvovec (e.g., Kebilidi)	2025006	Coverage criteria revised.	Yes	12/01/2025	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2025006

		Pediatric individual (less than 21 years of age) and has achieved skull maturity assessed by neuroimaging.			